UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCT LIABILITY LITIGATION	MDL No. 2921 Case No. 2:19-md-2921-BRM-JAD This Document Relates To: All Class Action Cases **JURY TRIAL DEMANDED**

CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

Plaintiffs, on behalf of themselves and all others similarly situated, by and through counsel and pursuant to the Federal Rules of Civil Procedure, bring this Class Action Complaint against Defendants Allergan plc n/k/a AbbVie, Inc., Allergan, Inc., and Allergan USA, Inc. (collectively "Defendant" or "Allergan") and allege as follows.

I. INTRODUCTION

1. Allergan manufactures and sells saline-filled and silicone-filled breast implants and tissue expanders under the BIOCELL brand. BIOCELL products have a textured surface, or shell, which was intended to reduce complications after implantation. Instead, these products subject patients to a significantly increased risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system.

2. On July 24, 2019, the FDA issued a Class I Recall notice for Allergan's BIOCELL products[1] ("Recalled BIOCELL Implants") after concluding that the vast majority of BIA-ALCL

[1] The Recalled BIOCELL Implants include: (1) Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles: Style 163, BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants; Style 168, BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile); Style 363, BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection; Style 468, BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants; (2) Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles: Style 110, BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants; Style 115, BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants; Style 120, BIOCELL Textured Round High Projection Gel Filled Breast Implants; Style TRL, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRLP, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRM, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRF, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TRX, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants; Style TCL, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCLP, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCM,

cases occurred in patients who had been implanted with the Recalled BIOCELL Implants. A Class I Recall is defined as "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[2]

3. In its safety communication, the FDA announced that more than 80% of the BIA-ALCL cases reported worldwide occurred in patients who had Recalled BIOCELL Implants implanted at the time of diagnosis. Moreover, "12 of the 13 patients for which the manufacturer of the implant is known [were] confirmed to have an Allergan breast implant."

4. The FDA further stated that its "analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers." It concluded that continued distribution of the Recalled BIOCELL Implants "would likely cause serious, adverse health consequences and potentially death from BIA-ALCL."

Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCF, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TCX, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants; Style TSL, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSLP, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSM, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSF, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; Style TSX, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants; (3) Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046. The following are the textured styles: Style 410FM; Style 410FF; Style 410MM; Style 410 MF; Style 410 FL; Style 410 ML; Style 410 LL; Style 410 LM; Style 410 LF; Style 410 FX; Style 410 MX; Style 410 LX; (4) Allergan tissue expanders originally cleared as: Natrelle 133 Plus Tissue Expander (K143354); Natrelle 133 Tissue Expander with Suture Tabs (K102806). As used hereafter, the term "Recalled BIOCELL Implants" also includes McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153. Style 153 is an affected BIOCELL product but is no longer on the market and therefore was not formally recalled.

[2] https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last accessed May 26, 2020).

5. Allergan, complying with the FDA's request, issued a worldwide recall for the Recalled BIOCELL Implants that same day.

6. As is clear from its post-recall conduct and representations, Allergan has failed—and has no plans—to provide medical monitoring for Plaintiffs and members of the proposed classes defined below to mitigate the increased risk of developing BIA-ALCL from the Recalled BIOCELL Implants.

7. In a July 30, 2019 letter to "Allergan Plastic Surgery Customer[s]", Carrie Strom, Allergan's Senior Vice President, U.S. Medical Aesthetics, announced a new "BIOCELL Replacement Warranty" for patients "currently implanted" with Recalled BIOCELL Implants. Under the "warranty," which extends until July 24, 2021, implanted patients who choose to undergo a revision surgery will receive smooth Allergan implants at no cost. Allergan will not, however, pay any other associated expenses, including surgical costs, even though surgical costs generally far exceed the cost of the implants themselves.

8. According to the letter, patients who choose to keep their Recalled BIOCELL Implants (and bear the significantly increased risk of developing BIA-ALCL) may be eligible for reimbursement for certain diagnostic and surgical fees, but that dollar figure is capped. Allergan will not provide surgical fee assistance for breast implant removal.

9. The recommended diagnostic testing for BIA-ALCL is invasive. The Directions for Use for doctors provides in pertinent part: "When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL." The symptoms of BIA-ALCL may occur well after the surgical incision has healed, often years after the implant placement.

10. Thousands of women are now at a higher risk for cancer because of the defects in the Recalled BIOCELL Implants and will require monitoring to ensure that the cancer does not develop or is detected early. Many women, including many breast cancer survivors, have opted to get the implants removed at their own expense and undergone costly and painful surgeries (who obtained implants in the first place as a result of a mastectomy). Other women have developed BIA-ALCL.

11. But Allergan refuses to appropriately care for, monitor, or compensate Plaintiffs and the class members. Plaintiffs and the class members have been and will continue to be forced to expend significant monies for removal of the recalled implants, surgical and diagnostic fees, medical monitoring, and the invasive diagnostic procedures necessitated by the increased risk to which Defendant has knowingly exposed Plaintiffs and the class members.

12. Plaintiffs would not have been exposed to these injuries or risks but for Allergan's actions.

13. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles are embedded into the surface of the implant, followed by a layer of silicone. The outer silicone layer is scrubbed off and the remaining shell then washed in an effort to remove all solid particles. The specified process, as approved by the FDA, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

14. However, the removal of all solid particles proved difficult or impossible for Recalled BIOCELL implants, because the final scrubbing/abrading process was performed manually, using a variable and uncontrolled method, conducted by different workers using diverse

brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual manufacturing process resulted in adulterated, overly-textured implants with degraded and loosened fragments of silicone, implant materials, and other unintended residues on the implant surface.

15. Allergan's manufacturing process failed to comply with applicable standards, specifications, and good manufacturing practices. Allergan's manufacturing process resulted in defectively manufactured and unreasonably dangerous breast implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas (accumulations of fluid in a tissue or organ), and BIA-ALCL.

16. Moreover, Allergan breached its duty to adequately warn and disclose to the FDA, medical professionals, and Plaintiffs about the dangers and true risks of the Recalled BIOCELL Implants, which Allergan knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

17. Allergan also breached its continuing duty to report post-approval information to the FDA concerning the devices, including information that was reasonably known to Defendant, such as adverse events, new clinical investigations and studies, and reports in scientific literature.

18. Instead, Allergan took steps intended to conceal the adverse events known to it from the FDA, healthcare providers, and the public.

19. In order to conceal the true number of adverse event reports, Allergan submitted reports with incorrect manufacturer names, including "Santa Barbra" and "Costa Rica," instead of under the name Allergan. As a result, consumers, healthcare professionals, and the FDA were unable to detect trends in Allergan's products, depriving the market of the necessary information to make an informed decision about whether Allergan's products were safe and effective.

20. Allergan received a substantial benefit from selling thousands of the Recalled BIOCELL Implants from 2006 through July 24, 2019, at the expense of Plaintiffs and the Class and Subclasses (as defined below), all of whom were exposed to an undisclosed, heightened risk of developing potentially fatal BIA-ALCL.

21. Plaintiffs thus bring this action individually and on behalf of others in the United States who have or had Recalled BIOCELL Implants to seek relief for damages caused by Defendant's conduct at their expense. Plaintiffs and the Class have been and will continue to be forced to expend substantial sums for the removal of the recalled implants, surgical and diagnostic fees, and/or medical monitoring and invasive diagnostic procedures required as a result of their exposure to the risk of contracting BIA-ALCL. Plaintiffs seek relief individually and for the Classes to remedy the harms from Defendant's sale of Recalled BIOCELL Implants to Plaintiffs and the Class.

II. PARTIES

A. Plaintiffs

22. Plaintiff Susan Adair is and at all relevant times was a citizen of the State of New Jersey and the United States. In or around September 2014, Plaintiff was implanted with Natrelle 133 Plus Tissue Expanders, a model of the Recalled BIOCELL Implants. In or around December 2014, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing

BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

23. Plaintiff Stephanie Adkins is and at all relevant times was a citizen of the State of Connecticut and the United States. On or about November 23, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX, a model of the Recalled BIOCELL Implants. On or about November 4, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

24. Plaintiff Kerry Andersen-Doumite is and at all relevant times was a citizen of the State of Louisiana and the United States. In February 2015, Plaintiff was implanted with a Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implant, a model of the Recalled BIOCELL Implants. On or about September 17, 2019 and December 17, 2019, Plaintiff underwent surgeries to have her Recalled BIOCELL Implant removed during a DIEP Flap breast reconstruction surgery. As a direct and proximate result of having the Recalled BIOCELL Implant implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implant implanted had she known prior to the procedure that the

Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

25. Plaintiff Frances Atkinson is and at all relevant times was a citizen of the State of New York and the United States. On or about December 12, 2010, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile), a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile) implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

26. Plaintiff B.E. Benefield is and at all relevant times was a citizen of the State of Illinois and the United States. In 2013, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. In 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a

significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

27. Plaintiff Starlene Bernal is and at all relevant times was a citizen of the State of Arizona and the United States. On or about February 27, 2001, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile), a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile), implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

28. Plaintiff W. Elaine Blythe is and at all relevant times was a citizen of the State of New Mexico and the United States. On or about June 5, 2013, Plaintiff was implanted with

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF, a model of the Recalled BIOCELL Implants. On or about November 13, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

29. Plaintiff Nichole Boucree is and at all relevant times was a citizen of the State of Louisiana and the United States. On or about January 8, 2015, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, a model of the Recalled BIOCELL Implants. On or about October 31, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

30. Plaintiff Dallas Buckman is and at all relevant times was a citizen of the State of Kentucky and the United States. On or about April 1, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX, a model of the Recalled BIOCELL Implants. On or about January 28, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

31. Plaintiff Kelsey Burrell is and at all relevant times was a citizen of the state of Oregon and the United States. On or about September 1, 2016, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TSF – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TSF – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat

BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

32. Plaintiff Shannon Cawley is and at all relevant times was a citizen of the State of Rhode Island and the United States. On or about December 1, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. On or about December 21, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

33. Plaintiff Cathy Coakley is and at all relevant times was a citizen of the State of California and the United States. On or about November 06, 1997, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast

Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

34. Plaintiff Sylvia Constantine is and at all relevant times was a citizen of the State of Iowa and the United States. On or about September 2, 2016, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about September 25, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

35. Plaintiff Laurie Cozad is and at all relevant times was a citizen of the State of Iowa and the United States. On or about January 15, 2016, Plaintiff was implanted with Natrelle 133 Plus Tissue Expanders, a model of the Recalled BIOCELL Implants. On or about May 17, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. On or about January

22, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 133 Plus Tissue Expanders and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

36. Plaintiff Kawana Curry is and at all relevant times was a citizen of the State of New Jersey and the United States. In or around June 2017, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MM, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MM implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

37. Plaintiff Dixie Daniels is and at all relevant times was a citizen of the State of Utah and the United States. On or about January 11, 2017, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast

Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

38. Plaintiff K.A. DeFalco is at all relevant times is and was a citizen of the United States. She lived in Illinois until 2019 and currently lives in Arizona. On or about October 26, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

39. Plaintiff Jacqueline A. Dorney is and at all relevant times was a citizen of the State of Delaware and the United States. On or about December 29, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

40. Plaintiff Rebecca Duval is and at all relevant times was a citizen of the Commonwealth of Massachusetts and the United States. On or about February 12, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

41. Plaintiff RoseAnn Earhart is and at all relevant times was a citizen of the State of South Carolina and the United States. On or about December 9, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a model of the Recalled BIOCELL Implants. On or about November 22, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

42. Plaintiff Robin Ellers is and at all relevant times was a citizen of the State of New Mexico and the United States. On or about July 24, 2017, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

43. Plaintiff AnnaMaria Fabiano is and at all relevant times was a citizen of the State of Connecticut and the United States. On or about July 23, 2010, Plaintiff was implanted with a model of the Recalled BIOCELL Expanders. On or about January 7, 2011, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implant (formerly Inamed Silicone-Filled Breast Implant), Style 110 – BIOCELL Textured Round Moderate Projection Gel Filled Breast Implant, a model of the Recalled BIOCELL Implants. On or about October 25, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implant and Expander implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the expander and Natrelle Silicone-Filled Textured Breast Implant (formerly Inamed Silicone-Filled Breast Implant), Style 110 – BIOCELL Textured Round Moderate Projection Gel Filled Breast Implant implanted had she known prior to the procedure that the Recalled BIOCELL Implant and Expander would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

44. Plaintiff Amber Ferrell-Steele is and at all relevant times was a citizen of the State of Texas and the United States. On or about June 1, 2016, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about January 28, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. I'm Plaintiff signed the Allergan "Product Claim form and *ConfidencePlus* Premier Warranty Release" on February 4, 2020. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a

significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

45. Plaintiff Amy Ferrera is and at all relevant times was a citizen of State of Florida and the United States. On or about December 23, 2009, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

46. Plaintiff Kimberly Forshey is and at all relevant times was a citizen of the State of Ohio and the United States. On or about October 30, 2013, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model

of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks replacement of her Recalled BIOCELL Implants at Defendant's full expense.

47. Plaintiff Heather Glidden is and at all relevant times was a citizen of the State of Maine and the United States. On or about November 18, 2011, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about December 10, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

48. Plaintiff Cindy Gobler is and at all relevant times was a citizen of the state of Washington and the United States. On or about October 13, 2013, Plaintiff was implanted with

Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about November 25, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

49. Plaintiff Bambi Hodge is and at all relevant times was a citizen of the State of Michigan and the United States. On or about April 20, 2018, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410MM, a model of the Recalled BIOCELL Implants. On or about October 17, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410MM implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

50. Plaintiff Melinda Howard is and at all relevant times was a citizen of the State of Idaho and the United States. On or about November 1, 2012, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about March 20, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. Plaintiff signed the Allergan "Product Claim Form and *ConfidencePlus* Premier Warranty Release" on February 4, 2020. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

51. Plaintiff Terri Karren is and at all relevant times was a citizen of the State of Wisconsin and the United States. On or about June 6, 2018, Plaintiff was implanted with a model of the Recalled BIOCELL Expanders. On or about November 19, 2018, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX, a model of the Recalled BIOCELL Implants. On or about March 20, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 133

Plus Tissue Expander and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

52. Plaintiff Lisa Kosto is and at all relevant times was a citizen of the State of Michigan and the United States. On or about November 4, 2004, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

53. Plaintiff Heidi Lee is and at all relevant times was a citizen of the State of Arizona and the United States. On or about June 20, 2017, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX, a model of the Recalled BIOCELL Implants. On or about November 15, 2019, Plaintiff had her Recalled

BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

54. Plaintiff Debbie Lenard is and at all relevant times was a citizen of the State of Alabama and the United States. On or about April 8, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

55. Plaintiff Tammy Lester is and at all relevant times was a citizen of the State of Missouri and the United States. On or about July 18, 2013, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled

BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

56. Plaintiff Leigh Lofgren is and at all relevant times was a citizen of the State of Georgia and the United States. On or about March 25, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. On or about November 5, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

57. Plaintiff Charlotte Machado is and at all relevant times was a citizen of the State of Alabama and the United States. In or about 1996, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as

168MP (168 Moderate Profile), a model of the Recalled BIOCELL Implants. On or about November 1, 2018, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile) implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

58. Plaintiff Margaret Massie is and at all relevant times was a citizen of the State of Washington and the United States. On or about August 17, 2007, Plaintiff was implanted with Natrelle 133 Plus Tissue Expanders. On or about December 20, 2007, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 363 – BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants and Tissue Expanders implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 133 Plus Tissue Expanders or the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 363 – BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection Implants implanted had she known prior to the procedure that

the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

59. Plaintiff Amy McKee is and at all relevant times was a citizen of the Commonwealth of Pennsylvania and the United States. On or about June 15, 2012, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about December 13, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Style Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

60. Plaintiff Fran McNeill is and at all relevant times was a citizen of the State of Montana and the United States. On or about July 28, 2015 and in December 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF, a model of the Recalled BIOCELL Implants. On or about December 3, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result

of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

61. Plaintiff Julia Musall is and at all relevant times was a citizen of the State of Nevada and the United States. On or about January 1, 2005, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants, a model of the Recalled BIOCELL Implants. On or about January 31, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

62. Plaintiff Ellen Newmann is and at all relevant times was a citizen of the State of Pennsylvania and the United States. On or about July 11, 2013, Plaintiff was implanted with

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

63. Plaintiff Kimberly Nichols is and at all relevant times was a citizen of the State of West Virginia and the United States. On or about November 2, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF, a model of the Recalled BIOCELL Implants. On or about January 31, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

64. Plaintiff Claudia Ochoa is and at all relevant times was a citizen of the State of Texas and the United States. On or about April 29, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a

model of the Recalled BIOCELL Implants. On or about May 15, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

65. Plaintiff Lynn Owens is and at all relevant times was a citizen of the State of North Carolina and the United States. On or about June 28, 2012, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about August 26, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

66. Plaintiff April Piepenburg is and at all relevant times was a citizen of the State of Colorado and the United States. On or about December 7, 2016, Plaintiff was implanted with

Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about October 21, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

67. Plaintiff Tammi Poling is and at all relevant times was a citizen of the State of Wyoming and the United States. On or about March 1, 2016, and in 2018 Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as

the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

68. Plaintiff B.E. Rivkind is and at all relevant times was a citizen of the Commonwealth of Pennsylvania and the United States. In November 2015, Plaintiff was implanted with Natrelle Silicone Filled Textured Breast Implants, Style 115, a model of the Recalled BIOCELL Implants. In September 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle Silicone Filled Textured Breast Implants, Style 115, implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA- ALCL.

69. Plaintiff Kelli Russell is and at all relevant times was a citizen of the State of Florida and the United States. On or about October 1, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a model of the Recalled BIOCELL Implants. On or about November 7, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly

increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

70. Plaintiff Kaylann Ryan is and at all relevant times was a citizen of the State of Texas and the United States. On or about December 8, 2016, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRM - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants, a model of the Recalled BIOCELL Implants. On or about March 3, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TRM - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

71. Plaintiff Beth Samenus is and at all relevant times was a citizen of the State of South Dakota and the United States. On or about February 27, 2019, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. On or about September 11, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted

had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

72. Plaintiffs Andrea Shiock is and at all relevant times was a citizen of the State of Pennsylvania and the United States. On or about September 2016, Plaintiff was implanted with Natrelle 133 Plus Tissue Expander, a model of the Recalled BIOCELL Expanders. On or about January 2017, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 LF, a model of the Recalled BIOCELL Implants. On or about March 17, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants and Tissue Expander implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 133 Plus Tissue Expander and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 LF implanted had she known prior to the procedure that the Recalled BIOCELL Expanders and Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

73. Plaintiff Jill Smith is and at all relevant times was a citizen of the State of Minnesota and the United States. On or about June 28, 2018, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF, a model of the Recalled BIOCELL Implants. On or about November 25, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is

in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410FF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

74. Plaintiff Diane Smyth is and at all relevant times was a citizen of the State of Tennessee and the United States. On or about October 25, 1996, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile), a model of the Recalled BIOCELL Implants. On or about September 25, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile) implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

75. Plaintiff Laura Sullivan is and at all relevant times was a citizen of the Commonwealth of Virginia and the United States. On or about June 5, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410MM, a model of the Recalled BIOCELL Implants. On or about October 31,

2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410MM implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

76. Plaintiff Pamela Thornton is and at all relevant times was a citizen of the State of California and the United States. On or about October 17, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

77. Plaintiff Pansy Tully is and at all relevant times was a citizen of the Commonwealth of Kentucky and the United States. On or about March 2008, Plaintiff was implanted with Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 163 – BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants. On

or about January 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants and Tissue Expanders implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 163 – BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

78. Plaintiff Francine Wagner is and at all relevant times was a citizen of the State of Florida and the United States. On or about 2015, Plaintiff was implanted with Allergan tissue expanders, a model of the Recalled BIOCELL Implants. On or about March 13, 2017, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 LX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants and Tissue Expanders implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 LX or Expanders implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

79. Plaintiff Joann Wagner is and at all relevant times was a citizen of the State of Colorado and the United States. On or about June 8, 2011, Plaintiff was implanted with a Natrelle 133FX Tissue Expander. On or about September 30, 2011, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implant, Style 410 MX and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implant, Style 410 ML, models of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants and Expander implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 133FX Tissue Expander, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implant, Style 410 MX and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implant, Style 410 ML implanted had she known prior to the procedure that the Recalled BIOCELL Implants and expander would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

80. Plaintiff Rhonda Way is and at all relevant times was a citizen of the State of West Virginia and the United States. On or about November 1, 2007, Plaintiff was implanted with Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implant), Style 110 – BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implant), Style 110 –

BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants implanted had she known prior to the procedure that the Recalled BIOCELL Implant would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

81. Plaintiff Francis Weber is and at all relevant times was a citizen of the State of New York and the United States. On or about August 6, 2015, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF, a model of the Recalled BIOCELL Implants. On or about August 22, 2019, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MF implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

82. Plaintiff Louise Womack is and at all relevant times was a citizen of the State of Oklahoma and the United States. On or about June 20, 2017, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 MX implanted had she

known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implants at Defendant's full expense.

83. Plaintiff Mary (Liza) Yowell is and at all relevant times was a citizen of the State of North Carolina and the United States. On or about April 15, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410MM, a model of the Recalled BIOCELL Implants. On or about March 2, 2020, Plaintiff had her Recalled BIOCELL Implants explanted. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410MM implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.

84. Plaintiff Dana Zettlemoyer is and at all relevant times was a citizen of the State of Tennessee and the United States. On or about November 29, 2016, Plaintiff was implanted with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX, a model of the Recalled BIOCELL Implants. As a direct and proximate result of having the Recalled BIOCELL Implants implanted, Plaintiff is at a significantly increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants, Style 410 FX implanted had she known prior to the procedure that the Recalled BIOCELL Implants would subject her to a

significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL. Plaintiff seeks removal of her Recalled BIOCELL Implant at Defendant's full expense.

B. Defendants

85. Defendant Allergan plc was a publicly traded corporation headquartered in Dublin, Ireland with headquarters in New Jersey. It was formerly known as Actavis plc; in 2015, Actavis, a pharmaceutical company headquartered in Dublin, Ireland with a principal place of business in New Jersey, purchased Allergan, Inc. and adopted the Allergan plc name.

86. Allergan plc was a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name pharmaceutical products, medical aesthetics, biosimilar, and over-the-counter pharmaceutical products, including the Recalled BIOCELL Implants.

87. Allergan plc announced the world-wide recall of its BIOCELL product line on July 24, 2019. Allergan plc's Senior Vice President, Carrie Strom, coordinated the recall of the Recalled BIOCELL Implants with the FDA and sent correspondence to patients with BIOCELL products regarding the recall.

88. In May 2020, Allergan plc was acquired by AbbVie, Inc. AbbVie is a Delaware corporation with its principal place of business in North Chicago, Illinois. Upon information and belief, AbbVie assumed the liabilities of Allergan plc (and thereby the liabilities of Allergan, Inc. and Allergan, USA, Inc.) upon conclusion of the acquisition.

89. Allergan, Inc. was a wholly-owned subsidiary of Allergan plc with its principal place of business in New Jersey. As a subsidiary of Allergan plc, Allergan, Inc. was acquired by AbbVie in the May 8, 2020 acquisition. Allergan, Inc. is the registered holder of the BIOCELL trademark. It also announced the recall of Recalled BIOCELL Implants.

90. Allergan USA, Inc. was also a wholly owned subsidiary of Allergan plc. It is incorporated under the laws of Delaware with its principal place of business in New Jersey. As a subsidiary of Allergan plc, Allergan USA, Inc. was acquired by AbbVie in the May 8, 2020 acquisition referenced above.

91. Allergan entered the breast implant market through California-based McGhan Medical Corporation ("McGhan"), its predecessor corporation. BIOCELL textured implants were originally developed in the 1980s and early 1990s by McGhan.

92. McGhan was a leading manufacturer of silicone products for plastic and reconstructive surgery. In 1985 it became a subsidiary of First American Corporation, a publicly held company. In 1986, First American changed its name to Inamed Corporation.

93. In March 2006, Allergan, Inc. acquired Inamed and its wholly-owned subsidiary, McGhan, as well as the BIOCELL trademark. In doing so, it assumed the liability for the past and present manufacturing of breast implant products. At the time, Inamed was one of the largest implant makers in the world and one of the two largest manufacturers in the United States.

94. Defendants Allergan plc n/k/a AbbVie, Inc.; Allergan, Inc.; and Allergan USA, Inc. are collectively referred to as "Defendant" or "Allergan."

95. At all relevant times, Allergan plc, n/k/a AbbVie, Inc.; Allergan, Inc; and Allergan USA, Inc. acted in all aspects as the agent and alter ego of each other and carried out a joint scheme, business plan, or policy in all respects pertinent hereto, and the acts of each entity are legally attributable to the other entities.

III. JURISDICTION AND VENUE

96. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because (a) there are

at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interest and costs; and (c) at least one Plaintiff is a citizen of a different state than Defendant.

97. The Court has personal jurisdiction over Defendant because Defendant has sufficient minimum contacts in this District to render the exercise of jurisdiction by this Court proper and fair.

98. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and (c)(2) because a substantial part of the acts giving rise to Plaintiffs' claims occurred in this District and because Defendant is subject to personal jurisdiction within this District.

IV. FACTUAL ALLEGATIONS

A. Overview of Breast Implants and Tissue Expanders

99. Breast implants are medical devices that are implanted under the breast tissues to replace breast tissue that has been removed due to cancer, surgery, or other trauma, change breast contour, correct developmental defects, or to modify breast size or shape. Tissue expanders are a type of inflatable breast implant, typically used in breast reconstruction surgeries. They are slowly filled with saline over a period of time until the implant reaches the desired size, stretching the skin and muscle to create space for a permanent implant once the expansion is complete.

100. The FDA has approved two types of implants for sale in the United States: saline (saltwater solution)-filled and silicone gel-filled. Both types of implants vary in size, shell thickness, gel viscosity, and shape, and have an outer shell made of either smooth or textured silicone.

101. Manufacturers use a variety of techniques to create textured implants. Allergan's process, which it uses for the Recalled BIOCELL Implants, creates the textured surface by dipping a silicone capsule into salt crystals before the silicone has fully solidified. A second layer of silicone is then added over the salt crystals. The outer surface is then scrubbed off and the

remaining silicone shell washed and cured, leaving behind a pitted surface with randomly-sized indentations.

102. Approximately 400,000 breast implants are placed per year in the United States. From 2000 to 2016, the annual number of breast augmentations in the United States increased 37%, and reconstructions after mastectomy increased 39%. Breast augmentation is the most common cosmetic surgery in the country.

103. Breast implants were first introduced in the United States in the 1960s. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), granting the FDA authority to review and approve new medical devices, including breast implants.

104. The FDA classifies medical devices based on the risks associated with the device and the degree of regulation the agency deems appropriate. Its three-tiered classification system includes Class I devices (low to moderate risk to the user), Class II devices (moderate to high risk to the user), and Class III devices (high risk to the user). Following enactment of the MDA, the FDA classified breast implants as Class II devices, to be reviewed through a premarket notification process or Section 510(k) process. This classification did not require manufacturers to conduct any formal testing of the product; rather, they needed only to provide "reasonable assurance" that their devices would not harm patients. 21 U.S.C. § 360e(d)(2).

105. In 1988, in response to growing safety concerns, following reports of gel bleed and capsular contracture and studies warning of the link between silicone implants and cancer, the FDA reclassified both saline- and silicone-filled breast implants as Class III devices.

106. In April 1991, after the publication of new regulations, the FDA began to require breast implant manufacturers to obtain specific premarket approval ("PMA"). Through its PMA

process, the FDA engages in scientific evaluations of the safety and efficacy of Class III medical devices.

107. Allergan's recalled tissue expanders did not go through the PMA process; rather, they were "cleared" through the FDA's 510k process, discussed *infra.*

B. Allergan's BIOCELL Breast Implants

1. The FDA's pre-market approval process for breast implants imposes continuing obligations on manufacturers.

108. Class III devices are those which the FDA has determined pose the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public. Through the PMA process, the FDA evaluates the safety and efficacy of Class III medical devices.

109. A PMA application must contain certain information that is critical to the FDA's evaluation of the safety and efficacy of the device at issue. A PMA application or supplement must include:

a. Proposed indications for use;

b. A description of the device, including the manufacturing process;

c. Any marketing history;

d. A summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the studies that address benefit and risk);

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and efficacy of the device that is known or should reasonably be known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

110. Following PMA approval, the FDA requires labeling that sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing. The labeling requirements extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, Directions for Use ("DFU"), and fillers.

111. A Class III medical device manufacturer with PMA approval is required to do the following, among other duties:

a. Comply with the FDA's Quality Systems Regulations ("QSRs"). 21 CFR § 820 *et seq*. The specific QSRs promulgated by the FDA are known as Current Good Manufacturing Practices ("CGMP"). 21 CFR § 820.1(a). A manufacturer must satisfy these quality standards in the manufacture and production of medical devices. *Id*.

b. Adopt procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 CFR §§ 820.1-.250.

c. "Establish and maintain procedures to identify and address any product that does not conform to specified requirements," such as a failure to conform to performance and design standards set forth in the manufacturer's PMAs and supplements. 21 CFR § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSRs also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the

product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21 CFR § 820.100.

d. Formulate and then effectively execute a Post-Marketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 CFR § 822.8.

e. Review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 CFR § 820.198(b).

f. Complete an investigation when a complaint involves the possible failure of a device, labeling or packaging to meet any of its specifications. 21 CFR § 820.198(c).

g. Establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 CFR § 820.250 and 21 C.F.R. § 820.1(a)(3).

h. Comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device. 21 U.S.C. § 360i.

i. Keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21. U.S.C. § 360i.

j. Report adverse events associated with a medical device within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction recurs. 21 CFR § 803.50(a). This reporting is mandatory and is a condition of continued PMA approval. 21 CFR. § 814.82. Such reports must contain all information reasonably known to a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 CFR § 803.50(b)(1).

k. Conduct an investigation of each adverse event and evaluate the cause of the adverse event. 21 CFR § 803.50(b)(3). A manufacturer must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 CFR § 803.52(f)(9).

l. Report to the FDA in five (5) business days after becoming aware of any MDR event or events, including a trend analysis, which necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. 21 CFR §803.53. This reporting is mandatory and a condition for continued PMA approval. 21 CFR. § 814.82.

m. Report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. 21 CFR § 806.10(a). FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by a manufacturer to reduce

a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 CFR § 806.10(b). The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. 21 CFR § 806.10(c). A manufacturer must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. 21 CFR § 806.109(c).

n. Prevent adulterated devices from being implanted in patients. 21 CFR § 820.70. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packaging, storage, or installation are not in conformity with the federal requirements. 21 U.S.C. §351(e), (h).

o. Implement changes to its device, its manufacturing processes or its labeling to enhance the safety of the device prior to obtaining FDA approval. These changes may include, but are not limited to, labeling changes that add or strengthen a contraindication, warning, precaution, information about an adverse reaction or information intended to enhance safe use, or changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provides additional assurance of purity, strength or reliability of the device. Conversely, a manufacturer is not permitted to change

design specifications or manufacturing processes if such changes could adversely affect safety or effectiveness. 21 CFR § 814.39(d)(1), (2) and 21 U.S.C. § 360e(d)(5)(A)(i).

2. On May 10, 2000, the FDA approved PMA P990074 for the McGhan RTV Saline-Filled Mammary Implant, now known as the Natrelle Saline Breast Implant.

112. McGhan originally developed BIOCELL textured implants in the late 1980s and early 1990s.

113. In 1991, McGhan applied for premarket approval for various styles of implants. The FDA denied approval of the application for implants for cosmetic purposes but determined there was a public health need for implants to be available for breast reconstruction.

114. In April 1992, the FDA concluded that none of the PMAs submitted for silicone gel-filled breast implants had sufficient data to support approval. Thus, silicone-filled breast implants for reconstruction were only available to women through entry into a clinical study. Saline-filled implants, including those from the BIOCELL line of products, remained available for augmentation and reconstruction during this time period via 510(k) clearance.

115. Based on the information currently available to Plaintiffs, Allergan's saline-filled breast implant BIOCELL line of products received 510(k) clearance from 1988 to 2000 and Allergan's silicone-filled breast implant BIOCELL line of products received an Investigative Device Exemption ("IDE") from 1998-2006. An IDE allows a device to be used in order to collect safety and effectiveness data required to support a PMA or 510(k) clearance.

116. The FDA required McGhan to submit data from the trials in accordance with an agreed schedule and to take reasonable steps to ensure that participating physicians complied with the protocols. Further, McGhan was required to cooperate with the FDA's review of the

application and monitoring of the clinical trials. Patient follow-up was to occur until five years post-implantation (Adjunct study) and ten years post-implantation (CORE study).

117. In 1999, the FDA issued a final rule requiring PMAs for saline-filled breast implants.

118. On May 10, 2000, the FDA approved McGhan's PMA Application No. P990074 for the McGhan RTV Saline-Filled Mammary Implant, now known as the Natrelle Saline Breast Implant, including BIOCELL Styles 163, 168, 363, and 468, which are subject to the July 24, 2019 recall.

119. As a condition of the PMA approval, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, Defendant was required to, *inter alia*,

a. conduct and provide reports on a 10-year post approval study "to assess the long term clinical performance of the device;"

b. conduct and provide reports on a retrieval study, which would "collect visual examination, physical, and histological data on explanted implants to determine the mode of failure of implants;"

c. conduct a focus-group study "to obtain immediate feedback on the patient informed decision brochure from both augmentation and reconstruction patients;"

d. conduct mechanical testing, "i.e., fatigue rupture and shelf-life;"

e. report any "adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and… has not been addressed by the device's labeling or…. has been addressed by the device's labeling, but is occurring with unexpected severity or frequency;" and

f. report, whenever it receives or becomes aware of information, from any source, that "reasonably suggests" that a device "may have caused or contributed to a death or serious injury; or has malfunctioned and

such device or similar device… would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."[3]

120. The PMA provided that "[f]ailure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the [FDCA]."

121. The Summary of Safety and Effectiveness Data ("SSED") and DFU associated with PMA 990074 did not contain any mention of BIA-ALCL, ALCL, or a risk of lymphoma.

3. In November 2006, the FDA approved PMA P020056 for the Inamed Silicone-Filled Breast Implant, now known as the Allergan Natrelle Silicone-Filled Breast Implant.

122. In 2002, Inamed, which had succeeded McGhan, submitted to the FDA a PMA for the Inamed Silicone-Filled Breast Implant, now known as the Allergan Natrelle Silicone-Filled Breast Implant. The primary clinical data set underlying the PMA was the CORE study.

123. In November 2006 the FDA approved this device (PMA P020056), including BIOCELL Styles 110, 115, 120, TRL, TRLP, TRM, TRF, TRX, TCL, TCLP, TCM, TCF, TCX, TSL, TSLP, TSM, TSF, and TSX, which are subject to the July 24, 2019 recall. The Summary of Safety and Effectiveness Data (SSED) and Directions for Use (DFU) for this PMA likewise contained no mention of BIA-ALCL, ALCL, or a risk of lymphoma.

124. As conditions of the 2006 approval, the FDA required Allergan to conduct six post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Allergan's Natrelle silicone-filled textured breast implants included:

a. Core Post-Approval Studies (Core Studies) – To assess long-term clinical performance of breast implants in women that enrolled in

[3] *See* PMA P990074 Approval Order, available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/P990074A.pdf (last accessed May 23, 2020).

studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

b. Large Post-Approval Studies (Large Studies) – To assess long-term outcomes and identify rare adverse events by enrolling approximately 40,000 silicone gel-filled breast implant patients, following them for 10 years.

c. Device Failure Studies (Failure Studies) – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

d. Focus Group Studies – To improve the format and content of the patient labeling.

e. Annual Physician-Informed Decision Survey (Informed Decision Study) – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

f. Adjunct Studies – To provide performance and safety information about silicone gel-filled breast implants for the period when implants could only be used for reconstruction and replacement of existing implants.

125. The PMA provided that "[f]ailure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the [FDCA]."

4. In February 2013, the FDA approved PMA P040046 for Defendant's Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.

126. In February 2013, the FDA approved Defendant's PMA (P040046) for its Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, including BIOCELL Styles 410FM, 410FF, 410MM, 410MF, 410FL, 410ML, 410LL, 410LM, 410LF, 410FX, 410MX, and 410LX, which are subject to the July 24, 2019 recall.

127. The FDA required Allergan to conduct a number of studies including: (1) a continued access study of 3,500 women for 5 years post-implantation; (2) a long-term clinical performance study of over 2,500 women for 10 years; (3) case control studies to evaluate "rare

endpoints" including lymphoma; and (4) a focus group study to evaluate augmentation and reconstruction patient labeling.

128. Once again, the PMA warned that "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law."

129. The SSED and DFU for this product contained misleading, incomplete and insufficient information about BIA-ALCL and the increased risk associated with Defendant's textured implants compared to smooth implants and textured implants from other manufacturers.

130. The SSED and DFU for the Natrelle 410 implants stated:

> Anaplastic Large Cell Lymphoma
>
> - Based on information reported to FDA and found in medical literature, a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing ALCL in the fluid or scar capsule adjacent to the implant.
>
> - ALCL has been reported globally in patients with an implant history that includes Allergan's and other manufacturers' breast implants.

131. However, the above statement failed to relay Allergan's actual knowledge of the established causal connection between its BIOCELL implants and BIA-ALCL, an association that was significantly greater than the risk posed by "other manufacturers' breast implants."

132. In October 2019, the FDA issued draft guidance recommending labeling changes to breast implants to warn about the risk of BIA-ALCL. This includes a boxed warning and a patient decision checklist contained in an information booklet/brochure.

5. In 2011 and 2015, the FDA approved Allergan's BIOCELL Tissue Expanders through the Section 510k process.

133. BIOCELL tissue expanders are not approved through the PMA process; they are "cleared" through the Section 510k process. A 510(k) application is a premarket submission to the FDA in which the manufacturer demonstrates that the device to be marketed is substantially equivalent to a legally marketed device. 21 CFR § 807.92(a)(3).

134. The 510(k) process requires the manufacturer to demonstrate that the device is as safe and effective as, and substantially equivalent to, a predicate 510(k) device. It does not require an independent assessment of the safety or efficacy of the device.

135. On January 5, 2011, Defendant's Natrelle 133 Tissue Expander with Suture Tabs received 510(k) clearance from the FDA and was classified as a Class II device subject to special controls set forth in 21 CFR § 878.3600.3F.[4] Its predicate device was the Natrelle Style 133 Series Tissue Expander Matrix, also known as the McGhan Magna-Site Tissue Expander, which was initially cleared in 1986 and is subject to the July 24, 2019 recall.

136. On August 20, 2015, Defendant's Natrelle 133 Plus Tissue Expander received 510(k) clearance from the FDA as an unclassified device.[5] Its predicate devices were the Mentor CPX 4 Breast Tissue Expander and Mentor CPX 4 with Suture Tabs Breast Tissue Expander, which were initially cleared in 2001.

137. The FDA's 510(k) clearance for the Defendant's tissue expanders required Defendant to comply with the labeling and medical device reporting requirements of the FDCA. 21 C.F.R. §§ 801, 803.

---

[4] *See* Clearance Letter for K102806, available at http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102806.pdf (last accessed May 23, 2020).
[5] *See* Clearance Letter for K143354, available at http://www.accessdata.fda.gov/cdrh_docs/pdf14/K143354.pdf (last accessed May 23, 2020).

C. The risk of BIA-ALCL with Allergan's Recalled BIOCELL Implants is approximately six times the risk than with textured implants from other manufacturers.

1. Background on BIA-ALCL

138. BIA-ALCL is not breast cancer. It is a type of non-Hodgkin's lymphoma—a cancer of the immune system. It presents as a late-onset seroma in the breast (accumulation of fluid between the capsule and the implant, resulting in swelling of the breast). BIA-ALCL is a serious cancer that typically occurs in the scar tissue and fluid near the breast implant. Left untreated, it can spread throughout the body and become fatal.

139. The primary symptoms of BIA-ALCL are persistent swelling, enlargement, a lump, mass, or pain in the area of the breast implant, enlarged lymph nodes, and rash, redness, or hardening of the breast. Symptoms typically occur between six months and 26 years after implantation, and can arise even after the expander or implant has been removed.

140. Diagnostic procedures are invasive and can include ultrasound, computed tomography scans ("CT scan"), magnetic resonance imaging ("MRI"), fluid sampling via fine needle aspiration, and biopsy. At a minimum, treatment generally includes extensive surgery to remove the implant (if still implanted) and surrounding tissue, including multiple procedures and operations in some cases. Patients may also require radiation, chemotherapy, or both.

2. Allergan sold the Recalled BIOCELL Implants despite knowledge that textured breast implants were associated with higher rates of BIA-ALCL.

141. As early as 1997, PLASTIC AND RECONSTRUCTIVE SURGERY, the peer-reviewed journal of the American Society of Plastic Surgeons, published a case report entitled *Anaplastic T-Cell Lymphoma in Proximity to a Saline Filled Breast Implant.* The case report involved McGhan BIOCELL implants and a woman who was diagnosed with anaplastic large cell lymphoma after having the implants for five years.

142. In 2003, a case report was published in THE ARCHIVES OF PATHOLOGY AND LABORATORY MEDICINE titled *Anaplastic Large Cell Lymphoma Arising in a Silicone Breast Implant Capsule: A Case Report and Review of the Literature*. The case report described a diagnosis of an ALCL after a silicone breast implant had been implanted for nine years.

143. In 2008, the JOURNAL OF PLASTIC, RECONSTRUCTIVE & AESTHETIC SURGERY reported another case of ALCL diagnosed in 2003 in a woman who had received McGhan 500 cc silicone gel implants in 1989.

144. In November 2008, the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION ("JAMA") published a retrospective analysis of 11 cases of ALCL between 1994 and 2006. It concluded that there is an association between silicone breast implants and ALCL.

145. In 2011, a summary of published studies, evidence, and reports entitled *Anaplastic Large T-cell Lymphoma and Breast Implants: A Review of the Literature* was published in PLASTIC AND RECONSTRUCTIVE SURGERY. The comprehensive review identified 27 cases of ALCL in breast implant recipients and concluded that there was an association reported between breast implants and ALCL. On January 26, 2011, the FDA released a Safety Communication, entitled "Reports of Anaplastic Large Cell Lymphoma (ALCL) in Women with Breast Implants." It reported that, "[b]ased on the published case studies and epidemiological research, the FDA believes there is a possible association between breast implants and ALCL."

146. The FDA further observed that "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell." Allergan's Recalled BIOCELL Implants have a textured outer shell.

147. In July 2014, the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHR") issued a Medical Device Alert "to further encourage healthcare professionals to report cases of ALCL in women who have breast implants or who have had them removed."

148. In March 2015, an article in PLASTIC AND RECONSTRUCTIVE SURGERY analyzed 173 cases of ALCL. That month, the French National Cancer Institute announced that "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant."

149. In a May 2016 response to the French Health Authority (ANSM), Allergan conceded that it had received 104 reports of confirmed, suspected, and pending confirmation ALCL cases associated with a textured breast implant between at least 2007 and 2015.

150. On May 19, 2016, The World Health Organization ("WHO") officially designated BIA-ALCL as a T-cell lymphoma, distinct from other categories of ALCL, that can develop following the implantation of breast implants.

151. Shortly thereafter, the National Comprehensive Cancer Network ("NCCN") established evidence-based consensus guidelines for the diagnosis and treatment of BIA-ALCL.

152. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel as part of its "ongoing monitoring of the association between breast implants and anaplastic large cell lymphoma."

153. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after a patient receives breast implants and stated that "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

154. In May 2017, a global analysis of approximately forty governmental databases published in PLASTIC AND RECONSTRUCTIVE SURGERY showed 363 cases of BIA-ALCL, of which 258 were reported to the FDA.

155. Experts began to call for the ban of textured breast implants. By September 2017, the FDA reported that it had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including reports of 9 deaths.

156. A January 2018 study in JAMA ONCOLOGY reported that the risk of developing ALCL in women with breast implants was 421.8 times higher than in women without, "implying an attributable risk approaching 100%."

157. On May 9, 2019, Australia's TGA reported 72 cases of ALCL in Australian patients.

158. Although the risk of ALCL is generally believed to be 1/300,000, textured implants increase that risk by up to 3000 times. The FDA recently announced that, according to recent studies, the risk of BIA-ALCL in women with textured implants ranges from 1/3,817 and 1/30,000. The American Society of Plastic Surgeons estimates the current risk of BIA-ALCL to be between 1/2,207 and 1/86,029 for women with textured implants. TGA reported the risk as 1/1,000 to 1/10,000.

159. In May 2019, a study published in the JOURNAL OF CLINICAL ONCOLOGY concluded that "the incidence rate of BIA-ALCL may be higher than previously reported."

160. Despite the studies and reports demonstrating this heightened risk of BIA-ALCL, Allergan continued to sell the Recalled BIOCELL Implants.

161. In December 2018, Allergan textured breast implants lost their European certification and subsequently were suspended from the European and Brazilian markets. Allergan textured implants were banned in France in April 2019 and in Canada in May 2019.

162. In February 2019, the FDA issued a Letter to Health Care Providers across the United States warning them about the link between BIA-ALCL and textured implants.

3. Allergan's "salt loss" manufacturing technique for the Recalled BIOCELL Implants was defective and deviated from the FDA-approved process

163. Compared to implantation of other breast implants, implantation of Allergan's Recalled BIOCELL Implants significantly increases a patient's risk of developing BIA-ALCL because of Allergan's inconsistent, variable, uncontrolled, and defective manufacturing process for the Recalled BIOCELL Implants.

164. Following implantation, the body forms scar tissue, called a "capsule," around the breast implant. An adhesive barrier then forms between the implant shell and the capsule. The implant naturally moves within the body, resulting in chronic microscopic friction between the capsule and the implant.

165. Early breast implants were made with a thick outer shell designed to reduce rupture; however, these shells frequently caused the capsule to harden and constrict, resulting in a complication called capsular contracture. As a result, breast implant manufacturers began "texturing" the outside shell of the implants, based on the theory that the irregular textured surface of the shell would inhibit the development of collagen and fibrous tissue from forming in excess around the implant and thereby reduce incidents of capsular contracture.

166. Texturizing necessarily increases the implant surface area and, therefore, the amount of tissue that is in contact with the implant.

167. To texturize the surface of its Recalled BIOCELL Implants, Allergan used a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant and subsequently covered by another layer of silicone. The outer silicone layer is then scrubbed off and the remaining shell is then washed in an effort to remove all solid particles.

168. The intended, specified manufacturing process, consistent with the approved process under the requisite PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."[6]

169. However, the removal of all solid particles proved difficult or impossible for Recalled BIOCELL implants because Allergan performed the final scrubbing/abrading process manually, using a highly variable and uncontrolled method that was conducted by different workers, using diverse brushes and unvalidated methods. This manual process resulted in overly- and improperly-textured implants with degraded, loosened, and diverse fragments of silicone, implant materials, and other residues present on the implant surface.

170. These residues and particles, along with the implant's significantly increased surface area as a result of the texturizing and the chronic friction that inevitably occurs between the body's tissues and the implant, cause BIA-ALCL. Together these conditions cause pernicious inflammation, an increase in T-cell activity, and malignant T-cell transformation.

171. Allergan's salt loss manufacturing process was inconsistent, variable, and nonstandard. It was characterized by a lack of quality control, testing, and validation.

[6] Method for making open-cell, silicone-elastomer medical implant, U.S. Patent No. US4889744A (filed May 2, 1988), available at https://patents.google.com/patent/US4889744A/en (last accessed May 25, 2020).

172. Under federal law, a device is considered adulterated when "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements." 21 U.S.C. § 351(h).

173. Manufacturers must establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. 21 CFR § 820.5. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. 21 CFR § 820.3(v).

174. Manufacturers are required to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. 21 CFR § 820.22.

175. Manufacturers are further required to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. 21 CFR § 820.30(a). They also must establish and maintain procedures: (1) for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements; (2) to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development; (3) for verifying the device design to confirm that the device design output meets the design input requirements; (4) for validating the device design; (5) to ensure that the device design is correctly translated into production specifications; and (6) for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation. 21 CFR § 820.30(d)-(i).

176. The FDA's CGMP require manufactures to "develop, conduct, control, and monitor production processes to ensure that a device conforms to is specifications." 21 C.F.R. § 820.70(a).

Further, "[w]here deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications." *Id.* § 820.70(a).

177. Specific requirements include:

- *Production and process changes*. Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. *Id.* § 820.70(b).

- *Environmental control.* Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed. *Id.* § 820.70(c).

- *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. *Id.* § 820.70(e).

- *Equipment*. Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use. *Id.* § 820.70(g).

- *Manufacturing material*. Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented. *Id.* § 820.70(h).

- *Automated processes.* When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and

issuance. These validation activities and results shall be documented. *Id.* § 820.70(i).

178. Manufacturers must ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. 21 CFR § 820.72.

179. Where the results of a process cannot be fully verified by subsequent inspection and testing, the process must be validated with a high degree of assurance and approved according to established procedures. 21 CFR. § 820.75(a). "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 CFR § 820.3(z)(1). Manufacturers must establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met and ensure that validated processes are performed by qualified individuals. 21 CFR § 820.75(b). Manufacturers must establish and maintain procedures to control product that does not conform to specified requirements. 21 CFR § 820.90.

180. Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. 21 CFR § 820.100. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;
b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

181. Allergan's manufacturing processes are not and at all relevant times were not in compliance with federal law and parallel state law requirements.

182. The details of Allergan's defective manufacturing process for producing the Recalled BIOCELL Implant were laid bare in November 2015 when the French Agency for the Safety of Health Products, Agence Nationale de Sécurité du Médicament et des Produits de Santé ("ANSM"), published a Preliminary Inspection Report of Allergan's European subsidiary that marketed Allergan's implants in Europe—Allergan Ltd Marlow.[7]

[7] *See* Agence Nationale de Sécurité du Médicament et des Produits de Santé, *Preliminary Inspection Report of Allergan Ltd Marlow*, available at https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf (last visited May 23, 2020).

183. ANSM conducted its inspection of Allergan's manufacturing facility in Costa Rica because of interests in "materiovigilance" due to high association of ALCL with Allergan's implants.[8]

184. During its inspection of Allergan's manufacturing processes, ANSM unearthed a number of "critical" and "major" "deviations" in Allergan's manufacturing and reporting processes with respect to "legal references" and "standards" applicable to medical devices."[9]

185. In fact, the French inspection documented a "major" deviation from standards and legal requirements in connection with Allergan's salt loss manufacturing technique for the BIOCELL implants, to wit, that Allergan "does not take all the necessary actions to keep under control the residues that may be contained in those [breast implants], which may compromise their biocompatibility and consequently their compliance with the essential requirements applicable to medical devices."[10] Further, another "major" deviation from standards and legal requirements was identified with respect to:

> [t]he implementation of actions within the scope of [Breast implant] production, particularly in terms of residue controls (salt, Xylene, D4/D5 short molecules, others...) and surface topography, associated with adequate specifications...[11]

186. ANSM summarized Allergan's regulatory violations as representing "a major risk regarding the materiovigilance, and safety of the breast implants marketed in Europe by Allergan…"[12]

---

[8] Agence Nationale de Sécurité du Médicament et des Produits de Santé, *Preliminary Inspection Report of Allergan Ltd Marlow*, note 12 *supra* at 7.
[9] *Id.* at 10.
[10] *Id.* at 16.
[11] *Id*. at 20.
[12] *Id*. at 26.

187. Allergan's formal response to the ANSM report effectively conceded that it had not monitored or reported cases with respect to surface (smooth versus textured) and that there were major manufacturing failures or "deviations," including with respect to controls of residual xylene (an industrial solvent) and texturing sodium chloride.[13]

188. Research studies have confirmed the particle-related defects of Allergan's manufacturing process. For instance, a 2017 study by researchers at the Mayo Clinic, Creighton University School of Medicine, and Arizona State University published an article titled *Textured Breast Implants: A Closer Look at the Surface Debris Under the Microscope.* The authors of the study examined a new Allergan BIOCELL textured implant. Viewing the textured salt loss surface, they found solid particles of silicone—"white flecks"—on the surface of the implant, which they concluded were "shed particles of silicone." [14]

189. Under state laws, which do not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes.

190. Allergan knew or reasonably should have known that its manufacturing process for the Recalled BIOCELL Implants was defective and resulted in an adulterated product. Allergan knew that particles or contaminants on the surface of the Recalled BIOCELL Implant should not be implanted into the patient and that surgeons should not use any implants with "particulate contamination." Allergan knew that leaving volumes of foreign and decomposed particles on the

[13] *See* Responses to the Preliminary Report from ANSM Following the Materiovigilence Inspection of Allergan Ltd Company in Marlow, UK from 27th April to 1st May 2015, at 24-25, https://ansm.sante.fr/var/ansm_site/storage/original/application/f251f06469a78097b648ec58117c0258.pdf (last visited May 23, 2020)..

[14] Webb et al. *Textured Breast Implants: A Closer Look at the Surface Debris Under the Microscope*, PLASTIC SURGERY 2017, Vol. 25 (3)179-183, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5626211/ (last visited May 23, 2020).

implant surface post-manufacture violated PMA and FDA requirements, including the prohibition of "adulterated" products and requirements under 21 C.F.R.§ 820.70 to establish appropriate environmental and contamination controls and remove manufacturing material.

4. Allergan's BIOCELL Implants are recalled

191. On July 24, 2019, Allergan announced a worldwide recall of BIOCELL after the FDA called for the action based on new information that Allergan's BIOCELL implants were tied to the vast majority of cases of BIA-ALCL. Allergan announced that BIOCELL would no longer be sold or distributed in any market.

192. In its July 24, 2019 safety communication requesting that Allergan recall the product, the FDA announced that a total of 573 unique BIA-ALCL cases had been reported, including 33 patient deaths. Of those 573 cases, 481 patients—more than 80%—were reported to have Allergan breast implants at the time of diagnosis. And of the 13 deaths for which product identification was available, 12 occurred in patients with an Allergan breast implant at the time of their diagnosis. The FDA noted this was a "significant increase" since its last update in early 2019—reflecting 116 new cases and 24 more deaths.

193. The FDA further stated that its "analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately six times the risk of BIA-ALCL with textured implants from other manufacturers." It concluded that continued distribution of Allergan's BIOCELL textured implants "would likely cause serious, adverse health consequences and potentially death from BIA-ALCL."

194. Dr. Amy Abernethy, principal FDA deputy commissioner stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

195. The FDA identified the recall as a "Class I recall, the most serious type of recall." A Class I recall is a response to "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." 21 C.F.R. § 7.3(m)(1).

196. On July 30, 2019, Carrie Strom, Senior Vice President, U.S. Medical Aesthetics, Allergan plc, sent the following letter to "Allergan Plastic Surgery Customer[s]":

> Dear Allergan Plastic Surgery Customer,
>
> In follow-up to Allergan's voluntary recall of unused BIOCELL® products, we created the **BIOCELL® Replacement Warranty** for all patients currently implanted with BIOCELL® textured implants.
>
> **For patients in the U.S. who, as a result of the recall announcement on July 24, 2019, choose to replace their BIOCELL® textured devices with smooth devices in consultation with their plastic surgeon, Allergan will provide Allergan smooth device replacements for free.** The program will run for 24 months, until July 24, 2021, and will apply to revision surgeries on or after the date of the recall announcement, July 24, 2019.
>
> The decision to get a breast implant revision is a personal decision between patients and their plastic surgeons, and must be decided based on the appropriate discussion of benefits and risks. **As part of this program, Allergan will not provide surgical fee assistance to revision patients.** This decision is in-line with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL") due to the low risk of developing BIA-ALCL. Patients who decide to keep their BIOCELL® textured devices will continue to be covered under the NATRELLE® ConfidencePlus® warranty, which includes reimbursement for up to $1,000 in diagnostic fees and up to $7,500 in surgical fees related to diagnosing and treating BIA-ALCL.
>
> Some frequently asked questions about this policy are attached. You may initiate a replacement request under the BIOCELL® Replacement Warranty by talking with your Allergan Plastic Surgery Sales representative or by contacting the Allergan Product Surveillance team prior to surgery at 1-800-624-4261.
>
> Sincerely,
> Carrie Strom
> Senior Vice President, U.S. Medical Aesthetics
> Allergan plc

197. For years, Allergan profited from selling defective products. And now, despite recalling the defective implants, Allergan refuses to pay for the cost to remove the Recalled BIOCELL Implants.

198. By refusing to pay for the costs of removing the implants or the costs of ongoing medical monitoring, Allergan has put the lives of thousands of women at risk. Many women are unable to afford the costs of removal, which is frequently not covered by insurance, and instead are forced to live with ticking time bombs in their bodies.

D. Allergan repeatedly concealed the risks of its Recalled BIOCELL Implants

199. Allergan is responsible for the safety of its Recalled BIOCELL Implants.

200. After receiving premarket approval for a Class III device, manufacturers are subject to a continuous obligation to comply with Medical Device Reporting pursuant to 21 U.S.C. § 360i(a)(1), 21 C.F.R. § 803.50(a), and 21 C.F.R. §§ 814, *et. seq*.

1. Allergan failed to submit timely and adequate adverse event reports or disclose complete and accurate safety information for its Recalled BIOCELL Implants.

201. Allergan was required to file adverse event reports with the FDA.

202. At all relevant times, Allergan was responsible for timely communicating complete and accurate safety information regarding its devices, including the Recalled BIOCELL Implants.

203. At all relevant times, Allergan had a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, including, specifically, adverse events, to the FDA, the healthcare community, and consumers.

204. According to the FDA, the purpose of filing adverse event reports is to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments.[15]

205. All manufacturers and importers of medical devices are required to report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

206. The FDA publishes adverse event reports for medical devices in its publicly searchable database entitled Manufacturer and User Facility Device Experience ("MAUDE"), which was instituted in 1995 and is updated monthly.

207. Consumers, patients, and medical personnel rely on the timely and accurate disclosure of this safety-related information in their decision-making. Researchers, including those studying the connection between breast implants and cancer or other serious health issues, also rely upon the MAUDE database in their studies.

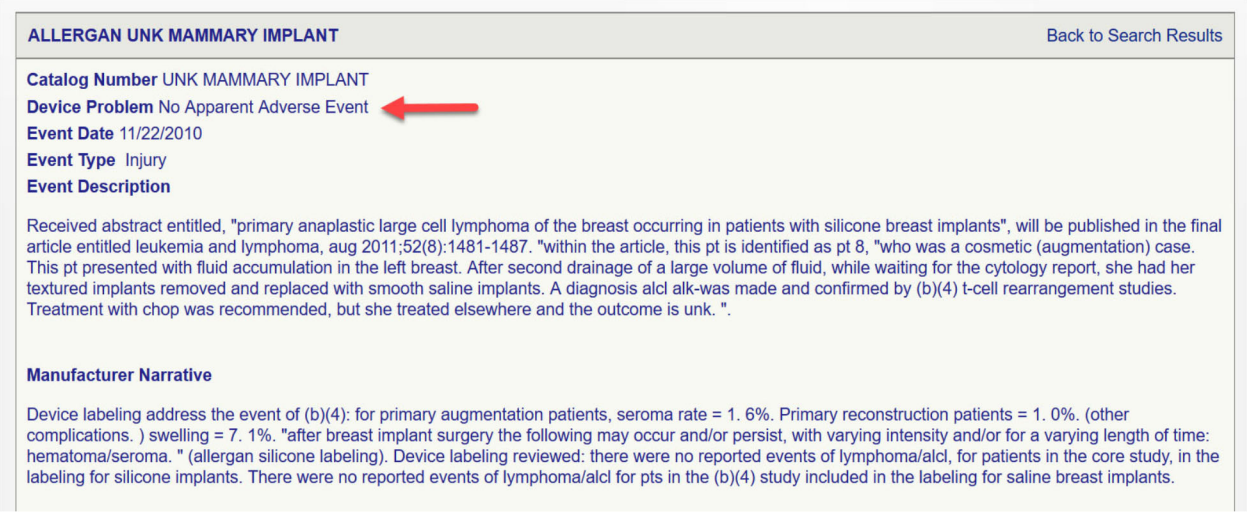
208. Delayed or inaccurate reporting prevents the healthcare community and the public from timely learning of risks that inevitably play a part in their decision-making regarding treatments and procedures, and thereby exposes countless additional women to potential harm and prevents their healthcare providers from giving them complete and accurate advice.

[15] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (last visited on May 23, 2020).

209. Allergan failed to timely, adequately, and appropriately submit adverse event reports and otherwise appropriately disclose complete and accurate safety information regarding its Recalled BIOCELL Implants.

210. In order to conceal the true number of adverse event reports, Allergan submitted reports under incorrect manufacturer names, including "Santa Barbra" and "Costa Rica," instead of under the name Allergan. As a result, consumers, healthcare professionals, and the FDA were unable to detect trends in Allergan's products, depriving the market of the necessary information to make an informed decision about whether Allergan's products were safe and effective.

211. Allergan also reported examples of ALCL with a "no apparent adverse event" determination by Allergan, thus obscuring the significance of the report.[16]



ALLERGAN UNK MAMMARY IMPLANT Back to Search Results

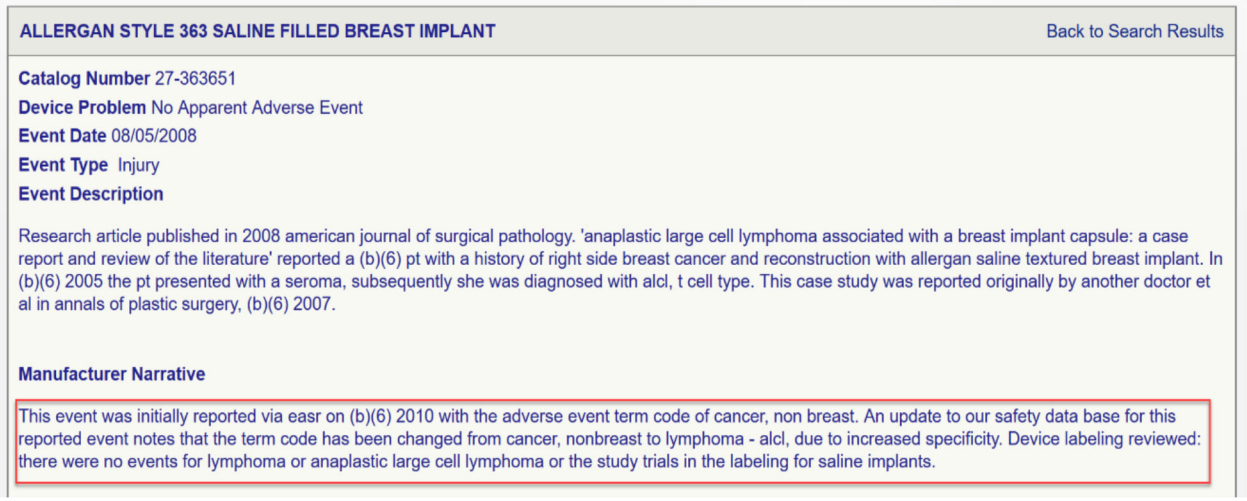
Catalog Number UNK MAMMARY IMPLANT
Device Problem No Apparent Adverse Event
Event Date 11/22/2010
Event Type Injury
Event Description

Received abstract entitled, "primary anaplastic large cell lymphoma of the breast occurring in patients with silicone breast implants", will be published in the final article entitled leukemia and lymphoma, aug 2011;52(8):1481-1487. "within the article, this pt is identified as pt 8, "who was a cosmetic (augmentation) case. This pt presented with fluid accumulation in the left breast. After second drainage of a large volume of fluid, while waiting for the cytology report, she had her textured implants removed and replaced with smooth saline implants. A diagnosis alcl alk-was made and confirmed by (b)(4) t-cell rearrangement studies. Treatment with chop was recommended, but she treated elsewhere and the outcome is unk. ".

Manufacturer Narrative

Device labeling address the event of (b)(4): for primary augmentation patients, seroma rate = 1. 6%. Primary reconstruction patients = 1. 0%. (other complications.) swelling = 7. 1%. "after breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: hematoma/seroma. " (allergan silicone labeling). Device labeling reviewed: there were no reported events of lymphoma/alcl, for patients in the core study, in the labeling for silicone implants. There were no reported events of lymphoma/alcl for pts in the (b)(4) study included in the labeling for saline breast implants.

[16] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=2210596; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=3693305&pc=FWM (last visited May 23, 2020).



ALLERGAN STYLE 363 SALINE FILLED BREAST IMPLANT Back to Search Results

Catalog Number 27-363651
Device Problem No Apparent Adverse Event
Event Date 08/05/2008
Event Type Injury
Event Description

Research article published in 2008 american journal of surgical pathology. 'anaplastic large cell lymphoma associated with a breast implant capsule: a case report and review of the literature' reported a (b)(6) pt with a history of right side breast cancer and reconstruction with allergan saline textured breast implant. In (b)(6) 2005 the pt presented with a seroma, subsequently she was diagnosed with alcl, t cell type. This case study was reported originally by another doctor et al in annals of plastic surgery, (b)(6) 2007.

Manufacturer Narrative

This event was initially reported via easr on (b)(6) 2010 with the adverse event term code of cancer, non breast. An update to our safety data base for this reported event notes that the term code has been changed from cancer, nonbreast to lymphoma - alcl, due to increased specificity. Device labeling reviewed: there were no events for lymphoma or anaplastic large cell lymphoma or the study trials in the labeling for saline implants.

212. Equally as troubling, Allergan's practice was to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure" until 2017.[17] "Alternative Summary Reports" ("ASRs") allow for multiple adverse event reports to be grouped together and made at one time under 21 CFR § 803.19.

213. ASRs require less detail—for instance, they do not contain any narrative describing the event. Because ASRs were not publicly available, including through the MAUDE website or a FOIA request, such submissions allowed Allergan to avoid public disclosure.

214. The ASR program was never intended to permit bulk filing of severe or unexpected injuries that necessitated remedial action—such reports must be disclosed individually via MAUDE. In fact, FDA spokesperson Stephanie Caccomo wrote in an email to *Cancer Therapy Advisor* that the agency had set up alternative reporting programs to increase efficiency of

[17] Sasha Chavkin, Breast Implant Injuries Kept Hidden As New Health Threats Surface, International Consortium of Investigative Journalists, November 26, 2018, available at https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface (last visited May 23, 2020).

reviewing "well-established risks." She also wrote that the reports were not intended to be allowed for reports of patient deaths or unusual adverse events such as BIA-ALCL.

215. Nonetheless, Allergan buried serious adverse events in non-public ASR reports, including possible cases of BIA-ALCL.[18] In doing so, it misled medical professionals, patients, the public, and researchers regarding the type and severity of problem associated with its breast implants, manipulating patients' decision-making process and exposing them to harm.

216. The FDA discontinued use of ASRs in 2017. Lest there be any doubt that serious breast implant adverse events had been buried in ASRs, following the discontinuation of the ASR program, the number of reported breast implant adverse events dramatically increased—from 200 a year to 4,567 in 2017 and 8,242 in the first half of 2018.

217. Allergan also did not report adverse events from its required post-market approval studies that would have suggested that the Recalled BIOCELL Implants caused or contributed to deaths or serious bodily injury.

218. Beginning at least as early as 2006, Allergen possessed information and evidence demonstrating that its Recalled BIOCELL Implants posed a significant risk of BIA-ALCL. Yet the Defendant refused or recklessly failed to identify, disclose, and warn of the health hazards and risks associated with the Recalled BIOCELL Implants and all adverse events known to it.

219. Allergan failed to comply with the conditions of its PMAs and applicable regulations, violated federal law, and violated state law—which does not impose duties and

[18] *See e.g.*, ALLERGAN (COSTA RICA) STYLE 168 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 ("[A] possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl), a type of non-hodgkin[]s lymphoma.") (last visited May 23, 2020).

requirements materially different from those imposed by federal law, by failing to adequately warn Plaintiffs and their implanting medical professionals about the dangers posed by the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL, and failing to properly investigate, identify, disclose, warn of, and report the risks of and adverse events associated with its Recalled BIOCELL Implants, including the risk of BIA-ALCL, and by continuing to market, advertise, promote, and sell the now-Recalled BIOCELL Implants.

220. This failure to report adverse events to the FDA directly impacted the ability of health care providers to be informed of the risks of textured breast implants, and the information was ultimately unable to reach consumers.

221. Allergan also disseminated a large number of voluntary statements that downplayed the risks of ALCL and BIA-ALCL and that were not the subject of a PMA, through channels such as promotional and marketing brochures and websites, sales representatives, and paid consultants. For example, referring to its Natrelle Breast Implants in a YouTube video, Allergan noted that the "Pre-Consultation Kit" is available to help a patient prepare for a consultation with her physician. In this direct-to-patient appeal, Allergan noted its implants are "FDA approved, tested, durable" and "Breast augmentation is the most common and uncomplicated plastic surgery procedure…Decades of experience with the science of breast augmentation have greatly improved safety…enhanced technology for safer and more beautiful options than ever before."[19] The publicly available video describes textured and smooth implants without making reference to in the significantly increased risks associated with the textured version of Allergan implants. Instead, the two types of implants were marketed as having the same benefits and potential complications, without any reference to BIA-ALCL.

[19] *See* https://www.youtube.com/watch?v=vu-0W8vSNrU (last visited May 23, 2020).

222. McGhan's Product Catalogue in September of 2004 stated, "The McGhan brand name has been built by providing an innovative, premium quality surgical solution with an unrivalled selection of products to meet our customer needs…INAMED Aesthetics are delighted to be at the forefront of technology and we will continue to invest to support your efforts." Further, "The BIOCELL textured surface is an integral part of the silicone elastomer shell that allows mild tissue adherence which has been associated with a reduced risk of capsular contracture." With respect to the textured tissue expanders, McGhan's Product Catalogue describes them as the "Proven BIOCELL Textured Surface."

223. McGhan Style 410's 2002 Brochure touted its implants as having "Superior quality, higher satisfaction and even wider choice"

> *"Naturally you want the best, the safest, the most predictable results. With the McGhan Style 410 range of products you can achieve these aims. For three decades we have been at the forefront of breast augmentation and reconstruction technology and our McGhan Style 410 range is widely acknowledged to be the very best breast implant available. Building on this success, and following years of research and development with the world's leading surgeons, we have created a new type of implant: The McGhan Style 410 Soft Touch." The McGhan Style 410 Soft Touch uses a softer gel while still maintaining all the characteristics that have made the McGhan Style 410 famous in our industry."*

224. In addition to engaging in an aggressive marketing scheme, directed to both consumers and physicians, boasting of the superiority, safety, quality and state-of-the-art design and manufacturing of its implants, Allergan turned a blind eye to the risks associated with the Recalled BIOCELL Implants. Even after the first BIA-ALCL warning was required pursuant to the 2013 Allergan PMA, Allergan made a concerted effort through its agents, employees and medical consultants to pepper the literature with anti-warning messages and to mock the serious and significant ALCL risk to which patients were exposed. Such statements were voluntary, non-PMA statements and violated the PMAs and parallel state laws. For example, a paid Allergan

consultant who was associated with BIOCELL studies and research stated that a patient is twice as likely to be struck by an asteroid than to develop ALCL. Similarly, an Allergan spokesperson reported that a patient is more likely to be struck by lightning than to develop ALCL. This characterization of risk was entirely unsupported and designed to mislead physicians and patients about the known risks associated with the Recalled BIOCELL Implants.

225. In addition, Allergan attempted to deflect attention from the risks associated with the BIOCELL line—and from its violations of federal and parallel state obligations—by blaming physicians and a collateral infection for the development of BIA-ALCL in patients implanted with Recalled BIOCELL Implants. In order to support its theory, which Allergan knew to be misleading and scientifically unsupported, Allergan funded physician consultants to develop a "14-point plan" for surgeons to follow during implantation to reduce the risk of infection and therefore, according to Allergan, reduce the risk of physician-caused BIA-ALCL. These voluntary, non-PMA statements included Allergan's representations to the medical community that BIA-ALCL mitigation can be effective using a 14-point plan to reduce the number of bacteria around implants at the time of implantation surgery. This campaign to mislead was knowingly false and in violation of state law and parallel federal requirements.

226. These statements are examples of many that contributed to shaping the opinions and understanding of the medical community, including each of Plaintiffs' treating physicians, were non-PMA statements, and were deliberately false and misleading

2. Allergan failed to comply with post-approval study requirements imposed by the FDA for its NATRELLE Silicone-Filled Breast Implants (PMA P020056).

227. In addition to periodic reporting requirements, the FDA ordered Allergan to conduct certain post-approval studies ("PAS") in accordance with 21 CFR § 814.82(a), to provide

information on long-term device performance, and to evaluate device performance under general conditions of use.

228. Under 21 C.F.R. § 814.82(a)(2) and (9), the FDA may impose PAS requirements as a condition of device approval when necessary to provide reasonable assurance, or the continued reasonable assurance, of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

229. Specifically, the FDA may require as a condition to approval the continuing evaluation by the applicant of the safety, effectiveness, and reliability of the device, including the number of patients to be evaluated, as well as other requirements the FDA determines are necessary to provide continued reasonable assurance of the safety and effectiveness of the device.

230. On May 14, 2020, the FDA sent Allergan a warning letter, stating that Allergan had failed to comply with the PAS requirements established under 21 CFR § 814.82(a) for its NATRELLE Silicone-Filled Breast Implants

231. The PMA Approval Order for PMA P020056 dated November 17, 2006 required Allergan to conduct a "Large Postapproval Study."

232. The FDA detailed certain requirements of the Large Postapproval Study, including: (i) Conduct a 10-year large postapproval study to evaluate certain safety endpoints pursuant to the protocol dated October 16, 2006; (ii) Enroll 39,390 Allergan silicone gel implant patients (Round Responsive implants) and 19,605 saline-filled breast implant patients as the control group; (iii) Collect data on the following safety endpoints: long-term local complications, connective tissue diseases (CTDs), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and rupture results; (iv) Collect data via annual subject questionnaires,

either completed via the web, mail, or telephone; and (v) Collect local complication data from physician evaluations at 1, 4, and 10 years.

233. In 2011, the FDA convened the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, which recommended a redesign of the Large Postapproval Study to address challenges with both subject enrollment and follow-up.

234. In 2015, the FDA approved Allergan's redesigned study (P020056/S023/A008 and P040046/S012/A003), "NATRELLE and 410 Combined Cohort."

235. The redesigned Large Postapproval Study included the following requirements: (i) Conduct a 10-year study to compare Round Responsive implants with Saline implants or national norms with regard to long-term safety; reproduction, pregnancy outcomes, and lactation; effects of mammography; effects of satisfaction with breasts and psychosocial well-being, and silicone subject compliance with magnetic resonance imaging (MRI) recommendations; (ii) Enroll at least 2,000 subjects with Round Responsive implants and 245 subjects with saline implants; (iii) Collect data on the following safety endpoints: long-term local complications, connective tissue diseases (CTDs), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and rupture results; (iv) Collect data via annual subject questionnaires, either completed via the web, mail, or telephone; and (v) Collect local complication data from physician evaluations at 1, 4, and 10 years.

236. According to the FDA, the redesigned Large Postapproval Study included approximately 2,000 Round Responsive implant and 245 Saline implant subjects from the originally enrolled subjects, who had numbered over 40,000. At the time of their enrollment in the

redesigned study, the subjects were selected using cluster sampling and had completed all baseline and years 1, 2, 3, and 4 follow-up questionnaires.

237. Under the redesigned study, subjects were to be followed for a total of 10 years after implantation of the devices. "Follow-up" under the redesigned study referred to the number of subjects who provide health information at baseline and annual questionnaire data for each of 10 years, and the implant subjects who complete a physical exam conducted by an investigator at years 1, 4, and 10 (each, an "office visit").

238. The FDA set an undisclosed target follow-up rate at the end of year 10 for Allergan.

239. Allergan submitted an update report to the FDA on August 2, 2016.[20]

240. Following Allergan's submission, the FDA issued a decision letter on October 6, 2016[21] to Allergan with "an advisory related to office visit follow-up rates." The advisory stated:

> Your 2016 report revealed that the office visit follow-up rates for the Round Responsive implant arm were [redacted in original] of 2,000) and [redacted in original] for years 1 and 4, respectively, even though the year 4 follow-up window was extended to 2-7 years post implantation (i.e., subjects would be counted as having completed the year 4 office visit follow-up provided that they were seen any time between 2 years (+1 day) to 7 years). Because the study was ongoing, and there were still many subjects who had not reached or exceeded their year 4 office visit follow-up window, these follow-up rates were considered acceptable at that time. The decision letter reminded your firm that it is important to keep reasonably high (>80%) office visit follow-up rates to ensure unbiased implementation of the study and to obtain meaningful results. Your firm was asked to consider strategies to ensure/improve office visit follow-up rates, and several strategies were recommended by FDA.

241. Allergan submitted an update report to the FDA on August 2, 2017.[22]

[20] P020056/R072 (Bundled with P040046/R020). Plaintiffs do not have a copy of this document.
[21] Plaintiffs do not have a copy of this document.
[22] P020056/R077 (Bundled with P040046/R024). Plaintiffs do not have a copy of this document.

242. Following Allergan's submission, the FDA issued a decision letter on November 08, 2017[23] to Allergan which "included a deficiency related to office visit follow-up rates." The letter stated:

> Specifically, compliance with the years 1 and 4 office visits were [redacted in original] of 2,000) and [redacted in original], respectively, for the Round Responsive implant arm. Given that the year 4 office visit follow-up window had been extended as described above, it was unclear why the study had made little progress in collecting more subjects' office visit data. Although your firm incorporated some recommended strategies to improve office visit compliance, including biannual telephone outreach to subjects and biannual calls to sites, the office visit follow-up rates remained low. To ensure the redesigned study was implemented and monitored in a timely manner, your firm was asked to provide additional information, such as obstacles you encountered, strategies that you took, and strategies that you planned to take to improve office visit compliance. This additional information was supplied in P020056/R077/A001 (Bundled with P040046/R024/A001), and the proposed strategies were deemed acceptable by FDA on February 1, 2018. However, as described below, the proposed strategies for improving office visit follow-up rates were ineffective.

243. Allergan submitted an update report to the FDA on August 3, 2018,[24] which was later amended.

244. On October 30, 2018, the FDA issued a decision letter[25] to Allergan identifying multiple deficiencies, and including a request for certain information to facilitate interpretation of office visit follow-up data.

245. The deficiencies included the low office visit follow-up rate, which "prevents the meaningful evaluation of outcome information, and, based on the late stage in the study period, [] your study will fail to meet the target follow-up rate of [redacted in original] at year 10."

---

[23] Plaintiffs do not have a copy of this document.
[24] P020056/(b)(4) (Bundled with P040046/(b)(4)), Plaintiffs do not have a copy of this document.
[25] Plaintiffs do not have a copy of this document.

246. The deficiencies also included a decrease in the number of Institutional Review Board (IRB)-approved sites participating in the Large Postapproval Study, which "has the potential to result in the loss of [redacted in original] subjects…."

247. The FDA issued a decision letter dated May 14, 2020 to Allergan "indicating that the study status on FDA's website would be changed to 'progress inadequate' due, in part, to the low office visit follow-up rate of the Round Responsive implant arm.

248. The FDA's May 14, 2020 warning letter also provided that Allergan "failed to collect local complication data, including safety endpoint data, during the year 4 physician evaluation at a follow-up rate necessary to meet the target follow-up rate of [redacted in original] at year 10. This failure prevents adequate evaluation of the safety, effectiveness, and reliability of the device at this late stage in the study period (year 9) and will prevent such an evaluation at the end of the study (year 10). You are thereby in violation of the requirements established as a condition to your device's approval under 21 C.F.R. § 814.82(a)(2) and (9)."

3. Allergan failed to comply with post-approval study requirements imposed by the FDA for its NATRELLE 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants (PMA P040046).

249. On May 14, 2020, the FDA sent Allergan a warning letter, stating that Allergan had failed to comply with the PAS requirements established under 21 CFR § 814.82(a) for its NATRELLE 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.

250. The FDA stated that Allergan failed to comply with the requirements to (i) "Evaluate the long-term clinical performance of Natrelle 410 Breast implants under general conditions of use in the postmarket environment"; and (ii) "Enroll [redacted in original] women receiving NATRELLE 410 Breast Implants and [redacted in original] women receiving NATRELLE Saline implants as the comparison group. Under the redesigned study (described above): Enroll 530 subjects with Style 410 implants and 245 subjects with Saline implants."

251. Under the redesigned study, Allergan had 14 months to completely enroll the Style 410 implant subjects. The study was initiated in November 2015 and subjects should have been completely enrolled by January 2017.

252. However, Allergan did not enroll an adequate number of subjects in the study.

253. As a result, the FDA found that Allergan's "failure to enroll the required number of subjects in the Style 410 implant arm prevents adequate continuing evaluation of the safety, effectiveness, and reliability of the device and the continued reasonable assurance of the safety and effectiveness of your device, in violation of the requirements established as a condition to your device's approval under 21 CFR § 814.82(a)(2) and (9)."

254. Moreover, Allergan advised the FDA on August 1, 2019 that it had stopped enrolling subjects in the study. In its May 14, 2020 warning letter, the FDA stated that it "believes it is important for you to complete the redesigned study to develop a long-term safety profile for the device."

4. Allergan failed to add or strengthen the warnings regarding the causal association between the Recalled BIOCELL Implants and BIA-ALCL.

255. Pursuant to 21 CFR § 814.39(d)(1)-(2), Allergan was required to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

256. Allergan continually acquired new information regarding the significantly increased risk of BIA-ALCL posed by its Recalled BIOCELL Implants.

257. Based on the newly acquired information, Allergan was obligated to change the Directions for Use for its Recalled BIOCELL Implants and to add or strengthen the warnings regarding the causal association between the devices and BIA-ALCL.

258. Rather than disclose the increasingly clear link between its product and BIA-ALCL, Allergan instead actively concealed its acquired knowledge of the causal link through its manipulation of adverse event reports and other public reports as described above.

259. Additionally, under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to revise its product labeling after becoming aware of otherwise-undisclosed dangers posed by its Recalled BIOCELL Implants. Allergan recklessly and intentionally failed to do so.

260. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan was required at all material times to promptly report any information suggesting that one of its products may have contributed to a serious injury, or had malfunctioned where the malfunction would be likely to contribute to a serious injury if it were to recur.

261. Allergan's insufficient follow-up rates and inadequate data, as detailed above, establish and confirm Allergan's reckless and intentional disregard for the safety of thousands of women in the United States.

262. Each of the above-cited deficiencies in Allergan's post-market compliance was a "failure to comply with any post-approval requirement" and each constituted a ground for withdrawal of the PMA. Defendant's conduct violated Defendant's duties under the law.

263. Notwithstanding Allergan's failures to comply with post-approval requirements, including the failures described above, Allergan continued to commercially distribute its Recalled BIOCELL Implants. As expressly provided in the PMA, such distribution was a violation of federal law.

264. Had Allergan substantially complied with the PMA, rather than flagrantly, recklessly, and intentionally underperforming the post-approval requirements as alleged above, Allergan's disclosures would have led to much wider knowledge of the risks associated with Allergan's products. In addition, Allergan's physician and patient labeling would have materially changed over time, and patients including Plaintiff, and medical providers including Plaintiff's physicians, would not have purchased or implanted Allergan's products.

265. Plaintiffs have not received, and Defendant has refused to provide, discovery related to this wrongful conduct. This discovery includes FDA correspondence, PMAs and PMA Supplements for the BIOCELL line, adverse event reporting, post marketing surveillance materials, manufacturing and quality control records, internal communications and presentations, manufacturing and related quality control documents, reports received of BIA-ALCL from third parties, reports made to regulatory agencies beyond the FDA, internal research regarding incidence or risk of BIA-ALCL, and inspection reports by any entity or agency, pertaining to the recalled products. Plaintiffs anticipate, upon information and belief, that these items will demonstrate more completely how Allergan failed to comply with the PMA and violated its obligations under federal and parallel state law requirements. This additional information is necessary to more fully describe Allergan's conduct and the issues and claims addressed in this Complaint.

V. EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

266. The running of any statute of limitations has been equitably tolled by reason of Defendant's fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Defendant actively concealed from Plaintiffs and Class members and their physicians the true risks associated with the Recalled BIOCELL Implants.

267. Instead of disclosing to consumers the link between the Recalled BIOCELL Implants and the BIA-ALCL, Defendant continued to manufacture and sell the Recalled BIOCELL Implants without disclosing this information. Further, Defendant misled the healthcare providers and the public into believing the Recalled BIOCELL Implants were safe by repeatedly touting the safety of Recalled BIOCELL Implants.

268. As a result of Defendant's actions, Plaintiffs and Class Members were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendant's acts and omissions.

VI. CLASS ALLEGATIONS

A. Nationwide Class Definition

269. All Plaintiffs bring this action in their individual capacity and on behalf of the following Nationwide Class pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Nationwide Class:** All individuals in the United States and its territories who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants, FDA-recalled Allergan tissue expanders for the breast that have BIOCELL texturing, and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.[26]

In addition to the Nationwide Class, Plaintiffs bring this action on behalf of their respective state subclasses, and/or groupings of state subclasses.

[26] *See* note 1, *supra*, for a full listing of the products at issue.

B. State Subclass Definitions

270. Plaintiffs bring this action in their individual capacities and on behalf of the following Alabama Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Alabama Subclass:** All individuals in Alabama who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

271. Plaintiffs bring this action in their individual capacities and on behalf of the following Alaska Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Alaska Subclass:** All individuals in Alaska who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

272. Plaintiffs bring this action in their individual capacities and on behalf of the following American Somoa Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **American Samoa Subclass:** All individuals in American Samoa who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and

who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

273. Plaintiffs bring this action in their individual capacities and on behalf of the following Arizona Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Arizona Subclass:** All individuals in Arizona who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

274. Plaintiffs bring this action in their individual capacities and on behalf of the following Arkansas Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Arkansas Subclass:** All individuals in Arkansas who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

275. Plaintiffs bring this action in their individual capacities and on behalf of the following California Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **California Subclass:** All individuals in California who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured

Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

276. Plaintiffs bring this action in their individual capacities and on behalf of the following Colorado Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Colorado Subclass:** All individuals in Colorado who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

277. Plaintiffs bring this action in their individual capacities and on behalf of the following Connecticut Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Connecticut Subclass:** All individuals in Connecticut who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

278. The Delaware Plaintiff brings this action in their individual capacity and on behalf of the following Delaware Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Delaware Subclass:** All individuals in Delaware who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture

Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

279. Plaintiffs bring this action in their individual capacities and on behalf of the following District of Columbia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **District of Columbia Subclass:** All individuals in the District of Columbia who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

280. Plaintiffs bring this action in their individual capacities and on behalf of the following Florida Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Florida Subclass:** All individuals in Florida who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

281. Plaintiffs bring this action in their individual capacities and on behalf of the following Georgia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Georgia Subclass:** All individuals in Georgia who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue

Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

282. Plaintiffs bring this action in their individual capacities and on behalf of the following Guam Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Guam Subclass:** All individuals in Guam who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

283. Plaintiffs bring this action in their individual capacities and on behalf of the following Hawaii Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Hawaii Subclass:** All individuals in Hawaii who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

284. Plaintiffs bring this action in their individual capacities and on behalf of the following Idaho Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Idaho Subclass:** All individuals in Idaho who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured

Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

285. Plaintiffs bring this action in their individual capacities and on behalf of the following Illinois Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Illinois Subclass:** All individuals in Illinois who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

286. Plaintiffs bring this action in their individual capacities and on behalf of the following Indiana Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Indiana Subclass:** All individuals in Indiana who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

287. Plaintiffs bring this action in their individual capacities and on behalf of the following Iowa Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Iowa Subclass:** All individuals in Iowa who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

288. Plaintiffs bring this action in their individual capacities and on behalf of the following Kansas Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Kansas Subclass:** All individuals in Kansas who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

289. Plaintiffs bring this action in their individual capacities and on behalf of the following Kentucky Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Kentucky Subclass:** All individuals in Kentucky who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

290. Plaintiffs bring this action in their individual capacities and on behalf of the following Louisiana Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Louisiana Subclass:** All individuals in Louisiana who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-

recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL® Silicone-Filled BIOCELL® Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

291. Plaintiffs bring this action in their individual capacities and on behalf of the following Maine Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Maine Subclass:** All individuals in Maine who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

292. Plaintiffs bring this action in their individual capacities and on behalf of the following Maryland Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Maryland Subclass:** All individuals in Maryland who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

293. Plaintiffs bring this action in their individual capacities and on behalf of the following Massachusetts Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Massachusetts Subclass: All individuals in Massachusetts who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

294. Plaintiffs bring this action in their individual capacities and on behalf of the following Michigan Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Michigan Subclass: All individuals in Michigan who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

295. Plaintiffs bring this action in their individual capacities and on behalf of the following Minnesota Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Minnesota Subclass: All individuals in Minnesota who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

296. Plaintiffs bring this action in their individual capacities and on behalf of the following Mississippi Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Mississippi Subclass: All individuals in Mississippi who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

297. Plaintiffs bring this action in their individual capacities and on behalf of the following Missouri Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Missouri Subclass: All individuals in Missouri who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

298. Plaintiffs bring this action in their individual capacities and on behalf of the following Montana Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Montana Subclass: All individuals in Montana who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

299. Plaintiffs bring this action in their individual capacities and on behalf of the following Nebraska Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Nebraska Subclass:** All individuals in Nebraska who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

300. Plaintiffs bring this action in their individual capacities and on behalf of the following Nevada Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Nevada Subclass:** All individuals in Nevada who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

301. Plaintiffs bring this action in their individual capacities and on behalf of the following New Hampshire Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New Hampshire Subclass:** All individuals in New Hampshire who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

302. Plaintiffs bring this action in their individual capacities and on behalf of the following New Jersey Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New Jersey Subclass:** All individuals in New Jersey who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

303. Plaintiffs bring this action in their individual capacities and on behalf of the following New Mexico Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New Mexico Subclass:** All individuals in New Mexico who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

304. Plaintiffs bring this action in their individual capacities and on behalf of the following New York Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New York Subclass:** All individuals in New York who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

305. Plaintiffs bring this action in their individual capacities and on behalf of the following North Carolina Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **North Carolina Subclass:** All individuals in North Carolina who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

306. Plaintiffs bring this action in their individual capacities and on behalf of the following North Dakota Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **North Dakota Subclass:** All individuals in North Dakota who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

307. Plaintiffs bring this action in their individual capacities and on behalf of the following Northern Mariana Islands Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Northern Mariana Islands Subclass:** All individuals in the Northern Mariana Islands who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

308. Plaintiffs bring this action in their individual capacities and on behalf of the following Ohio Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Ohio Subclass: All individuals in Ohio who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

309. Plaintiffs bring this action in their individual capacities and on behalf of the following Oklahoma Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Oklahoma Subclass: All individuals in Oklahoma who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

310. Plaintiffs bring this action in their individual capacities and on behalf of the following Oregon Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Oregon Subclass: All individuals in Oregon who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

311. Plaintiffs bring this action in their individual capacities and on behalf of the following Pennsylvania Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Pennsylvania Subclass:** All individuals in Pennsylvania who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

312. Plaintiffs bring this action in their individual capacities and on behalf of the following Puerto Rico Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Puerto Rico Subclass:** All individuals in Puerto Rico who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

313. Plaintiffs bring this action in their individual capacities and on behalf of the following Rhode Island Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Rhode Island Subclass:** All individuals in Rhode Island who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

314. Plaintiffs bring this action in their individual capacities and on behalf of the following South Carolina Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **South Carolina Subclass:** All individuals in South Carolina who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

315. Plaintiffs bring this action in their individual capacities and on behalf of the following South Dakota Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **South Dakota Subclass:** All individuals in South Dakota who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

316. Plaintiffs bring this action in their individual capacities and on behalf of the following Tennessee Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Tennessee Subclass:** All individuals in Tennessee who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

317. Plaintiffs bring this action in their individual capacities and on behalf of the following Texas Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Texas Subclass: All individuals in Texas who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

318. Plaintiffs bring this action in their individual capacities and on behalf of the following U.S. Virgin Islands Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

U.S. Virgin Islands Subclass: All individuals in the U.S. Virgin Islands who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

319. Plaintiffs bring this action in their individual capacities and on behalf of the following Utah Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Utah Subclass: All individuals in Utah who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

320. Plaintiffs bring this action in their individual capacities and on behalf of the following Vermont Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Vermont Subclass: All individuals in Vermont who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

321. Plaintiffs bring this action in their individual capacities and on behalf of the following Virginia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Virginia Subclass: All individuals in Virginia who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

322. Plaintiffs bring this action in their individual capacities and on behalf of the following Washington Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Washington Subclass: All individuals in Washington who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

323. Plaintiffs bring this action in their individual capacities and on behalf of the following West Virginia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

West Virginia Subclass: All individuals in West Virginia who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

324. Plaintiffs bring this action in their individual capacities and on behalf of the following Wisconsin Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Wisconsin Subclass: All individuals in Wisconsin who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

325. Plaintiffs bring this action in their individual capacities and on behalf of the following Wyoming Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

Wyoming Subclass: All individuals in Wyoming who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

C. Non-PMA Device State Subclass Definitions

326. "Non-PMA BIOCELL Implants" refers to (i) recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant)

implanted prior to PMA approval (*i.e.,* May 10, 2000); (ii) recalled Allergan Natrelle 133 Plus Tissue Expanders and Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and (iii) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153.

327. Plaintiffs bring this action in their individual capacities and on behalf of the following Alabama Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Alabama Non-PMA Device Subclass:** All individuals in Alabama who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

328. Plaintiffs bring this action in their individual capacities and on behalf of the following Alaska Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Alaska Non-PMA Device Subclass:** All individuals in Alaska who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

329. Plaintiffs bring this action in their individual capacities and on behalf of the following American Somoa Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **American Samoa Non-PMA Device Subclass:** All individuals in American Samoa who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue

Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

330. Plaintiffs bring this action in their individual capacities and on behalf of the following Arizona Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Arizona Non-PMA Device Subclass:** All individuals in Arizona who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

331. Plaintiffs bring this action in their individual capacities and on behalf of the following Arkansas Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Arkansas Non-PMA Device Subclass:** All individuals in Arkansas who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

332. Plaintiffs bring this action in their individual capacities and on behalf of the following California Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **California Non-PMA Device Subclass:** All individuals in California who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with

Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

333. Plaintiffs bring this action in their individual capacities and on behalf of the following Colorado Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Colorado Non-PMA Device Subclass:** All individuals in Colorado who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

334. Plaintiffs bring this action in their individual capacities and on behalf of the following Connecticut Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Connecticut Non-PMA Device Subclass:** All individuals in Connecticut who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

335. The Delaware Plaintiff brings this action in their individual capacity and on behalf of the following Delaware Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Delaware Non-PMA Device Subclass:** All individuals in Delaware who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL

Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

336. Plaintiffs bring this action in their individual capacities and on behalf of the following District of Columbia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **District of Columbia Non-PMA Device Subclass:** All individuals in the District of Columbia who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

337. Plaintiffs bring this action in their individual capacities and on behalf of the following Florida Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Florida Non-PMA Device Subclass:** All individuals in Florida who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

338. Plaintiffs bring this action in their individual capacities and on behalf of the following Georgia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Georgia Non-PMA Device Subclass:** All individuals in Georgia who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

339. Plaintiffs bring this action in their individual capacities and on behalf of the following Guam Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Guam Non-PMA Device Subclass:** All individuals in Guam who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

340. Plaintiffs bring this action in their individual capacities and on behalf of the following Hawaii Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Hawaii Non-PMA Device Subclass:** All individuals in Hawaii who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

341. Plaintiffs bring this action in their individual capacities and on behalf of the following Idaho Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Idaho Non-PMA Device Subclass:** All individuals in Idaho who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

342. Plaintiffs bring this action in their individual capacities and on behalf of the following Illinois Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Illinois Non-PMA Device Subclass:** All individuals in Illinois who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

343. Plaintiffs bring this action in their individual capacities and on behalf of the following Indiana Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Indiana Non-PMA Device Subclass:** All individuals in Indiana who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

344. Plaintiffs bring this action in their individual capacities and on behalf of the following Iowa Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Iowa Non-PMA Device Subclass:** All individuals in Iowa who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

345. Plaintiffs bring this action in their individual capacities and on behalf of the following Kansas Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Kansas Non-PMA Device Subclass:** All individuals in Kansas who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

346. Plaintiffs bring this action in their individual capacities and on behalf of the following Kentucky Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Kentucky Non-PMA Device Subclass:** All individuals in Kentucky who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

347. Plaintiffs bring this action in their individual capacities and on behalf of the following Louisiana Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Louisiana Non-PMA Device Subclass:** All individuals in Louisiana who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

348. Plaintiffs bring this action in their individual capacities and on behalf of the following Maine Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Maine Non-PMA Device Subclass:** All individuals in Maine who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

349. Plaintiffs bring this action in their individual capacities and on behalf of the following Maryland Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Maryland Non-PMA Device Subclass:** All individuals in Maryland who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

350. Plaintiffs bring this action in their individual capacities and on behalf of the following Massachusetts Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Massachusetts Non-PMA Device Subclass:** All individuals in Massachusetts who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

351. Plaintiffs bring this action in their individual capacities and on behalf of the following Michigan Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Michigan Non-PMA Device Subclass:** All individuals in Michigan who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

352. Plaintiffs bring this action in their individual capacities and on behalf of the following Minnesota Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Minnesota Non-PMA Device Subclass:** All individuals in Minnesota who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

353. Plaintiffs bring this action in their individual capacities and on behalf of the following Mississippi Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Mississippi Non-PMA Device Subclass:** All individuals in Mississippi who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

354. Plaintiffs bring this action in their individual capacities and on behalf of the following Missouri Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Missouri Non-PMA Device Subclass:** All individuals in Missouri who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

355. Plaintiffs bring this action in their individual capacities and on behalf of the following Montana Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Montana Non-PMA Device Subclass:** All individuals in Montana who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

356. Plaintiffs bring this action in their individual capacities and on behalf of the following Nebraska Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Nebraska Non-PMA Device Subclass:** All individuals in Nebraska who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

357. Plaintiffs bring this action in their individual capacities and on behalf of the following Nevada Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Nevada Non-PMA Device Subclass:** All individuals in Nevada who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

358. Plaintiffs bring this action in their individual capacities and on behalf of the following New Hampshire Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New Hampshire Non-PMA Device Subclass:** All individuals in New Hampshire who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

359. Plaintiffs bring this action in their individual capacities and on behalf of the following New Jersey Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New Jersey Non-PMA Device Subclass:** All individuals in New Jersey who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

360. Plaintiffs bring this action in their individual capacities and on behalf of the following New Mexico Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New Mexico Non-PMA Device Subclass:** All individuals in New Mexico who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

361. Plaintiffs bring this action in their individual capacities and on behalf of the following New York Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **New York Non-PMA Device Subclass:** All individuals in New York who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

362. Plaintiffs bring this action in their individual capacities and on behalf of the following North Carolina Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **North Carolina Non-PMA Device Subclass:** All individuals in North Carolina who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

363. Plaintiffs bring this action in their individual capacities and on behalf of the following North Dakota Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **North Dakota Non-PMA Device Subclass:** All individuals in North Dakota who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

364. Plaintiffs bring this action in their individual capacities and on behalf of the following Northern Mariana Islands Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Northern Mariana Islands Non-PMA Device Subclass:** All individuals in the Northern Mariana Islands who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

365. Plaintiffs bring this action in their individual capacities and on behalf of the following Ohio Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Ohio Non-PMA Device Subclass:** All individuals in Ohio who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

366. Plaintiffs bring this action in their individual capacities and on behalf of the following Oklahoma Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Oklahoma Non-PMA Device Subclass:** All individuals in Oklahoma who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

367. Plaintiffs bring this action in their individual capacities and on behalf of the following Oregon Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Oregon Non-PMA Device Subclass:** All individuals in Oregon who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

368. Plaintiffs bring this action in their individual capacities and on behalf of the following Pennsylvania Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Pennsylvania Non-PMA Device Subclass:** All individuals in Pennsylvania who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

369. Plaintiffs bring this action in their individual capacities and on behalf of the following Puerto Rico Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Puerto Rico Non-PMA Device Subclass:** All individuals in Puerto Rico who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

370. Plaintiffs bring this action in their individual capacities and on behalf of the following Rhode Island Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Rhode Island Non-PMA Device Subclass:** All individuals in Rhode Island who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

371. Plaintiffs bring this action in their individual capacities and on behalf of the following South Carolina Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **South Carolina Non-PMA Device Subclass:** All individuals in South Carolina who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

372. Plaintiffs bring this action in their individual capacities and on behalf of the following South Dakota Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **South Dakota Non-PMA Device Subclass:** All individuals in South Dakota who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

373. Plaintiffs bring this action in their individual capacities and on behalf of the following Tennessee Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Tennessee Non-PMA Device Subclass:** All individuals in Tennessee who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

374. Plaintiffs bring this action in their individual capacities and on behalf of the following Texas Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Texas Non-PMA Device Subclass:** All individuals in Texas who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

375. Plaintiffs bring this action in their individual capacities and on behalf of the following U.S. Virgin Islands Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **U.S. Virgin Islands Non-PMA Device Subclass:** All individuals in the U.S. Virgin Islands who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

376. Plaintiffs bring this action in their individual capacities and on behalf of the following Utah Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Utah Non-PMA Device Subclass:** All individuals in Utah who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

377. Plaintiffs bring this action in their individual capacities and on behalf of the following Vermont Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Vermont Non-PMA Device Subclass:** All individuals in Vermont who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

378. Plaintiffs bring this action in their individual capacities and on behalf of the following Virginia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Virginia Non-PMA Device Subclass:** All individuals in Virginia who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

379. Plaintiffs bring this action in their individual capacities and on behalf of the following Washington Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Washington Non-PMA Device Subclass:** All individuals in Washington who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

380. Plaintiffs bring this action in their individual capacities and on behalf of the following West Virginia Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **West Virginia Non-PMA Device Subclass:** All individuals in West Virginia who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

381. Plaintiffs bring this action in their individual capacities and on behalf of the following Wisconsin Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Wisconsin Non-PMA Device Subclass:** All individuals in Wisconsin who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

382. Plaintiffs bring this action in their individual capacities and on behalf of the following Wyoming Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Wyoming Non-PMA Device Subclass:** All individuals in Wyoming who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (*i.e.,* May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

D. Release Subclass Definition

383. Plaintiffs Melinda Howard and Amber Ferrell-Steele also bring this action in their individual capacities and on behalf of the following Release Subclass pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> **Releases Subclass:** All individuals in the United States who: (i) for personal use, implanted Allergan Natrelle Saline-Filled Textured Breast Implants, Allergan Natrelle Silicone-Filled Textured Breast Implants, Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants, Allergan Natrelle 133 Plus Tissue Expander, or Allergan Natrelle 133 Tissue Expander with Suture Tabs that have been recalled by the FDA; and (ii) signed a *ConfidencePlus* Warranty Release or *ConfidencePlus* Premium Warranty Release.

384. The Nationwide Class and Subclasses may collectively be referred to as the "Classes." Excluded from the Classes are Defendant and any of their affiliates, parents, subsidiaries, officers, and directors; any entity in which Defendant has a controlling interest; all persons who make a timely election to be excluded from the class; governmental entities; and all judges assigned to hear any aspect of this litigation, including their immediate family members.

385. Plaintiffs reserve the right to modify or amend the class definitions, including the addition of one or more subclasses, after having the opportunity to conduct discovery.

E. Fed. R. Civ. P. 23 Requirements

386. ***Numerosity:*** The FDA has reported that the number of devices recalled in the United States is 246,381.[27] The members of the Classes are thus so numerous that joinder is impractical.

387. ***Typicality:*** Plaintiffs' claims are typical of the claims of putative class members in that each was implanted with one or more styles of the Recalled BIOCELL Implants and faces an increased risk of BIA-ALCL. Plaintiffs and the Class Members were injured through Defendant's common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the Class Members.

388. ***Adequacy:*** Plaintiffs will fairly and adequately protect the interests of the Class Members. Plaintiffs' interests and the interests of all other members of each respective class are identical, and Plaintiffs are cognizant of their respective duties and responsibilities to the Class Members. Further, the interests of the Class Members are not conflicting or divergent but, rather, are common. Accordingly, Plaintiffs can fairly and adequately represent the interests of both classes. Moreover, Plaintiffs' counsel are competent and experienced in litigating class actions,

[27] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

including litigation of this kind. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the Class Members' interests.

389. ***Commonality and Predominance:*** There are numerous questions of law and fact common to the classes, and these common questions predominate over any issues affecting only individual class members. Questions common to the classes include, but are not limited to:

a. Whether the Recalled BIOCELL Implants significantly increase the risk of developing BIA-ALCL;

b. Whether Allergan knew or should have known that the Recalled BIOCELL Implants significantly increase the risk of developing BIA-ALCL;

c. Whether Allergan's warnings regarding the risks of BIA-ALCL were adequate;

d. Whether the Recalled BIOCELL Implants were manufactured using a defective process in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements;

e. Whether Allergan was negligent in selling the Recalled BIOCELL Implants;

f. Whether Allergan failed to warn consumers regarding the risks of the Recalled BIOCELL Implants;

g. Whether Allergan violated federal standards and requirements for the marketing, warning, and reporting of the Recalled BIOCELL Implants;

h. Whether Allergan breached implied warranties connected with the Recalled BIOCELL Implants;

i. Whether Plaintiffs and the class members are entitled to compensatory damages and the amount thereof;

j. Whether Plaintiffs and class members are entitled to equitable relief, including medical monitoring;

k. Whether Plaintiffs and class members are entitled to recover the costs of explantation in order to mitigate their risk of developing BIA-ALCL;

l. Whether the releases obtained through the *ConfidencePlus* Warranty Program obtained after the filing of the first class action lawsuit related to the Recalled BIOCELL Implants are enforceable.

390. ***Superiority:*** A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiffs and the Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendant, and thus, individual litigation to redress Defendant's wrongful conduct would be impracticable. Individual litigation by each Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

391. ***Injunctive and Declaratory Relief:*** Class certification is also appropriate under Rule 23(b)(2) because Allergan has acted and refused to act on grounds generally applicable to the class as a whole, such that final injunctive relief is appropriate with respect to the class as a whole. Such injunctive relief includes, but is not limited to, the implementation and funding of a medical

monitoring program for the Plaintiffs and the class members that is sufficient to monitor their health and to ensure the beneficial early detection of diseases, specifically BIA-ALCL, caused by exposure to Defendant's Recalled BIOCELL Implants.

392. This action is also properly maintainable under Rule 23(c)(4) in that particular issues common to the class, as described above in part, are most appropriately and efficiently resolved via class action, and would advance the disposition of this matter and the parties' interests therein.

VII. CAUSES OF ACTION

A. STRICT LIABILITY – FAILURE TO WARN

COUNT 1
Strict Products Liability—Failure to Warn
Alabama

393. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

394. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Non-PMA Device Subclass.

395. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Alabama Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Alabama Non-PMA Device Subclass Members.

396. At all relevant times, Defendant owed a duty to use reasonable care in the labeling, marketing, advertising, promotion, and sale of the Non-PMA BIOCELL Implants and a duty to warn the Alabama Non-PMA Device Subclass Members and the medical community, including the Alabama Non-PMA Device Subclass Members' treating physicians, of the true risk associated with implanting the Non-PMA BIOCELL Implants.

397. The Non-PMA BIOCELL Implants were not reasonably safe for their intended use and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings to the Alabama Non-PMA Device Subclass Members and the medical community, including the Alabama Non-PMA Device Subclass Members' treating physicians, regarding, among other subjects:

398. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

399. That the Non-PMA BIOCELL Implants were not manufactured in conformance with legal and good manufacturing requirements; and

400. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

401. At the time the Alabama Non-PMA Device Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that the implants were defectively manufactured. The risk and defective nature of the implants was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution, including through available adverse event reports, Defendant's own clinical studies, available scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

402. The Alabama Non-PMA Device Subclass Members and their treating physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Non-PMA BIOCELL Implants for implantation. The Alabama Non-PMA Device

Subclass Members and their treating physicians did not, and could not have, recognized the true risks associated with the Non-PMA BIOCELL Implants.

403. The Non-PMA BIOCELL Implants presented a substantial risk to the Alabama Non-PMA Device Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Non-PMA BIOCELL Implants would be implanted in the Alabama Non-PMA Device Subclass Members' and ordinary consumers' bodies without inspection of defects and without knowledge of the risks involved in their use.

404. The inadequate warnings were a substantial factor in bringing about the Alabama Non-PMA Device Subclass Members' injuries which would not have occurred but for the use of the Non-PMA BIOCELL Implants. If Defendant had warned the medical community, the Alabama Non-PMA Device Subclass Members' treating physicians, and the general public about the true risk, the information would have been known to the Alabama Non-PMA Device Subclass Members and their treating physicians, and the Alabama Non-PMA Device Subclass Members and their treating physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. The Alabama Non-PMA Device Subclass Members and their treating physicians would not have used a Non-PMA BIOCELL Implant if they had known of the true safety risks associated with the implants.

405. Accordingly, the Alabama Non-PMA Device Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Non-PMA BIOCELL Implants.

406. As a direct and proximate result of Defendant's actions and omissions, the Alabama Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 2
Strict Product Liability—Failure to Warn
Alaska

407. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

408. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

409. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Alaska Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Alaska Subclass Members.

410. The Recalled BIOCELL Implants that were implanted into Alaska Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

411. Under Alaska law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Alaska Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

412. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

413. Defendant failed to adequately warn the FDA, medical professionals, and Alaska Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

414. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

415. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

416. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

417. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Alaska Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

418. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled

BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

419. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

420. Alaska Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Alaska Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

421. The Recalled BIOCELL Implants presented a substantial risk to Alaska Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in

Alaska Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

422. The inadequate warnings were a substantial factor in bringing about Alaska Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

423. If, as mandated by Alaska law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Alaska Subclass Members and their physicians, and Alaska Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Alaska Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Alaska Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

424. As a direct and proximate result of Defendant's actions and omissions, Alaska Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 3
Strict Products Liability—Failure to Warn
Arizona

425. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

426. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arizona Non-PMA Device Subclass.

427. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Arizona Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Arizona Non-PMA Device Subclass Members.

428. At all relevant times, Defendant owed a duty to use reasonable care in the labeling, marketing, advertising, promotion, and sale of the Non-PMA BIOCELL Implants and a duty to warn the Arizona Non-PMA Device Subclass Members and the medical community, including the Arizona Non-PMA Device Subclass Members' treating physicians, of the true risk associated with implanting the Non-PMA BIOCELL Implants.

429. The Non-PMA BIOCELL Implants were not reasonably safe for their intended use and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings to the Arizona Non-PMA Device Subclass Members and the medical community, including the

Arizona Non-PMA Device Subclass Members' treating physicians, regarding, among other subjects:

430. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

431. That the Non-PMA BIOCELL Implants were not manufactured in conformance with legal and good manufacturing requirements; and

432. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

433. At the time the Arizona Non-PMA Device Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that the implants were defectively manufactured. The risk and defective nature of the implants was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution, including through available adverse event reports, Defendant's own clinical studies, available scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

434. The Arizona Non-PMA Device Subclass Members and their treating physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Non-PMA BIOCELL Implants for implantation. The Arizona Non-PMA Device Subclass Members and their treating physicians did not, and could not have, recognized the true risks associated with the Non-PMA BIOCELL Implants.

435. The Non-PMA BIOCELL Implants presented a substantial risk to the Arizona Non-PMA Device Subclass Members and ordinary consumers when used for their intended purpose or

in a reasonably foreseeable manner. Defendant knew that the Non-PMA BIOCELL Implants would be implanted in the Arizona Non-PMA Device Subclass Members' and ordinary consumers' bodies without inspection of defects and without knowledge of the risks involved in their use.

436. The inadequate warnings were a substantial factor in bringing about the Arizona Non-PMA Device Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. If Defendant had warned the medical community, the Arizona Non-PMA Device Subclass Members' treating physicians, and the general public about the true risk, the information would have been known to the Arizona Non-PMA Device Subclass Members and their treating physicians, and the Arizona Non-PMA Device Subclass Members and their treating physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. The Arizona Non-PMA Device Subclass Members and their treating physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

437. Accordingly, the Arizona Non-PMA Device Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

438. As a direct and proximate result of Defendant's actions and omissions, the Arizona Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including

surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 4
Strict Product Liability—Failure to Warn
American Samoa

439. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

440. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Subclass.

441. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into American Somoa Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including American Somoa Subclass Members.

442. The Recalled BIOCELL Implants that were implanted into American Somoa Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

443. Under American Samoa law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and American Somoa Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

444. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

445. Defendant failed to adequately warn the FDA, medical professionals, and American Somoa Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

446. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

447. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

448. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

449. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time American Somoa Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

450. Rather than disclose the truth, Defendant, in violation of its duty to disclose under American Samoa law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

451. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

452. American Somoa Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. American Somoa Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

453. The Recalled BIOCELL Implants presented a substantial risk to American Somoa Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in American Somoa Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

454. The inadequate warnings were a substantial factor in bringing about American Somoa Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other

means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

455. If, as mandated by American Samoa law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to American Somoa Subclass Members and their physicians, and American Somoa Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. American Somoa Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, American Somoa Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

456. As a direct and proximate result of Defendant's actions and omissions, American Somoa Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs

of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 5
Strict Product Liability—Failure to Warn
Arkansas

457. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

458. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Subclass.

459. Under the Arkansas Product Liability Act, Ark. Code Ann. § 16–116–202(5), Defendant is strict liability for personal injury, death, or property damage caused to Arkansas Subclass Members, and caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of the Recalled BIOCELL Implants.

460. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Arkansas Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Arkansas Subclass Members.

461. The Recalled BIOCELL Implants that were implanted into Arkansas Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

462. Under Arkansas law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Arkansas Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

463. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

464. Defendant failed to adequately warn the FDA, medical professionals, and Arkansas Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

465. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

466. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

467. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

468. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Arkansas Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

469. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled

BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

470. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

471. Arkansas Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Arkansas Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

472. The Recalled BIOCELL Implants presented a substantial risk to Arkansas Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in

Arkansas Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

473. The inadequate warnings were a substantial factor in bringing about Arkansas Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

474. If, as mandated by Arkansas law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Arkansas Subclass Members and their physicians, and Arkansas Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Arkansas Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Arkansas Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

475. As a direct and proximate result of Defendant's actions and omissions, Arkansas Subclass Members have sustained physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 6
Strict Product Liability—Failure to Warn
California

476. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

477. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass.

478. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into California Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including California Subclass Members.

479. The Recalled BIOCELL Implants that were implanted into California Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

480. Under California law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and California Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

481. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA

concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

482. Defendant failed to adequately warn the FDA, medical professionals, and California Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

483. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

484. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

485. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

486. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time California Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

487. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA

requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

488. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

489. California Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. California Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

490. The Recalled BIOCELL Implants presented a substantial risk to California Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in California Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

491. The inadequate warnings were a substantial factor in bringing about California Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

492. If, as mandated by California law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to California Subclass Members and their physicians, and California Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. California Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

493. As a direct and proximate result of Defendant's actions and omissions, California Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 7
Strict Product Liability—Failure to Warn
Colorado

494. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

495. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

496. Defendant is strictly liable under the Colorado Product Liability Act, Colo. Rev. Stat. §§ 13–21–401 *et seq.*, as "manufacturers" engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

497. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Colorado Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Colorado Subclass Members.

498. The Recalled BIOCELL Implants that were implanted into Colorado Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

499. Under Colorado law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Colorado Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

500. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

501. Defendant failed to adequately warn the FDA, medical professionals, and Colorado Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

502. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

503. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

504. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

505. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Colorado Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

506. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

507. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including

the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

508. Colorado Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Colorado Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

509. The Recalled BIOCELL Implants presented a substantial risk to Colorado Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Colorado Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

510. The inadequate warnings were a substantial factor in bringing about Colorado Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate

information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

511. If, as mandated by Colorado law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Colorado Subclass Members and their physicians, and Colorado Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Colorado Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

512. As a direct and proximate result of Defendant's actions and omissions, Colorado Subclass Members have a significantly increased risk of BIA-ALCL and suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 8
Strict Product Liability—Failure to Warn
District of Columbia

513. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

514. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the District of Columbia Subclass.

515. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into District of

Columbia Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including District of Columbia Subclass Members.

516. The Recalled BIOCELL Implants that were implanted into District of Columbia Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

517. Under District of Columbia law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and District of Columbia Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

518. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

519. Defendant failed to adequately warn the FDA, medical professionals, and District of Columbia Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

520. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

521. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

522. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

523. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time District of Columbia Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

524. Rather than disclose the truth, Defendant, in violation of its duty to disclose under District of Columbia law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

525. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of

developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

526. District of Columbia Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. District of Columbia Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

527. The Recalled BIOCELL Implants presented a substantial risk to District of Columbia Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in District of Columbia Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

528. The inadequate warnings were a substantial factor in bringing about District of Columbia Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

529. If, as mandated by District of Columbia law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to District of Columbia Subclass Members and their physicians, and District of Columbia Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. District of Columbia Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

530. As a direct and proximate result of Defendant's actions and omissions, District of Columbia Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 9
Strict Product Liability—Failure to Warn
Florida

531. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

532. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass.

533. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Florida Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Florida Subclass Members.

534. The Recalled BIOCELL Implants that were implanted into Florida Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been

manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

535. Under Florida law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Florida Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

536. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

537. Defendant failed to adequately warn the FDA, medical professionals, and Florida Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

538. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

539. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

540. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

541. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Florida Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge

from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

542. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

543. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

544. Florida Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Florida Subclass Members, ordinary consumers, and medical

professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

545. The Recalled BIOCELL Implants presented a substantial risk to Florida Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Florida Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

546. The inadequate warnings were a substantial factor in bringing about Florida Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

547. If, as mandated by Florida law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Florida Subclass Members and their physicians, and Florida Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Florida Subclass Members and their physicians would not have used a Recalled BIOCELL Implant

if they had known of the true safety risks associated with the implants. As a direct and proximate result of Defendant's actions and omissions, Florida Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 10
Strict Product Liability—Failure to Warn
Georgia

548. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

549. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Subclass.

550. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Georgia Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Georgia Subclass Members.

551. The Recalled BIOCELL Implants that were implanted into Georgia Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

552. Under Georgia law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Georgia Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

553. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA

concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

554. Defendant failed to adequately warn the FDA, medical professionals, and Georgia Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

555. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

556. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

557. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

558. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Georgia Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

559. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants.

Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

560. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

561. Georgia Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Georgia Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

562. The Recalled BIOCELL Implants presented a substantial risk to Georgia Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Georgia Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

563. The inadequate warnings were a substantial factor in bringing about Georgia Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

564. If, as mandated by Georgia law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Georgia Subclass Members and their physicians, and Georgia Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Georgia Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Georgia Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

565. As a direct and proximate result of Defendant's actions and omissions, Georgia Subclass Members have sustained physical injury, have a significantly increased risk of developing

BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 11
Strict Product Liability—Failure to Warn
Guam

566. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

567. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass.

568. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Guam Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Guam Subclass Members.

569. The Recalled BIOCELL Implants that were implanted into Guam Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

570. Under Guam law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Guam Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

571. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

572. Defendant failed to adequately warn the FDA, medical professionals, and Guam Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

573. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

574. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

575. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

576. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Guam Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

577. Rather than disclose the truth, Defendant, in violation of its duty to disclose under Guam law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

578. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

579. Guam Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Guam Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

580. The Recalled BIOCELL Implants presented a substantial risk to Guam Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Guam Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

581. The inadequate warnings were a substantial factor in bringing about Guam Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—

routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

582. If, as mandated by Guam law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Guam Subclass Members and their physicians, and Guam Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Guam Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Guam Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

583. As a direct and proximate result of Defendant's actions and omissions, Guam Subclass Members have sustained physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 12
Strict Product Liability—Failure to Warn
Hawaii

584. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

585. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Subclass.

586. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Hawaii Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Hawaii Subclass Members.

587. The Recalled BIOCELL Implants that were implanted into Hawaii Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

588. Under Hawaii law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Hawaii Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

589. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

590. Defendant failed to adequately warn the FDA, medical professionals, and Hawaii Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

591. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

592. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

593. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

594. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Hawaii Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

595. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

596. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including

the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

597. Hawaii Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Hawaii Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

598. The Recalled BIOCELL Implants presented a substantial risk to Hawaii Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Hawaii Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

599. The inadequate warnings were a substantial factor in bringing about Hawaii Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate

information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

600. If, as mandated by Hawaii law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Hawaii Subclass Members and their physicians, and Hawaii Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Hawaii Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Hawaii Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

601. As a direct and proximate result of Defendant's actions and omissions, Hawaii Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 13
Strict Product Liability—Failure to Warn
Idaho

602. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

603. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Subclass.

604. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Idaho Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Idaho Subclass Members.

605. The Recalled BIOCELL Implants that were implanted into Idaho Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

606. Under Idaho law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Idaho Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

607. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

608. Defendant failed to adequately warn the FDA, medical professionals, and Idaho Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

609. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

610. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

611. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

612. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Idaho Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

613. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

614. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

615. Idaho Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Idaho Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

616. The Recalled BIOCELL Implants presented a substantial risk to Idaho Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Idaho Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

617. The inadequate warnings were a substantial factor in bringing about Idaho Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated

by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

618. If, as mandated by Idaho law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Idaho Subclass Members and their physicians, and Idaho Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Idaho Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Idaho Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

619. As a direct and proximate result of Defendant's actions and omissions, Idaho Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 14
Strict Product Liability—Failure to Warn
Illinois

620. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

621. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Subclass.

622. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Illinois Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Illinois Subclass Members.

623. The Recalled BIOCELL Implants that were implanted into Illinois Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

624. Under Illinois law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Illinois Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

625. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

626. Defendant failed to adequately warn the FDA, medical professionals, and Illinois Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

627. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

628. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

629. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

630. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Illinois Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

631. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

632. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of

developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

633. Illinois Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Illinois Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

634. The Recalled BIOCELL Implants presented a substantial risk to Illinois Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Illinois Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

635. The inadequate warnings were a substantial factor in bringing about Illinois Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

636. If, as mandated by Illinois law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Illinois Subclass Members and their physicians, and Illinois Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Illinois Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

637. As a direct and proximate result of Defendant's actions and omissions, Illinois Subclass Members have a significantly increased risk of BIA-ALCL and suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 15
Strict Product Liability—Failure to Warn
Indiana

638. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

639. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass.

640. The Indiana Product Liability Act (Ind. Code Ann. § 34–20–1–1) governs all actions brought by a user or consumer against a manufacturer for physical harm caused by a product.

641. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Indiana Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Indiana Subclass Members.

642. The Recalled BIOCELL Implants that were implanted into Indiana Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

643. Under Indiana law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Indiana Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

644. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

645. Defendant failed to adequately warn the FDA, medical professionals, and Indiana Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

646. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

647. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

648. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

649. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Indiana Subclass Members received

their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

650. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

651. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

652. Indiana Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Indiana Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

653. The Recalled BIOCELL Implants presented a substantial risk to Indiana Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Indiana Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

654. The inadequate warnings were a substantial factor in bringing about Indiana Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

655. The Recalled BIOCELL Implants were defective under Burns Ind. Code Ann. § 34-20-4-2 because Allergan failed to: (1) properly package or label the product to give reasonable warnings of danger about the product; or (2) give reasonably complete instructions on proper use

of the product; when Allergan, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer.

656. If, as mandated by Indiana law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Indiana Subclass Members and their physicians, and Indiana Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL.

657. Indiana Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Indiana Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

658. As a direct and proximate result of Defendant's actions and omissions, Indiana Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 16
Strict Product Liability—Failure to Warn
Iowa

659. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

660. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass.

661. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Iowa Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Iowa Subclass Members.

662. The Recalled BIOCELL Implants that were implanted into Iowa Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

663. Under Iowa law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Iowa Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

664. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

665. Defendant failed to adequately warn the FDA, medical professionals, and Iowa Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

666. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

667. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

668. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

669. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Iowa Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

670. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

671. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of

developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

672. Iowa Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Iowa Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

673. The Recalled BIOCELL Implants presented a substantial risk to Iowa Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Iowa Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

674. The inadequate warnings were a substantial factor in bringing about Iowa Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

675. If, as mandated by Iowa law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Iowa Subclass Members and their physicians, and Iowa Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Iowa Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Iowa Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

676. As a direct and proximate result of Defendant's actions and omissions, Iowa Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 17
Strict Product Liability—Failure to Warn
Kansas

677. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

678. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Subclass.

679. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Kansas Subclass

Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Kansas Subclass Members.

680. The Recalled BIOCELL Implants that were implanted into Kansas Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

681. Under Kansas law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Kansas Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

682. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

683. Defendant failed to adequately warn the FDA, medical professionals, and Kansas Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

684. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

685. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

686. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

687. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Kansas Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

688. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

689. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite

opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

690. Kansas Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Kansas Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

691. The Recalled BIOCELL Implants presented a substantial risk to Kansas Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Kansas Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

692. The inadequate warnings were a substantial factor in bringing about Kansas Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

693. If, as mandated by Kansas law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled

BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Kansas Subclass Members and their physicians, and Kansas Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Kansas Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Kansas Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

694. As a direct and proximate result of Defendant's actions and omissions, Kansas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 18
Strict Product Liability—Failure to Warn
Kentucky

695. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

696. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Subclass.

697. The Kentucky Product Liability Act (K.R.S. § 411.300), governs all product liability actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture of any product.

698. Defendant is strictly liable under Kentucky law because Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

699. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Kentucky Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Kentucky Subclass Members.

700. The Recalled BIOCELL Implants that were implanted into Kentucky Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

701. Under Kentucky law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Kentucky Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

702. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

703. Defendant failed to adequately warn the FDA, medical professionals, and Kentucky Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

704. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

705. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

706. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

707. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Kentucky Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

708. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

709. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

710. Kentucky Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Kentucky Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

711. The Recalled BIOCELL Implants presented a substantial risk to Kentucky Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Kentucky Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

712. The inadequate warnings were a substantial factor in bringing about Kentucky Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As

demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

713. If, as mandated by Kentucky law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Kentucky Subclass Members and their physicians, and Kentucky Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Kentucky Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Kentucky Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

714. As a direct and proximate result of Defendant's actions and omissions, Kentucky Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 19
Strict Product Liability—Failure to Warn
Maine

715. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

716. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass.

717. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Maine Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Maine Subclass Members.

718. The Recalled BIOCELL Implants that were implanted into Maine Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

719. Under Maine law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Maine Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

720. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

721. Defendant failed to adequately warn the FDA, medical professionals, and Maine Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

722. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

723. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

724. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

725. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Maine Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

726. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

727. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of

developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

728. Maine Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Maine Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

729. The Recalled BIOCELL Implants presented a substantial risk to Maine Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Maine Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

730. The inadequate warnings were a substantial factor in bringing about Maine Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

731. If, as mandated by Maine law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Maine Subclass Members and their physicians, and Maine Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Maine Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Maine Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

732. As a direct and proximate result of Defendant's actions and omissions, Maine Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 20
Strict Product Liability—Failure to Warn
Maryland

733. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

734. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Subclass.

735. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Maryland Subclass

Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Maryland Subclass Members.

736. The Recalled BIOCELL Implants that were implanted into Maryland Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

737. Under Maryland law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Maryland Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

738. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

739. Defendant failed to adequately warn the FDA, medical professionals, and Maryland Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

740. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

741. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

742. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

743. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Maryland Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

744. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

745. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite

opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

746. Maryland Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Maryland Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

747. The Recalled BIOCELL Implants presented a substantial risk to Maryland Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Maryland Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

748. The inadequate warnings were a substantial factor in bringing about Maryland Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

749. If, as mandated by Maryland law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled

BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Maryland Subclass Members and their physicians, and Maryland Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Maryland Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

750. As a direct and proximate result of Defendant's actions and omissions, Maryland Subclass Members have a significantly increased risk of BIA-ALCL, have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 21
Strict Product Liability—Failure to Warn
Massachusetts

751. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

752. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

753. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Massachusetts Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Massachusetts Subclass Members.

754. The Recalled BIOCELL Implants that were implanted into Massachusetts Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

755. Under Massachusetts law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Massachusetts Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

756. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

757. Defendant failed to adequately warn the FDA, medical professionals, and Massachusetts Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

758. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

759. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

760. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

761. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Massachusetts Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-

long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

762. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

763. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

764. Massachusetts Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Massachusetts Subclass Members, ordinary consumers, and

medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

765. The Recalled BIOCELL Implants presented a substantial risk to Massachusetts Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Massachusetts Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

766. The inadequate warnings were a substantial factor in bringing about Massachusetts Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

767. If, as mandated by Massachusetts law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Massachusetts Subclass Members and their physicians, and Massachusetts Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Massachusetts Subclass Members and their physicians would not have used a Recalled

BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Massachusetts Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

768. As a direct and proximate result of Defendant's actions and omissions, Massachusetts Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 22
Strict Products Liability—Failure to Warn
Mississippi

769. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

770. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Non-PMA Device Subclass.

771. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Mississippi Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Mississippi Non-PMA Device Subclass Members.

772. At all relevant times, Defendant owed a duty to use reasonable care in the labeling, marketing, advertising, promotion, and sale of the Non-PMA BIOCELL Implants and a duty to warn the Mississippi Non-PMA Device Subclass Members and the medical community, including

the Mississippi Non-PMA Device Subclass Members' treating physicians, of the true risk associated with implanting the Non-PMA BIOCELL Implants.

773. The Non-PMA BIOCELL Implants were not reasonably safe for their intended use and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings to the Mississippi Non-PMA Device Subclass Members and the medical community, including the Mississippi Non-PMA Device Subclass Members' treating physicians, regarding, among other subjects:

774. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

775. That the Non-PMA BIOCELL Implants were not manufactured in conformance with legal and good manufacturing requirements; and

776. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

777. At the time the Mississippi Non-PMA Device Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that the implants were defectively manufactured. The risk and defective nature of the implants was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution, including through available adverse event reports, Defendant's own clinical studies, available scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

778. The Mississippi Non-PMA Device Subclass Members and their treating physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Non-PMA BIOCELL Implants for implantation. The Mississippi Non-PMA Device Subclass Members and their treating physicians did not, and could not have, recognized the true risks associated with the Non-PMA BIOCELL Implants.

779. The Non-PMA BIOCELL Implants presented a substantial risk to the Mississippi Non-PMA Device Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Non-PMA BIOCELL Implants would be implanted in the Mississippi Non-PMA Device Subclass Members' and ordinary consumers' bodies without inspection of defects and without knowledge of the risks involved in their use.

780. The inadequate warnings were a substantial factor in bringing about the Mississippi Non-PMA Device Subclass Members' injuries which would not have occurred but for the use of the Non-PMA BIOCELL Implants. If Defendant had warned the medical community, the Mississippi Non-PMA Device Subclass Members' treating physicians, and the general public about the true risk, the information would have been known to the Mississippi Non-PMA Device Subclass Members and their treating physicians, and the Mississippi Non-PMA Device Subclass Members and their treating physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. The Mississippi Non-PMA Device Subclass Members and their treating physicians would not have used a Non-PMA BIOCELL Implant if they had known of the true safety risks associated with the implants.

781. Accordingly, the Mississippi Non-PMA Device Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies,

including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Non-PMA BIOCELL Implants.

782. As a direct and proximate result of Defendant's actions and omissions, the Mississippi Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 23
Strict Product Liability—Failure to Warn
Minnesota

783. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

784. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass.

785. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Minnesota Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Minnesota Subclass Members.

786. The Recalled BIOCELL Implants that were implanted into Minnesota Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

787. Under Minnesota law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Minnesota Subclass Members about the dangers and true risks

of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

788. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

789. Defendant failed to adequately warn the FDA, medical professionals, and Minnesota Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

790. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

791. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

792. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

793. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Minnesota Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

794. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

795. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

796. Minnesota Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Minnesota Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

797. The Recalled BIOCELL Implants presented a substantial risk to Minnesota Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Minnesota Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

798. The inadequate warnings were a substantial factor in bringing about Minnesota Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

799. If, as mandated by Minnesota law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Minnesota Subclass Members and their physicians, and Minnesota Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Minnesota Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Minnesota Subclass Members would not have (a) been subjected to the accumulation of foreign

and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

800. As a direct and proximate result of Defendant's actions and omissions, Minnesota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 24
Strict Product Liability—Failure to Warn
Missouri

801. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

802. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Subclass.

803. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Missouri Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Missouri Subclass Members.

804. The Recalled BIOCELL Implants that were implanted into Missouri Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

805. Under Missouri law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Missouri Subclass Members about the dangers and true risks of

the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

806. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

807. Defendant failed to adequately warn the FDA, medical professionals, and Missouri Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

808. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

809. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

810. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

811. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Missouri Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

812. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

813. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

814. Missouri Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Missouri Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

815. The Recalled BIOCELL Implants presented a substantial risk to Missouri Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Missouri Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

816. The inadequate warnings were a substantial factor in bringing about Missouri Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

817. If, as mandated by Missouri law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Missouri Subclass Members and their physicians, and Missouri Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Missouri Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

818. As a direct and proximate result of Defendant's actions and omissions, Missouri Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 25
Strict Product Liability—Failure to Warn
Montana

819. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

820. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass.

821. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Montana Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Montana Subclass Members.

822. The Recalled BIOCELL Implants that were implanted into Montana Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

823. Under Montana law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Montana Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

824. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA

concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

825. Defendant failed to adequately warn the FDA, medical professionals, and Montana Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

826. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

827. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

828. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

829. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Montana Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

830. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants.

Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

831. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

832. Montana Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Montana Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

833. The Recalled BIOCELL Implants presented a substantial risk to Montana Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Montana Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

834. The inadequate warnings were a substantial factor in bringing about Montana Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

835. If, as mandated by Montana law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Montana Subclass Members and their physicians, and Montana Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Montana Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

836. As a direct and proximate result of Defendant's actions and omissions, Montana Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 26
Strict Product Liability—Failure to Warn
Nebraska

837. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

838. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass.

839. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Nebraska Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Nebraska Subclass Members.

840. The Recalled BIOCELL Implants that were implanted into Nebraska Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

841. Under Nebraska law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Nebraska Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

842. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

843. Defendant failed to adequately warn the FDA, medical professionals, and Nebraska Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

844. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

845. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

846. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

847. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Nebraska Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

848. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

849. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

850. Nebraska Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Nebraska Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

851. The Recalled BIOCELL Implants presented a substantial risk to Nebraska Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Nebraska Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

852. The inadequate warnings were a substantial factor in bringing about Nebraska Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As

demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

853. If, as mandated by Nebraska law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Nebraska Subclass Members and their physicians, and Nebraska Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Nebraska Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Nebraska Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

854. As a direct and proximate result of Defendant's actions and omissions, Nebraska Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 27
Strict Product Liability—Failure to Warn
Nevada

855. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

856. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Subclass.

857. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Nevada Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Nevada Subclass Members.

858. The Recalled BIOCELL Implants that were implanted into Nevada Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

859. Under Nevada law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Nevada Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

860. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

861. Defendant failed to adequately warn the FDA, medical professionals, and Nevada Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

862. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

863. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

864. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

865. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Nevada Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

866. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

867. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of

developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

868. Nevada Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Nevada Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

869. The Recalled BIOCELL Implants presented a substantial risk to Nevada Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Nevada Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

870. The inadequate warnings were a substantial factor in bringing about Nevada Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

871. If, as mandated by Nevada law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Nevada Subclass Members and their physicians, and Nevada Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Nevada Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

872. As a direct and proximate result of Defendant's actions and omissions, Nevada Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 28
Strict Product Liability—Failure to Warn
New Hampshire

873. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

874. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Subclass.

875. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into New Hampshire Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including New Hampshire Subclass Members.

876. The Recalled BIOCELL Implants that were implanted into New Hampshire Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture,

having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

877. Under New Hampshire law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and New Hampshire Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

878. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

879. Defendant failed to adequately warn the FDA, medical professionals, and New Hampshire Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

880. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

881. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

882. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

883. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time New Hampshire Subclass Members

received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

884. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

885. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

886. New Hampshire Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. New Hampshire Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

887. The Recalled BIOCELL Implants presented a substantial risk to New Hampshire Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in New Hampshire Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

888. The inadequate warnings were a substantial factor in bringing about New Hampshire Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

889. If, as mandated by New Hampshire law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to New Hampshire Subclass Members and their physicians,

and New Hampshire Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. New Hampshire Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, New Hampshire Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

890. As a direct and proximate result of Defendant's actions and omissions, New Hampshire Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 29
Strict Product Liability—Failure to Warn
New Mexico

891. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

892. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass.

893. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into New Mexico Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including New Mexico Subclass Members.

894. The Recalled BIOCELL Implants that were implanted into New Mexico Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

895. Under New Mexico law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and New Mexico Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

896. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

897. Defendant failed to adequately warn the FDA, medical professionals, and New Mexico Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

898. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

899. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

900. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

901. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time New Mexico Subclass Members

received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

902. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

903. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

904. New Mexico Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. New Mexico Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

905. The Recalled BIOCELL Implants presented a substantial risk to New Mexico Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in New Mexico Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

906. The inadequate warnings were a substantial factor in bringing about New Mexico Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

907. If, as mandated by New Mexico law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to New Mexico Subclass Members and their physicians, and

New Mexico Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. New Mexico Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, New Mexico Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

908. As a direct and proximate result of Defendant's actions and omissions, New Mexico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 30
Strict Product Liability—Failure to Warn
New York

909. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

910. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Subclass.

911. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into New York Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including New York Subclass Members.

912. The Recalled BIOCELL Implants that were implanted into New York Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been

manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

913. Under New York law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and New York Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

914. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

915. Defendant failed to adequately warn the FDA, medical professionals, and New York Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

916. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

917. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

918. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

919. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time New York Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained

this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

920. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

921. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

922. New York Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. New York Subclass Members, ordinary consumers, and medical

professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

923. The Recalled BIOCELL Implants presented a substantial risk to New York Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in New York Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

924. The inadequate warnings were a substantial factor in bringing about New York Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

925. If, as mandated by New York law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to New York Subclass Members and their physicians, and New York Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. New York Subclass Members and their physicians would not have used a Recalled BIOCELL

Implant if they had known of the true safety risks associated with the implants. Accordingly, New York Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

926. As a direct and proximate result of Defendant's actions and omissions, New York Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 31
Strict Product Liability—Failure to Warn
North Dakota

927. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

928. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota subclass.

929. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into North Dakota Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including North Dakota Subclass Members.

930. The Recalled BIOCELL Implants that were implanted into North Dakota Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

931. Under North Dakota law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and North Dakota Subclass Members about the dangers and true

risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

932. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

933. Defendant failed to adequately warn the FDA, medical professionals, and North Dakota Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

934. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

935. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

936. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

937. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time North Dakota Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

938. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

939. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

940. North Dakota Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. North Dakota Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

941. The Recalled BIOCELL Implants presented a substantial risk to North Dakota Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in North Dakota Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

942. The inadequate warnings were a substantial factor in bringing about North Dakota Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

943. If, as mandated by North Dakota law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to North Dakota Subclass Members and their physicians, and North Dakota Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. North Dakota Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, North Dakota Subclass Members would not have (a) been subjected to the accumulation of foreign and

adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

944. As a direct and proximate result of Defendant's actions and omissions, North Dakota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 32
Strict Product Liability—Failure to Warn
Northern Mariana Islands

945. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

946. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass.

947. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Northern Mariana Islands Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Northern Mariana Islands Subclass Members.

948. The Recalled BIOCELL Implants that were implanted into Northern Mariana Islands Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

949. Under Northern Mariana Islands law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Northern Mariana Islands Subclass Members

about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

950. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

951. Defendant failed to adequately warn the FDA, medical professionals, and Northern Mariana Islands Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

952. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

953. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

954. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

955. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Northern Mariana Islands Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive

decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

956. Rather than disclose the truth, Defendant, in violation of its duty to disclose under Northern Mariana Islands law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

957. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

958. Northern Mariana Islands Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Northern Mariana Islands Subclass Members,

ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

959. The Recalled BIOCELL Implants presented a substantial risk to Northern Mariana Islands Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Northern Mariana Islands Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

960. The inadequate warnings were a substantial factor in bringing about Northern Mariana Islands Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

961. If, as mandated by Northern Marianas Islands law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Northern Mariana Islands Subclass Members and their physicians, and Northern Mariana Islands Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Northern Mariana Islands Subclass Members and their physicians would

not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Northern Mariana Islands Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

962. As a direct and proximate result of Defendant's actions and omissions, Northern Mariana Islands Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 33
Strict Product Liability—Failure to Warn
Ohio

963. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

964. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Subclass.

965. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Ohio Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Ohio Subclass Members.

966. The Recalled BIOCELL Implants that were implanted into Ohio Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

967. Under Ohio law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Ohio Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

968. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

969. Defendant failed to adequately warn the FDA, medical professionals, and Ohio Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

970. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

971. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

972. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

973. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Ohio Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical

studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

974. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

975. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

976. Ohio Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Ohio Subclass Members, ordinary consumers, and medical

professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

977. The Recalled BIOCELL Implants presented a substantial risk to Ohio Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Ohio Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

978. The inadequate warnings were a substantial factor in bringing about Ohio Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

979. If, as mandated by Ohio law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Ohio Subclass Members and their physicians, and Ohio Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Ohio Subclass Members and their

physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

980. As a direct and proximate result of Defendant's actions and omissions, Ohio Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 34
Strict Product Liability—Failure to Warn
Oklahoma

981. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

982. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Subclass.

983. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Oklahoma Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Oklahoma Subclass Members.

984. The Recalled BIOCELL Implants that were implanted into Oklahoma Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

985. Under Oklahoma law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Oklahoma Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

986. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

987. Defendant failed to adequately warn the FDA, medical professionals, and Oklahoma Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

988. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

989. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

990. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

991. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Oklahoma Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

992. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA,

manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

993. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

994. Oklahoma Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Oklahoma Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

995. The Recalled BIOCELL Implants presented a substantial risk to Oklahoma Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be

implanted in Oklahoma Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

996. The inadequate warnings were a substantial factor in bringing about Oklahoma Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

997. If, as mandated by Oklahoma law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Oklahoma Subclass Members and their physicians, and Oklahoma Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Oklahoma Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Oklahoma Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of

BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

998. As a direct and proximate result of Defendant's actions and omissions, Oklahoma Subclass Members have incurred physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 35
Strict Product Liability—Failure to Warn
Oregon

999. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1000. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Subclass.

1001. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Oregon Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Oregon Subclass Members.

1002. The Recalled BIOCELL Implants that were implanted into Oregon Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1003. Under Oregon law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Oregon Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1004. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1005. Defendant failed to adequately warn the FDA, medical professionals, and Oregon Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1006. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1007. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1008. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1009. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Oregon Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1010. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled

BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1011. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1012. Oregon Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Oregon Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1013. The Recalled BIOCELL Implants presented a substantial risk to Oregon Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in

Oregon Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1014. The inadequate warnings were a substantial factor in bringing about Oregon Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1015. If, as mandated by Oregon law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Oregon Subclass Members and their physicians, and Oregon Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Oregon Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Oregon Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1016. As a direct and proximate result of Defendant's actions and omissions, Oregon Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 36
Strict Product Liability—Failure to Warn
Pennsylvania

1017. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1018. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass.

1019. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Pennsylvania Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Pennsylvania Subclass Members.

1020. The Recalled BIOCELL Implants that were implanted into Pennsylvania Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1021. Under Pennsylvania law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Pennsylvania Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1022. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA

concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1023. Defendant failed to adequately warn the FDA, medical professionals, and Pennsylvania Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1024. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1025. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1026. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1027. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Pennsylvania Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1028. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA

requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1029. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1030. Pennsylvania Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Pennsylvania Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1031. The Recalled BIOCELL Implants presented a substantial risk to Pennsylvania Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Pennsylvania Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1032. The inadequate warnings were a substantial factor in bringing about Pennsylvania Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1033. If, as mandated by Pennsylvania law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Pennsylvania Subclass Members and their physicians, and Pennsylvania Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Pennsylvania Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

1034. As a direct and proximate result of Defendant's actions and omissions, Pennsylvania Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 37
Strict Product Liability—Failure to Warn
Puerto Rico

1035. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1036. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Subclass.

1037. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Puerto Rico Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Puerto Rico Subclass Members.

1038. The Recalled BIOCELL Implants that were implanted into Puerto Rico Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1039. Under Puerto Rico law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Puerto Rico Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1040. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1041. Defendant failed to adequately warn the FDA, medical professionals, and Puerto Rico Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1042. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1043. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1044. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1045. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Puerto Rico Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1046. Rather than disclose the truth, Defendant, in violation of its duty to disclose under Puerto Rico law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1047. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1048. Puerto Rico Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Puerto Rico Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1049. The Recalled BIOCELL Implants presented a substantial risk to Puerto Rico Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Puerto Rico Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1050. The inadequate warnings were a substantial factor in bringing about Puerto Rico Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As

demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1051. If, as mandated by Puerto Rico law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Puerto Rico Subclass Members and their physicians, and Puerto Rico Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Puerto Rico Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Puerto Rico Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1052. As a direct and proximate result of Defendant's actions and omissions, Puerto Rico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 38
Strict Product Liability—Failure to Warn
Rhode Island

1053. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1054. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass.

1055. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Rhode Island Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Rhode Island Subclass Members.

1056. The Recalled BIOCELL Implants that were implanted into Rhode Island Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1057. Under Rhode Island law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Rhode Island Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1058. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1059. Defendant failed to adequately warn the FDA, medical professionals, and Rhode Island Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1060. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1061. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1062. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1063. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Rhode Island Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1064. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1065. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of

developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1066. Rhode Island Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Rhode Island Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1067. The Recalled BIOCELL Implants presented a substantial risk to Rhode Island Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Rhode Island Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1068. The inadequate warnings were a substantial factor in bringing about Rhode Island Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1069. If, as mandated by Rhode Island law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Rhode Island Subclass Members and their physicians, and Rhode Island Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Rhode Island Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Rhode Island Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1070. As a direct and proximate result of Defendant's actions and omissions, Rhode Island Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 39
Strict Product Liability—Failure to Warn
South Carolina

1071. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1072. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass.

1073. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into South Carolina Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including South Carolina Subclass Members.

1074. The Recalled BIOCELL Implants that were implanted into South Carolina Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1075. Under South Carolina law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and South Carolina Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1076. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1077. Defendant failed to adequately warn the FDA, medical professionals, and South Carolina Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1078. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1079. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1080. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1081. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time South Carolina Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1082. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1083. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1084. South Carolina Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. South Carolina Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1085. The Recalled BIOCELL Implants presented a substantial risk to South Carolina Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in South Carolina Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1086. The inadequate warnings were a substantial factor in bringing about South Carolina Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As

demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1087. If, as mandated by South Carolina law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to South Carolina Subclass Members and their physicians, and South Carolina Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. South Carolina Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, South Carolina Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1088. As a direct and proximate result of Defendant's actions and omissions, South Carolina Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 40
Strict Liability - Failure to Warn
South Dakota

1089. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1090. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Subclass.

1091. Defendant is strictly liable under South Dakota's product liability statute (S.D. Codified Laws § 20-9-9) for manufacturing the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to South Dakota Subclass Members.

1092. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into South Dakota Subclass Members.

1093. The Recalled BIOCELL Implants that were implanted into South Dakota Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1094. Under South Dakota law, Defendant owed South Dakota Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and South Dakota Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1095. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1096. Defendant failed to adequately warn the FDA, medical professionals, and South Dakota Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1097. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1098. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1099. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1100. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. South Dakota Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1101. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1102. It was readily foreseeable to Defendant that South Dakota Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that South Dakota Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to South Dakota Subclass Members and other women, and that South Dakota

Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1103. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1104. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached South Dakota Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. South Dakota Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, South Dakota Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1105. As a direct and proximate result of Defendant's actions and omissions, South Dakota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 41
Strict Product Liability—Failure to Warn
Tennessee

1106. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1107. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass.

1108. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Tennessee Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Tennessee Subclass Members.

1109. The Recalled BIOCELL Implants that were implanted into Tennessee Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1110. Under Tennessee law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Tennessee Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1111. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1112. Defendant failed to adequately warn the FDA, medical professionals, and Tennessee Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1113. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1114. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1115. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1116. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Tennessee Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1117. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1118. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1119. Tennessee Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Tennessee Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1120. The Recalled BIOCELL Implants presented a substantial risk to Tennessee Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Tennessee Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1121. The inadequate warnings were a substantial factor in bringing about Tennessee Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As

demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1122. If, as mandated by Tennessee law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Tennessee Subclass Members and their physicians, and Tennessee Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Tennessee Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

1123. As a direct and proximate result of Defendant's actions and omissions, Tennessee Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 42
Strict Product Liability—Failure to Warn
Texas

1124. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1125. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass.

1126. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Texas Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Texas Subclass Members.

1127. The Recalled BIOCELL Implants that were implanted into Texas Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1128. Under Texas law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Texas Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1129. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1130. Defendant failed to adequately warn the FDA, medical professionals, and Texas Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1131. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1132. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1133. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1134. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Texas Subclass Members received

their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1135. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1136. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1137. Texas Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Texas Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1138. The Recalled BIOCELL Implants presented a substantial risk to Texas Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Texas Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1139. The inadequate warnings were a substantial factor in bringing about Texas Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1140. If, as mandated by Texas law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Texas Subclass Members and their physicians, and Texas Subclass Members

and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Texas Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Texas Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1141. As a direct and proximate result of Defendant's actions and omissions, Texas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 43
Strict Product Liability—Failure to Warn
U.S. Virgin Islands

1142. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1143. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the U.S. Virgin Islands Subclass.

1144. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into U.S. Virgin Islands Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including U.S. Virgin Islands Subclass Members.

1145. The Recalled BIOCELL Implants that were implanted into U.S. Virgin Islands Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture,

having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1146. Under U.S. Virgin Islands law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and U.S. Virgin Islands Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1147. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1148. Defendant failed to adequately warn the FDA, medical professionals, and U.S. Virgin Islands Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1149. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1150. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1151. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1152. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time U.S. Virgin Islands Subclass

Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1153. Rather than disclose the truth, Defendant, in violation of its duty to disclose under U.S. Virgin Islands law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1154. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1155. U.S. Virgin Islands Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. U.S. Virgin Islands Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1156. The Recalled BIOCELL Implants presented a substantial risk to U.S. Virgin Islands Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in U.S. Virgin Islands Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1157. The inadequate warnings were a substantial factor in bringing about U.S. Virgin Islands Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1158. If, as mandated by U.S. Virgin Islands law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to U.S. Virgin Islands Subclass Members and their

physicians, and U.S. Virgin Islands Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. U.S. Virgin Islands Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, U.S. Virgin Islands Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1159. As a direct and proximate result of Defendant's actions and omissions, U.S. Virgin Islands Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 44
Strict Product Liability—Failure to Warn
Utah

1160. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1161. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass.

1162. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Utah Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Utah Subclass Members.

1163. The Recalled BIOCELL Implants that were implanted into Utah Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1164. Under Utah law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Utah Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1165. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1166. Defendant failed to adequately warn the FDA, medical professionals, and Utah Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1167. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1168. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1169. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1170. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Utah Subclass Members received

their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1171. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1172. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1173. Utah Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Utah Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1174. The Recalled BIOCELL Implants presented a substantial risk to Utah Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Utah Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1175. The inadequate warnings were a substantial factor in bringing about Utah Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1176. If, as mandated by Utah law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Utah Subclass Members and their physicians, and Utah Subclass Members

and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Utah Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

1177. As a direct and proximate result of Defendant's actions and omissions, Utah Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 45
Strict Product Liability—Failure to Warn
Vermont

1178. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1179. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Subclass.

1180. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Vermont Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Vermont Subclass Members.

1181. The Recalled BIOCELL Implants that were implanted into Vermont Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1182. Under Vermont law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Vermont Subclass Members about the dangers and true risks of

the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1183. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1184. Defendant failed to adequately warn the FDA, medical professionals, and Vermont Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1185. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1186. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1187. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1188. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Vermont Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1189. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1190. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1191. Vermont Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Vermont Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1192. The Recalled BIOCELL Implants presented a substantial risk to Vermont Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Vermont Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1193. The inadequate warnings were a substantial factor in bringing about Vermont Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1194. If, as mandated by Vermont law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Vermont Subclass Members and their physicians, and Vermont Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Vermont Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Vermont Subclass Members would not have (a) been subjected to the accumulation of foreign and

adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1195. As a direct and proximate result of Defendant's actions and omissions, Vermont Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 46
Strict Product Liability—Failure to Warn
West Virginia

1196. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1197. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

1198. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into West Virginia Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including West Virginia Subclass Members.

1199. The Recalled BIOCELL Implants that were implanted into West Virginia Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1200. Under West Virginia law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and West Virginia Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1201. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1202. Defendant failed to adequately warn the FDA, medical professionals, and West Virginia Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1203. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1204. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1205. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1206. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time West Virginia Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1207. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA,

manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1208. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1209. West Virginia Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. West Virginia Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1210. The Recalled BIOCELL Implants presented a substantial risk to West Virginia Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be

implanted in West Virginia Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1211. The inadequate warnings were a substantial factor in bringing about West Virginia Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1212. If, as mandated by West Virginia law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to West Virginia Subclass Members and their physicians, and West Virginia Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. West Virginia Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants.

1213. As a direct and proximate result of Defendant's actions and omissions, West Virginia Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 47
Strict Product Liability—Failure to Warn
Wisconsin

1214. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1215. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Subclass.

1216. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Wisconsin Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Wisconsin Subclass Members.

1217. The Recalled BIOCELL Implants that were implanted into Wisconsin Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1218. Under Wisconsin law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Wisconsin Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1219. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1220. Defendant failed to adequately warn the FDA, medical professionals, and Wisconsin Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1221. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1222. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1223. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1224. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Wisconsin Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1225. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1226. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including

the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1227. Wisconsin Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Wisconsin Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1228. The Recalled BIOCELL Implants presented a substantial risk to Wisconsin Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Wisconsin Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1229. The inadequate warnings were a substantial factor in bringing about Wisconsin Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate

information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1230. If, as mandated by Wisconsin law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Wisconsin Subclass Members and their physicians, and Wisconsin Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Wisconsin Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Wisconsin Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1231. As a direct and proximate result of Defendant's actions and omissions, Wisconsin Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 48
Strict Product Liability—Failure to Warn
Wyoming

1232. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1233. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass.

1234. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Wyoming Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Wyoming Subclass Members.

1235. The Recalled BIOCELL Implants that were implanted into Wyoming Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

1236. Under Wyoming law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Wyoming Subclass Members about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

1237. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1238. Defendant failed to adequately warn the FDA, medical professionals, and Wyoming Subclass Members about the true risk of using its Recalled BIOCELL Implants, including:

1239. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1240. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

1241. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1242. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Wyoming Subclass Members received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

1243. Rather than disclose the truth, Defendant, in violation of its duty to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

1244. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and

unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

1245. Wyoming Subclass Members and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Wyoming Subclass Members, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

1246. The Recalled BIOCELL Implants presented a substantial risk to Wyoming Subclass Members and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Wyoming Subclass Members and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

1247. The inadequate warnings were a substantial factor in bringing about Wyoming Subclass Members' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As

demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

1248. If, as mandated by Wyoming law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Wyoming Subclass Members and their physicians, and Wyoming Subclass Members and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Wyoming Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Wyoming Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1249. As a direct and proximate result of Defendant's actions and omissions, Wyoming Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

B. NEGLIGENCE -- FAILURE TO WARN

COUNT 49
Negligent Failure to Warn
Alabama

1250. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1251. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Non-PMA Device Subclass.

1252. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Alabama Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Alabama Non-PMA Device Subclass Members.

1253. At all relevant times, Defendant owed a duty to use reasonable care in the labeling, marketing, advertising, promotion, and sale of the Non-PMA BIOCELL Implants and a duty to warn the Alabama Non-PMA Device Subclass Members and the medical community, including the Alabama Non-PMA Device Subclass Members' treating physicians, of the true risk associated with implanting the Non-PMA BIOCELL Implants.

1254. Defendant breached these duties by not providing sufficient or adequate warnings to the Alabama Non-PMA Device Subclass Members and the medical community, including the Alabama Non-PMA Device Subclass Members' treating physicians, regarding, among other subjects:

1255. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1256. That the Non-PMA BIOCELL Implants were not manufactured in conformance with legal and good manufacturing requirements; and

1257. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1258. As a result, the Non-PMA BIOCELL Implants were not reasonably safe for their intended use and were defective as a matter of law due to their lack of appropriate and necessary warnings.

1259. Although Defendant knew that the Non-PMA BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to medical professionals and consumers.

1260. It was readily foreseeable to Defendant that the Alabama Non-PMA Device Subclass Members and other consumers would be harmed as a result of its failure to exercise ordinary care and to warn Plaintiff and the medical profession of the true risks of the Non-PMA BIOCELL Implants. Defendant knew that the Alabama Non-PMA Device Subclass Members and their treating physicians would use the Non-PMA BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to the Alabama Non-PMA Device Subclass Members and other women, and that the Alabama Non-PMA Device Subclass Members and their treating physicians would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Non-PMA BIOCELL Implant.

1261. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and revealed the true risk of BIA-ALCL associated with the Non-PMA BIOCELL Implants to medical professionals and consumers.

1262. Had Defendant adequately warned of the known risks associated with the Non-PMA BIOCELL Implants, the information would have reached the Alabama Non-PMA Device Subclass Members and their treating physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. The Alabama Non-PMA

Device Subclass Members and their treating physicians would not have used a Non-PMA BIOCELL Implant if they had known of the true safety risks. Accordingly, the Alabama Non-PMA Device Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Non-PMA BIOCELL Implants.

1263. As a direct and proximate result of Defendant' actions and omissions, the Alabama Non-PMA Device Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 50
Negligent Failure to Warn
Alaska

1264. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1265. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

1266. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Alaska Subclass Members.

1267. The Recalled BIOCELL Implants that were implanted into Alaska Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1268. Under Alaska law, Defendant owed Alaska Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Alaska Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1269. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1270. Defendant breached its duty to adequately warn of the danger, by, among other things:

1271. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1272. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1273. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1274. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1275. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Alaska Subclass Members and their physicians reasonably relied on information regarding adverse events, or the

lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1276. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1277. It was readily foreseeable to Defendant that Alaska Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Alaska Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Alaska Subclass Members and other women, and that Alaska Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1278. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1279. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Alaska Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Alaska Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

Accordingly, Alaska Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1280. As a direct and proximate result of Defendant's actions and omissions, Alaska Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 51
Negligent Failure to Warn
Arizona

1281. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1282. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arizona Non-PMA Device Subclass.

1283. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Arizona Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Arizona Non-PMA Device Subclass Members.

1284. At all relevant times, Defendant owed a duty to use reasonable care in the labeling, marketing, advertising, promotion, and sale of the Non-PMA BIOCELL Implants and a duty to warn the Arizona Non-PMA Device Subclass Members and the medical community, including the

Arizona Non-PMA Device Subclass Members' treating physicians, of the true risk associated with implanting the Non-PMA BIOCELL Implants.

1285. Defendant breached these duties by not providing sufficient or adequate warnings to the Arizona Non-PMA Device Subclass Members and the medical community, including the Arizona Non-PMA Device Subclass Members' treating physicians, regarding, among other subjects:

1286. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1287. That the Non-PMA BIOCELL Implants were not manufactured in conformance with legal and good manufacturing requirements; and

1288. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1289. As a result, the Non-PMA BIOCELL Implants were not reasonably safe for their intended use and were defective as a matter of law due to their lack of appropriate and necessary warnings.

1290. Although Defendant knew that the Non-PMA BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to medical professionals and consumers.

1291. It was readily foreseeable to Defendant that the Arizona Non-PMA Device Subclass Members and other consumers would be harmed as a result of its failure to exercise ordinary care and to warn Plaintiff and the medical profession of the true risks of the Non-PMA BIOCELL Implants. Defendant knew that the Arizona Non-PMA Device Subclass Members and their treating physicians would use the Non-PMA BIOCELL Implants for their intended purpose, that

their intended use would pose a substantial health risk to the Arizona Non-PMA Device Subclass Members and other women, and that the Arizona Non-PMA Device Subclass Members and their treating physicians would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Non-PMA BIOCELL Implant.

1292. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and revealed the true risk of BIA-ALCL associated with the Non-PMA BIOCELL Implants to medical professionals and consumers.

1293. Had Defendant adequately warned of the known risks associated with the Non-PMA BIOCELL Implants, the information would have reached the Arizona Non-PMA Device Subclass Members and their treating physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. The Arizona Non-PMA Device Subclass Members and their treating physicians would not have used a Non-PMA BIOCELL Implant if they had known of the true safety risks. Accordingly, the Arizona Non-PMA Device Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Non-PMA BIOCELL Implants.

1294. As a direct and proximate result of Defendant' actions and omissions, the Arizona Non-PMA Device Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 52
Negligent Failure to Warn
American Samoa

1295. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1296. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Subclass.

1297. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into American Samoa Subclass Members.

1298. The Recalled BIOCELL Implants that were implanted into American Samoa Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1299. Under American Samoa law, Defendant owed American Samoa Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and American Samoa Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1300. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1301. Defendant breached its duty to adequately warn of the danger, by, among other things:

1302. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1303. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1304. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1305. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1306. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. American Samoa Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1307. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1308. It was readily foreseeable to Defendant that American Samoa Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that American Samoa Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose

a substantial health risk to American Samoa Subclass Members and other women, and that American Samoa Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1309. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1310. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached American Samoa Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. American Samoa Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, American Samoa Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1311. As a direct and proximate result of Defendant's actions and omissions, American Samoa Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 53
Negligent Failure to Warn
Arkansas

1312. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1313. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Subclass.

1314. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Arkansas Subclass Members.

1315. The Recalled BIOCELL Implants that were implanted into Arkansas Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1316. Under Arkansas law, Defendant owed Arkansas Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Arkansas Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1317. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1318. Defendant breached its duty to adequately warn of the danger, by, among other things:

1319. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1320. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1321. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1322. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1323. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Arkansas Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1324. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1325. It was readily foreseeable to Defendant that Arkansas Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Arkansas Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Arkansas Subclass Members and other women, and that Arkansas Subclass Members and the medical community would rely on its representations and omissions

regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1326. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1327. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Arkansas Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Arkansas Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Arkansas Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1328. As a direct and proximate result of Defendant's actions and omissions, Arkansas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 54
Negligent Failure to Warn
California

1329. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1330. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass.

1331. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into California Subclass Members.

1332. The Recalled BIOCELL Implants that were implanted into California Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1333. Under California law, Defendant owed California Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and California Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1334. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, California Subclass Members had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1335. Defendant breached its duty to adequately warn of the danger, by, among other things:

1336. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1337. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1338. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1339. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1340. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. California Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1341. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1342. It was readily foreseeable to Defendant that California Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that California Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to California Subclass Members and other women, and that California Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1343. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1344. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached California Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. California Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1345. As a direct and proximate result of Defendant's actions and omissions, California Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 55
Negligent Failure to Warn
Colorado

1346. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1347. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

1348. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Colorado Subclass Members.

1349. The Recalled BIOCELL Implants that were implanted into Colorado Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1350. Under Colorado law, Defendant owed Colorado Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Colorado Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1351. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1352. Defendant breached its duty to adequately warn of the danger, by, among other things:

1353. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1354. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1355. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1356. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1357. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Colorado Subclass Members and their physicians reasonably relied on information regarding adverse events, or the

lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1358. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1359. It was readily foreseeable to Defendant that Colorado Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Colorado Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Colorado Subclass Members and other women, and that Colorado Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1360. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1361. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Colorado Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Colorado Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1362. As a direct and proximate result of Defendant's actions and omissions, Colorado Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 56
Negligent Failure to Warn
Delaware

1363. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1364. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Delaware Subclass.

1365. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Delaware Subclass Members.

1366. The Recalled BIOCELL Implants that were implanted into Delaware Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1367. Under Delaware law, Defendant owed Delaware Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Delaware Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1368. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the

devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1369. Defendant breached its duty to adequately warn of the danger, by, among other things:

1370. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1371. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1372. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1373. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1374. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Delaware Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1375. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1376. It was readily foreseeable to Defendant that Delaware Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the

FDA. Defendant knew that Delaware Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Delaware Subclass Members and other women, and that Delaware Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1377. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1378. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Delaware Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Delaware Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Delaware Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1379. As a direct and proximate result of Defendant's actions and omissions, Delaware Subclass Members sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 57
Negligent Failure to Warn
District of Columbia

1380. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1381. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the D.C. Subclass.

1382. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into D.C. Subclass Members.

1383. The Recalled BIOCELL Implants that were implanted into D.C. Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1384. Under District of Columbia law, Defendant owed D.C. Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and D.C. Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1385. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1386. Defendant breached its duty to adequately warn of the danger, by, among other things:

1387. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1388. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1389. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1390. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1391. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. D.C. Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1392. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1393. It was readily foreseeable to Defendant that D.C. Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that D.C. Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to D.C. Subclass Members and other women, and that D.C. Subclass Members and the medical community would rely on its representations and omissions regarding the safety and

performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1394. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1395. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached D.C. Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. D.C. Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1396. As a direct and proximate result of Defendant's actions and omissions, D.C. Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 58
Negligent Failure to Warn
Florida

1397. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1398. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass.

1399. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Florida Subclass Members.

1400. The Recalled BIOCELL Implants that were implanted into Florida Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been

manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1401. Under Florida law, Defendant owed Florida Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Florida Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1402. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1403. Defendant breached its duty to adequately warn of the danger, by, among other things:

1404. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1405. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1406. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1407. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1408. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Florida Subclass

Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1409. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1410. It was readily foreseeable to Defendant that Florida Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Florida Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Florida Subclass Members and other women, and that Florida Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1411. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1412. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Florida Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative

product that did not present the same risks. Florida Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1413. As a direct and proximate result of Defendant's actions and omissions, Florida Subclass Members and members of the putative class have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 59
Negligent Failure to Warn
Georgia

1414. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1415. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Subclass.

1416. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Georgia Subclass Members.

1417. The Recalled BIOCELL Implants that were implanted into Georgia Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1418. Under Georgia law, Defendant owed Georgia Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Georgia Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1419. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1420. Defendant breached its duty to adequately warn of the danger, by, among other things:

1421. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1422. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1423. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1424. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1425. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Georgia Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1426. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1427. It was readily foreseeable to Defendant that Georgia Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Georgia Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Georgia Subclass Members and other women, and that Georgia Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1428. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1429. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Georgia Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Georgia Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Georgia Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1430. As a direct and proximate result of Defendant's actions and omissions, Georgia Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 60
Negligent Failure to Warn
Guam

1431. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1432. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass.

1433. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Guam Subclass Members.

1434. The Recalled BIOCELL Implants that were implanted into Guam Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1435. Under Guam law, Defendant owed Guam Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Guam Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1436. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the

devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1437. Defendant breached its duty to adequately warn of the danger, by, among other things:

1438. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1439. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1440. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1441. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1442. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Guam Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1443. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1444. It was readily foreseeable to Defendant that Guam Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the

FDA. Defendant knew that Guam Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Guam Subclass Members and other women, and that Guam Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1445. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1446. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Guam Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Guam Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Guam Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1447. As a direct and proximate result of Defendant's actions and omissions, Guam Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 61
Negligent Failure to Warn
Hawaii

1448. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1449. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Subclass.

1450. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Hawaii Subclass Members.

1451. The Recalled BIOCELL Implants that were implanted into Hawaii Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1452. Under Hawaii law, Defendant owed Hawaii Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Hawaii Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1453. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1454. Defendant breached its duty to adequately warn of the danger, by, among other things:

1455. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1456. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1457. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1458. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1459. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Hawaii Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1460. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1461. It was readily foreseeable to Defendant that Hawaii Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Hawaii Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Hawaii Subclass Members and other women, and that Hawaii Subclass Members and the medical community would rely on its representations and omissions regarding the safety

and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1462. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1463. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Hawaii Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Hawaii Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Hawaii Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1464. As a direct and proximate result of Defendant's actions and omissions, Hawaii Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 62
Negligent Failure to Warn
Idaho

1465. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1466. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Subclass.

1467. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Idaho Subclass Members.

1468. The Recalled BIOCELL Implants that were implanted into Idaho Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1469. Under Idaho law, Defendant owed Idaho Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Idaho Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1470. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1471. Defendant breached its duty to adequately warn of the danger, by, among other things:

1472. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1473. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1474. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1475. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1476. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Idaho Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1477. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1478. It was readily foreseeable to Defendant that Idaho Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Idaho Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Idaho Subclass Members and other women, and that Idaho Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1479. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1480. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Idaho Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Idaho Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Idaho Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1481. As a direct and proximate result of Defendant's actions and omissions, Idaho Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 63
Negligent Failure to Warn
Illinois

1482. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1483. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Subclass.

1484. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Illinois Subclass Members.

1485. The Recalled BIOCELL Implants that were implanted into Illinois Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1486. Under Illinois law, Defendant owed Illinois Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Illinois Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1487. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1488. Defendant breached its duty to adequately warn of the danger, by, among other things:

1489. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1490. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1491. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1492. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1493. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Illinois Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1494. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1495. It was readily foreseeable to Defendant that Illinois Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Illinois Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Illinois Subclass Members and other women, and that Illinois Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1496. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1497. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Illinois Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Illinois Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1498. As a direct and proximate result of Defendant's actions and omissions, Illinois Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 64
Negligent Failure to Warn
Indiana

1499. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1500. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass.

1501. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Indiana Subclass Members.

1502. The Recalled BIOCELL Implants that were implanted into Indiana Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1503. Under Indiana law, Defendant owed Indiana Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Indiana Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1504. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1505. Defendant breached its duty to adequately warn of the danger, by, among other things:

1506. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1507. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1508. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1509. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1510. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Indiana Subclass Members and their physicians reasonably relied on information regarding adverse events, or the

lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1511. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1512. It was readily foreseeable to Defendant that Indiana Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Indiana Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Indiana Subclass Members and other women, and that Indiana Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1513. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1514. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Indiana Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Indiana Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1515. As a direct and proximate result of Defendant's actions and omissions, Indiana Subclass Members have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 65
Negligent Failure to Warn
Iowa

1516. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1517. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass.

1518. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Iowa Subclass Members.

1519. The Recalled BIOCELL Implants that were implanted into Iowa Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1520. Under Iowa law, Defendant owed Iowa Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Iowa Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1521. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the

devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1522. Defendant breached its duty to adequately warn of the danger, by, among other things:

1523. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1524. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1525. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1526. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1527. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Iowa Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1528. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1529. It was readily foreseeable to Defendant that Iowa Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the

FDA. Defendant knew that Iowa Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Iowa Subclass Members and other women, and that Iowa Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1530. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1531. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Iowa Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Iowa Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Iowa Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1532. As a direct and proximate result of Defendant's actions and omissions, Iowa Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 66
Negligent Failure to Warn
Kansas

1533. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1534. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Subclass.

1535. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Kansas Subclass Members.

1536. The Recalled BIOCELL Implants that were implanted into Kansas Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1537. Under Kansas law, Defendant owed Kansas Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Kansas Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1538. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1539. Defendant breached its duty to adequately warn of the danger, by, among other things:

1540. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1541. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1542. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1543. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1544. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Kansas Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1545. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1546. It was readily foreseeable to Defendant that Kansas Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Kansas Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Kansas Subclass Members and other women, and that Kansas Subclass Members and the medical community would rely on its representations and omissions regarding the safety

and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1547. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1548. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Kansas Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Kansas Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Kansas Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1549. As a direct and proximate result of Defendant's actions and omissions, Kansas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 67
Negligent Failure to Warn
Kentucky

1550. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1551. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Subclass.

1552. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Kentucky Subclass Members.

1553. The Recalled BIOCELL Implants that were implanted into Kentucky Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1554. Under Kentucky law, Defendant owed Kentucky Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Kentucky Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1555. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1556. Defendant breached its duty to adequately warn of the danger, by, among other things:

1557. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1558. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1559. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1560. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1561. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Kentucky Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1562. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1563. It was readily foreseeable to Defendant that Kentucky Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Kentucky Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Kentucky Subclass Members and other women, and that Kentucky Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1564. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1565. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Kentucky Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Kentucky Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Kentucky Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1566. As a direct and proximate result of Defendant's actions and omissions, Kentucky Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 68
Negligent Failure to Warn
Louisiana

1567. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1568. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Louisiana Subclass.

1569. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Louisiana Subclass Members.

1570. The Recalled BIOCELL Implants that were implanted into Louisiana Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1571. Under Louisiana law, Defendant owed Louisiana Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Louisiana Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1572. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1573. Defendant breached its duty to adequately warn of the danger, by, among other things:

1574. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1575. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1576. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1577. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1578. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Louisiana Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1579. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1580. It was readily foreseeable to Defendant that Louisiana Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Louisiana Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Louisiana Subclass Members and other women, and that Louisiana Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1581. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1582. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Louisiana Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Louisiana Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Louisiana Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1583. As a direct and proximate result of Defendant's actions and omissions, Louisiana Subclass Members have a sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 69
Negligent Failure to Warn
Maine

1584. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1585. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass.

1586. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Maine Subclass Members.

1587. The Recalled BIOCELL Implants that were implanted into Maine Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1588. Under Maine law, Defendant owed Maine Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Maine Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1589. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1590. Defendant breached its duty to adequately warn of the danger, by, among other things:

1591. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1592. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1593. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1594. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1595. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Maine Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1596. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1597. It was readily foreseeable to Defendant that Maine Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Maine Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Maine Subclass Members and other women, and that Maine Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1598. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1599. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Maine Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Maine Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Maine Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1600. As a direct and proximate result of Defendant's actions and omissions, Maine Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 70
Negligent Failure to Warn
Maryland

1601. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1602. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Subclass.

1603. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Maryland Subclass Members.

1604. The Recalled BIOCELL Implants that were implanted into Maryland Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1605. Under Maryland law, Defendant owed Maryland Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Maryland Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1606. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1607. Defendant breached its duty to adequately warn of the danger, by, among other things:

1608. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1609. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1610. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1611. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1612. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Maryland Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1613. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1614. It was readily foreseeable to Defendant that Maryland Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Maryland Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Maryland Subclass Members and other women, and that Maryland Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1615. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1616. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Maryland Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Maryland Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1617. As a direct and proximate result of Defendant's actions and omissions, Maryland Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 71
NEGLIGENT FAILURE TO WARN
Massachusetts

1618. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1619. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

1620. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Massachusetts Subclass Members.

1621. The Recalled BIOCELL Implants that were implanted into Massachusetts Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1622. Under Massachusetts law, Defendant owed Massachusetts Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Massachusetts Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1623. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1624. Defendant breached its duty to adequately warn of the danger, by, among other things:

1625. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1626. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1627. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1628. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1629. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Massachusetts Subclass Members and their physicians reasonably relied on information regarding adverse events,

or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1630. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1631. It was readily foreseeable to Defendant that Massachusetts Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Massachusetts Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Massachusetts Subclass Members and other women, and that Massachusetts Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1632. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1633. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Massachusetts Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Massachusetts Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety

risks. Accordingly, Massachusetts Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1634. As a direct and proximate result of Defendant's actions and omissions, Massachusetts Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 72
Negligent Failure to Warn
Michigan

1635. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1636. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Michigan Subclass.

1637. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Michigan Subclass Members.

1638. The Recalled BIOCELL Implants that were implanted into Michigan Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1639. Under Michigan law, Defendant owed Michigan Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the

Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Michigan Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1640. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1641. Defendant breached its duty to adequately warn of the danger, by, among other things:

1642. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1643. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1644. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1645. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1646. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Michigan Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1647. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1648. It was readily foreseeable to Defendant that Michigan Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Michigan Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Michigan Subclass Members and other women, and that Michigan Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1649. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1650. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Michigan Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Michigan Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Michigan Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation,

cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1651. As a direct and proximate result of Defendant's actions and omissions, Michigan Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 73
Negligent Failure to Warn
Minnesota

1652. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1653. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass.

1654. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Minnesota Subclass Members.

1655. The Recalled BIOCELL Implants that were implanted into Minnesota Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1656. Under Minnesota law, Defendant owed Minnesota Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Minnesota Subclass

Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1657. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1658. Defendant breached its duty to adequately warn of the danger, by, among other things:

1659. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1660. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1661. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1662. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1663. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Minnesota Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1664. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to

manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1665. It was readily foreseeable to Defendant that Minnesota Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Minnesota Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Minnesota Subclass Members and other women, and that Minnesota Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1666. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1667. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Minnesota Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Minnesota Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Minnesota Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a

significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1668. As a direct and proximate result of Defendant's actions and omissions, Minnesota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 74
Negligent Failure to Warn
Mississippi

1669. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1670. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Non-PMA Device Subclass.

1671. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Mississippi Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Mississippi Non-PMA Device Subclass Members.

1672. At all relevant times, Defendant owed a duty to use reasonable care in the labeling, marketing, advertising, promotion, and sale of the Non-PMA BIOCELL Implants and a duty to warn the Mississippi Non-PMA Device Subclass Members and the medical community, including the Mississippi Non-PMA Device Subclass Members' treating physicians, of the true risk associated with implanting the Non-PMA BIOCELL Implants.

1673. Defendant breached these duties by not providing sufficient or adequate warnings to the Mississippi Non-PMA Device Subclass Members and the medical community, including

the Mississippi Non-PMA Device Subclass Members' treating physicians, regarding, among other subjects:

1674. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

1675. That the Non-PMA BIOCELL Implants were not manufactured in conformance with legal and good manufacturing requirements; and

1676. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

1677. As a result, the Non-PMA BIOCELL Implants were not reasonably safe for their intended use and were defective as a matter of law due to their lack of appropriate and necessary warnings.

1678. Although Defendant knew that the Non-PMA BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to medical professionals and consumers.

1679. It was readily foreseeable to Defendant that the Mississippi Non-PMA Device Subclass Members and other consumers would be harmed as a result of its failure to exercise ordinary care and to warn Plaintiff and the medical profession of the true risks of the Non-PMA BIOCELL Implants. Defendant knew that the Mississippi Non-PMA Device Subclass Members and their treating physicians would use the Non-PMA BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to the Mississippi Non-PMA Device Subclass Members and other women, and that the Mississippi Non-PMA Device Subclass Members and their treating physicians would rely on its representations and omissions regarding

the safety and performance of its products in deciding whether to purchase and/or implant a Non-PMA BIOCELL Implant.

1680. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and revealed the true risk of BIA-ALCL associated with the Non-PMA BIOCELL Implants to medical professionals and consumers.

1681. Had Defendant adequately warned of the known risks associated with the Non-PMA BIOCELL Implants, the information would have reached the Mississippi Non-PMA Device Subclass Members and their treating physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. The Mississippi Non-PMA Device Subclass Members and their treating physicians would not have used a Non-PMA BIOCELL Implant if they had known of the true safety risks. Accordingly, the Mississippi Non-PMA Device Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Non-PMA BIOCELL Implants.

1682. As a direct and proximate result of Defendant' actions and omissions, the Mississippi Non-PMA Device Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 75
Negligent Failure to Warn
Missouri

1683. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1684. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Subclass.

1685. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Missouri Subclass Members.

1686. The Recalled BIOCELL Implants that were implanted into Missouri Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1687. Under Missouri law, Defendant owed Missouri Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Missouri Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1688. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1689. Defendant breached its duty to adequately warn of the danger, by, among other things:

1690. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1691. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1692. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1693. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1694. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Missouri Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1695. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1696. It was readily foreseeable to Defendant that Missouri Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Missouri Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Missouri Subclass Members and other women, and that Missouri Subclass Members and the medical community would rely on its representations and omissions regarding

the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1697. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1698. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Missouri Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Missouri Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1699. As a direct and proximate result of Defendant's actions and omissions, Missouri Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 76
Negligent Failure to Warn
Montana

1700. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1701. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass.

1702. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Montana Subclass Members.

1703. The Recalled BIOCELL Implants that were implanted into Montana Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been

manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1704. Under Montana law, Defendant owed Montana Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Montana Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1705. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1706. Defendant breached its duty to adequately warn of the danger, by, among other things:

1707. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1708. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1709. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1710. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1711. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Montana Subclass

Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1712. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1713. It was readily foreseeable to Defendant that Montana Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Montana Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Montana Subclass Members and other women, and that Montana Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1714. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1715. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Montana Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative

product that did not present the same risks. Montana Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1716. As a direct and proximate result of Defendant's actions and omissions, Montana Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 77
Negligent Failure to Warn
Nebraska

1717. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1718. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass.

1719. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Nebraska Subclass Members.

1720. The Recalled BIOCELL Implants that were implanted into Nebraska Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1721. Under Nebraska law, Defendant owed Nebraska Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Nebraska Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1722. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1723. Defendant breached its duty to adequately warn of the danger, by, among other things:

1724. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1725. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1726. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1727. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1728. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Nebraska Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1729. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1730. It was readily foreseeable to Defendant that Nebraska Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Nebraska Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Nebraska Subclass Members and other women, and that Nebraska Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1731. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1732. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Nebraska Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Nebraska Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Nebraska Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1733. As a direct and proximate result of Defendant's actions and omissions, Nebraska Subclass Members have sustained physical injury, have as significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 78
Negligent Failure to Warn
Nevada

1734. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1735. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada subclass.

1736. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Nevada Subclass Members.

1737. The Recalled BIOCELL Implants that were implanted into Nevada Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1738. Under Nevada law, Defendant owed Nevada Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Nevada Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1739. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the

devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1740. Defendant breached its duty to adequately warn of the danger, by, among other things:

1741. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1742. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1743. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1744. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1745. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Nevada Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1746. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1747. It was readily foreseeable to Defendant that Nevada Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the

FDA. Defendant knew that Nevada Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Nevada Subclass Members and other women, and that Nevada Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1748. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1749. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Nevada Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Nevada Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1750. As a direct and proximate result of Defendant's actions and omissions, Nevada Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 79
Negligent Failure to Warn
New Hampshire

1751. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1752. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Subclass.

1753. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into New Hampshire Subclass Members.

1754. The Recalled BIOCELL Implants that were implanted into New Hampshire Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1755. Under New Hampshire law, Defendant owed New Hampshire Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and New Hampshire Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1756. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1757. Defendant breached its duty to adequately warn of the danger, by, among other things:

1758. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1759. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1760. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1761. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1762. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. New Hampshire Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1763. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1764. It was readily foreseeable to Defendant that New Hampshire Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that New Hampshire Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to New Hampshire Subclass Members and other women, and that New Hampshire Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1765. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1766. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached New Hampshire Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. New Hampshire Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, New Hampshire Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1767. As a direct and proximate result of Defendant's actions and omissions, New Hampshire Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 80
Negligent Failure to Warn
New Mexico

1768. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1769. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass.

1770. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into New Mexico Subclass Members.

1771. The Recalled BIOCELL Implants that were implanted into New Mexico Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1772. Under New Mexico law, Defendant owed New Mexico Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and New Mexico Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1773. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1774. Defendant breached its duty to adequately warn of the danger, by, among other things:

1775. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1776. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1777. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1778. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1779. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. New Mexico Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1780. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1781. It was readily foreseeable to Defendant that New Mexico Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that New Mexico Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to New Mexico Subclass Members and other women, and that New Mexico Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1782. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1783. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached New Mexico Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. New Mexico Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, New Mexico Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1784. As a direct and proximate result of Defendant's actions and omissions, New Mexico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 81
Negligent Failure to Warn
New York

1785. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1786. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Subclass.

1787. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into New York Subclass Members.

1788. The Recalled BIOCELL Implants that were implanted into New York Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1789. Under New York law, Defendant owed New York Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and New York Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1790. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1791. Defendant breached its duty to adequately warn of the danger, by, among other things:

1792. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1793. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1794. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1795. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1796. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. New York Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1797. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1798. It was readily foreseeable to Defendant that New York Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that New York Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to New York Subclass Members and other women, and that New York Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1799. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1800. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached New York Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. New York Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, New York Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1801. As a direct and proximate result of Defendant's actions and omissions, New York Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 82
Negligent Failure to Warn
North Carolina

1802. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1803. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Carolina Subclass.

1804. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into North Carolina Subclass Members.

1805. The Recalled BIOCELL Implants that were implanted into North Carolina Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1806. Under North Carolina law, Defendant owed North Carolina Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and North Carolina Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1807. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1808. Defendant breached its duty to adequately warn of the danger, by, among other things:

1809. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1810. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1811. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1812. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1813. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. North Carolina Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1814. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1815. It was readily foreseeable to Defendant that North Carolina Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that North Carolina Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to North Carolina Subclass Members and other women, and that North Carolina Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1816. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1817. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached North Carolina Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. North Carolina Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, North Carolina Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1818. As a direct and proximate result of Defendant's actions and omissions, North Carolina Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 83
Negligent Failure to Warn
North Dakota

1819. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1820. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Subclass.

1821. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into North Dakota Subclass Members.

1822. The Recalled BIOCELL Implants that were implanted into North Dakota Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1823. Under North Dakota law, Defendant owed North Dakota Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and North Dakota Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1824. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1825. Defendant breached its duty to adequately warn of the danger, by, among other things:

1826. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1827. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1828. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1829. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1830. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. North Dakota Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1831. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1832. It was readily foreseeable to Defendant that North Dakota Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that North Dakota Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to North Dakota Subclass Members and other women, and that North Dakota Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1833. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1834. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached North Dakota Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. North Dakota Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, North Dakota Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1835. As a direct and proximate result of Defendant's actions and omissions, North Dakota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 84
Negligent Failure to Warn
Northern Mariana Islands

1836. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1837. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass.

1838. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Northern Mariana Islands Subclass Members.

1839. The Recalled BIOCELL Implants that were implanted into Northern Mariana Islands Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1840. Under Northern Mariana Islands law, Defendant owed Northern Mariana Islands Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Northern Mariana Islands Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1841. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1842. Defendant breached its duty to adequately warn of the danger, by, among other things:

1843. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1844. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1845. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1846. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1847. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Northern Mariana Islands Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1848. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1849. It was readily foreseeable to Defendant that Northern Mariana Islands Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Northern Mariana Islands Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Northern Mariana Islands Subclass Members and other women, and that Northern Mariana Islands Subclass Members and the medical

community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1850. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1851. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Northern Mariana Islands Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Northern Mariana Islands Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Northern Mariana Islands Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1852. As a direct and proximate result of Defendant's actions and omissions, Northern Mariana Islands Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 85
Negligent Failure to Warn
Ohio

1853. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1854. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Subclass.

1855. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Ohio Subclass Members.

1856. The Recalled BIOCELL Implants that were implanted into Ohio Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1857. Under Ohio law, Defendant owed Ohio Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Ohio Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1858. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1859. Defendant breached its duty to adequately warn of the danger, by, among other things:

1860. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1861. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1862. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1863. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1864. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Ohio Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1865. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1866. It was readily foreseeable to Defendant that Ohio Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Ohio Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Ohio Subclass Members and other women, and that Ohio Subclass Members and the medical community would rely on its representations and omissions regarding the safety and

performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1867. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1868. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Ohio Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Ohio Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1869. As a direct and proximate result of Defendant's actions and omissions, Ohio Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 86
Negligent Failure to Warn
Oklahoma

1870. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1871. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Subclass.

1872. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Oklahoma Subclass Members.

1873. The Recalled BIOCELL Implants that were implanted into Oklahoma Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been

manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1874. Under Oklahoma law, Defendant owed Oklahoma Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Oklahoma Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1875. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1876. Defendant breached its duty to adequately warn of the danger, by, among other things:

1877. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1878. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1879. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1880. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1881. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Oklahoma Subclass

Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1882. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1883. It was readily foreseeable to Defendant that Oklahoma Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Oklahoma Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Oklahoma Subclass Members and other women, and that Oklahoma Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1884. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1885. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Oklahoma Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Oklahoma Subclass Members and their

physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Oklahoma Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1886. As a direct and proximate result of Defendant's actions and omissions, Oklahoma Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 87
Negligent Failure to Warn
Oregon

1887. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1888. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Subclass.

1889. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Oregon Subclass Members.

1890. The Recalled BIOCELL Implants that were implanted into Oregon Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1891. Under Oregon law, Defendant owed Oregon Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the

Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Oregon Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1892. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1893. Defendant breached its duty to adequately warn of the danger, by, among other things:

1894. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1895. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1896. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1897. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1898. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Oregon Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1899. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1900. It was readily foreseeable to Defendant that Oregon Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Oregon Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Oregon Subclass Members and other women, and that Oregon Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1901. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1902. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Oregon Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Oregon Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Oregon Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation,

cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1903. As a direct and proximate result of Defendant's actions and omissions, Oregon Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 88
Negligent Failure to Warn
Pennsylvania

1904. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1905. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass.

1906. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Pennsylvania Subclass Members.

1907. The Recalled BIOCELL Implants that were implanted into Pennsylvania Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1908. Under Pennsylvania a law, Defendant owed Pennsylvania Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Pennsylvania Subclass

Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1909. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1910. Defendant breached its duty to adequately warn of the danger, by, among other things:

1911. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1912. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1913. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1914. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1915. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Pennsylvania Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1916. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to

manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1917. It was readily foreseeable to Defendant that Pennsylvania Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Pennsylvania Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Pennsylvania Subclass Members and other women, and that Pennsylvania Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1918. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1919. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Pennsylvania Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Pennsylvania Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

1920. As a direct and proximate result of Defendant's actions and omissions, Pennsylvania Subclass Members have a significantly increased risk of BIA-ALCL and have

suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 89
Negligent Failure to Warn
Puerto Rico

1921. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1922. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Subclass.

1923. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Puerto Rico Subclass Members.

1924. The Recalled BIOCELL Implants that were implanted into Puerto Rico Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1925. Under Puerto Rico law, Defendant owed Puerto Rico Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Puerto Rico Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1926. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1927. Defendant breached its duty to adequately warn of the danger, by, among other things:

1928. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1929. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1930. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1931. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1932. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Puerto Rico Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1933. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1934. It was readily foreseeable to Defendant that Puerto Rico Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Puerto Rico Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a

substantial health risk to Puerto Rico Subclass Members and other women, and that Puerto Rico Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1935. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1936. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Puerto Rico Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Puerto Rico Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Puerto Rico Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1937. As a direct and proximate result of Defendant's actions and omissions, Puerto Rico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 90
Negligent Failure to Warn
Rhode Island

1938. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1939. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass.

1940. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Rhode Island Subclass Members.

1941. The Recalled BIOCELL Implants that were implanted into Rhode Island Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1942. Under Rhode Island law, Defendant owed Rhode Island Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Rhode Island Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1943. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1944. Defendant breached its duty to adequately warn of the danger, by, among other things:

1945. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1946. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1947. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1948. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1949. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Rhode Island Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1950. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1951. It was readily foreseeable to Defendant that Rhode Island Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Rhode Island Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Rhode Island Subclass Members and other women, and that Rhode Island Subclass Members and the medical community would rely on its representations and omissions

regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1952. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1953. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Rhode Island Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Rhode Island Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Rhode Island Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1954. As a direct and proximate result of Defendant's actions and omissions, Rhode Island Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 91
Negligent Failure to Warn
South Carolina

1955. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1956. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass.

1957. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into South Carolina Subclass Members.

1958. The Recalled BIOCELL Implants that were implanted into South Carolina Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1959. Under South Carolina law, Defendant owed South Carolina Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and South Carolina Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1960. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1961. Defendant breached its duty to adequately warn of the danger, by, among other things:

1962. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1963. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1964. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1965. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1966. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. South Carolina Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1967. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1968. It was readily foreseeable to Defendant that South Carolina Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that South Carolina Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to South Carolina Subclass Members and other women, and that South Carolina Subclass Members and the medical community would rely on its representations and

omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1969. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1970. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached South Carolina Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. South Carolina Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, South Carolina Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1971. As a direct and proximate result of Defendant's actions and omissions, South Carolina Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 92
Negligent Failure to Warn
South Dakota

1972. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1973. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Subclass.

1974. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into South Dakota Subclass Members.

1975. The Recalled BIOCELL Implants that were implanted into South Dakota Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1976. Under South Dakota law, Defendant owed South Dakota Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and South Dakota Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1977. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1978. Defendant breached its duty to adequately warn of the danger, by, among other things:

1979. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1980. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1981. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1982. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

1983. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. South Dakota Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

1984. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

1985. It was readily foreseeable to Defendant that South Dakota Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that South Dakota Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to South Dakota Subclass Members and other women, and that South Dakota Subclass Members and the medical community would rely on its representations and omissions

regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

1986. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

1987. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached South Dakota Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. South Dakota Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, South Dakota Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

1988. As a direct and proximate result of Defendant's actions and omissions, South Dakota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 93
Negligent Failure to Warn
Tennessee

1989. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

1990. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass.

1991. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Tennessee Subclass Members.

1992. The Recalled BIOCELL Implants that were implanted into Tennessee Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

1993. Under Tennessee law, Defendant owed Tennessee Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Tennessee Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

1994. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

1995. Defendant breached its duty to adequately warn of the danger, by, among other things:

1996. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

1997. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

1998. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

1999. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2000. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Tennessee Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2001. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2002. It was readily foreseeable to Defendant that Tennessee Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Tennessee Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Tennessee Subclass Members and other women, and that Tennessee Subclass Members and the medical community would rely on its representations and omissions

regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2003. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2004. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Tennessee Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Tennessee Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

2005. As a direct and proximate result of Defendant's actions and omissions, Tennessee Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 94
Negligent Failure to Warn
Texas

2006. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2007. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass.

2008. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Texas Subclass Members.

2009. The Recalled BIOCELL Implants that were implanted into Texas Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2010. Under Texas law, Defendant owed Texas Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Texas Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2011. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2012. Defendant breached its duty to adequately warn of the danger, by, among other things:

2013. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2014. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2015. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2016. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2017. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Texas Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2018. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2019. It was readily foreseeable to Defendant that Texas Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Texas Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Texas Subclass Members and other women, and that Texas Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2020. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2021. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Texas Subclass Members

and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Texas Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Texas Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2022. As a direct and proximate result of Defendant's actions and omissions, Texas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 95
Negligent Failure to Warn
U.S. Virgin Islands

2023. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2024. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the U.S. Virgin Islands Subclass.

2025. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into U.S. Virgin Islands Subclass Members.

2026. The Recalled BIOCELL Implants that were implanted into U.S. Virgin Islands Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2027. Under U.S. Virgin Islands law, Defendant owed U.S. Virgin Islands Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and U.S. Virgin Islands Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2028. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2029. Defendant breached its duty to adequately warn of the danger, by, among other things:

2030. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2031. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2032. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2033. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2034. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. U.S. Virgin Islands Subclass Members and their physicians reasonably relied on information regarding adverse events,

or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2035. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2036. It was readily foreseeable to Defendant that U.S. Virgin Islands Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that U.S. Virgin Islands Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to U.S. Virgin Islands Subclass Members and other women, and that U.S. Virgin Islands Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2037. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2038. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached U.S. Virgin Islands Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. U.S. Virgin Islands Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true

safety risks. Accordingly, U.S. Virgin Islands Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2039. As a direct and proximate result of Defendant's actions and omissions, U.S. Virgin Islands Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 96
Negligent Failure to Warn
Utah

2040. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2041. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass.

2042. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Utah Subclass Members.

2043. The Recalled BIOCELL Implants that were implanted into Utah Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2044. Under Utah law, Defendant owed Utah Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled

BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Utah Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2045. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2046. Defendant breached its duty to adequately warn of the danger, by, among other things:

2047. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2048. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2049. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2050. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2051. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Utah Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2052. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2053. It was readily foreseeable to Defendant that Utah Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Utah Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Utah Subclass Members and other women, and that Utah Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2054. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2055. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Utah Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Utah Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

2056. As a direct and proximate result of Defendant's actions and omissions, Utah Subclass Members have a significantly increased risk of BIA-ALCL, have suffered and will suffer

economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 97
Negligent Failure to Warn
Vermont

2057. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2058. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Subclass.

2059. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Vermont Subclass Members.

2060. The Recalled BIOCELL Implants that were implanted into Vermont Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2061. Under Vermont law, Defendant owed Vermont Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Vermont Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2062. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2063. Defendant breached its duty to adequately warn of the danger, by, among other things:

2064. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2065. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2066. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2067. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2068. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Vermont Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2069. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2070. It was readily foreseeable to Defendant that Vermont Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Vermont Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a

substantial health risk to Vermont Subclass Members and other women, and that Vermont Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2071. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2072. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Vermont Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Vermont Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Vermont Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2073. As a direct and proximate result of Defendant's actions and omissions, Vermont Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 98
Negligent Failure to Warn
Virginia

2074. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2075. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virginia Subclass.

2076. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Virginia Subclass Members.

2077. The Recalled BIOCELL Implants that were implanted into Virginia Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2078. Under Virginia law, Defendant owed Virginia Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Virginia Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2079. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2080. Defendant breached its duty to adequately warn of the danger, by, among other things:

2081. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2082. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2083. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2084. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2085. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Virginia Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2086. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2087. It was readily foreseeable to Defendant that Virginia Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Virginia Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Virginia Subclass Members and other women, and that Virginia Subclass Members and the medical community would rely on its representations and omissions regarding

the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2088. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2089. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Virginia Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Virginia Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Virginia Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2090. As a direct and proximate result of Defendant's actions and omissions, Virginia Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 99
Negligent Failure to Warn
West Virginia

2091. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2092. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

2093. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into West Virginia Subclass Members.

2094. The Recalled BIOCELL Implants that were implanted into West Virginia Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2095. Under West Virginia law, Defendant owed West Virginia Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and West Virginia Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2096. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2097. Defendant breached its duty to adequately warn of the danger, by, among other things:

2098. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2099. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2100. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2101. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2102. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. West Virginia Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2103. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2104. It was readily foreseeable to Defendant that West Virginia Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that West Virginia Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to West Virginia Subclass Members and other women, and that West Virginia Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2105. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2106. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached West Virginia Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. West Virginia Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks.

2107. As a direct and proximate result of Defendant's actions and omissions, West Virginia Subclass Members have a significantly increased risk of BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 100
Negligent Failure to Warn
Wisconsin

2108. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2109. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Subclass.

2110. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Wisconsin Subclass Members.

2111. The Recalled BIOCELL Implants that were implanted into Wisconsin Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been

manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2112. Under Wisconsin law, Defendant owed Wisconsin Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Wisconsin Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2113. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2114. Defendant breached its duty to adequately warn of the danger, by, among other things:

2115. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2116. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2117. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2118. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2119. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Wisconsin Subclass

Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2120. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2121. It was readily foreseeable to Defendant that Wisconsin Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Wisconsin Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Wisconsin Subclass Members and other women, and that Wisconsin Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2122. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2123. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Wisconsin Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Wisconsin Subclass Members and their

physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Wisconsin Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2124. As a direct and proximate result of Defendant's actions and omissions, Wisconsin Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 101
Negligent Failure to Warn
Wyoming

2125. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2126. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass.

2127. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Wyoming Subclass Members.

2128. The Recalled BIOCELL Implants that were implanted into Wyoming Subclass Members were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA standards and FDA requirements.

2129. Under Wyoming law, Defendant owed Wyoming Subclass Members a duty to use reasonable care in designing, testing, manufacturing, marketing, distributing, and selling the

Recalled BIOCELL Implants in accordance with the PMAs and other FDA regulations. In addition, Defendant had a duty to the FDA, medical professionals, and Wyoming Subclass Members to exercise reasonable care to provide adequate warnings about the risks and dangers of the Recalled BIOCELL Implants based on information known or readily knowable to Defendant.

2130. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as a manufacturer of Class III medical devices, Defendant had a continuing duty to report post-approval information concerning the devices to the FDA—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

2131. Defendant breached its duty to adequately warn of the danger, by, among other things:

2132. Concealing material information regarding the true risk of BIA-ALCL to the FDA;

2133. Failing to accurately and timely report adverse events regarding the Recalled BIOCELL Implants to the FDA;

2134. Not disclosing that the Recalled BIOCELL Implants were defective and failed to meet the requirements set forth under the PMAs and other FDA regulations; and

2135. Failing to update any existing warnings to disclose the true risks of developing BIA-ALCL, including that the risk was substantially greater than those of competing products.

2136. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks and adverse events associated with their products. Wyoming Subclass Members and their physicians reasonably relied on information regarding adverse events, or the lack thereof, as provided to the FDA by Defendant, in deciding whether to use a Recalled BIOCELL Implant.

2137. Although Defendant knew, or should have known, that the Recalled BIOCELL Implants presented a serious risk of bodily harm to consumers, Defendant continued to manufacture and market them without disclosing the risks to the FDA, medical professionals, and consumers.

2138. It was readily foreseeable to Defendant that Wyoming Subclass Members and other consumers would be harmed as a result of Defendant's failure to exercise ordinary care and to report material information regarding the true risks of the Recalled BIOCELL Implants to the FDA. Defendant knew that Wyoming Subclass Members and their physicians would use the Recalled BIOCELL Implants for their intended purpose, that their intended use would pose a substantial health risk to Wyoming Subclass Members and other women, and that Wyoming Subclass Members and the medical community would rely on its representations and omissions regarding the safety and performance of its products in deciding whether to purchase and/or implant a Recalled BIOCELL Implant.

2139. Under the same or similar circumstances, a reasonable manufacturer would have warned of the danger and reported the true risk of BIA-ALCL associated with the Recalled BIOCELL Implants to the FDA, medical professionals, and consumers.

2140. Had Defendant timely reported the known risks associated with the Recalled BIOCELL Implants to the FDA, the information would have reached Wyoming Subclass Members and their physicians, and allowed them to make an informed decision about using an alternative product that did not present the same risks. Wyoming Subclass Members and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks. Accordingly, Wyoming Subclass Members would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation,

cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2141. As a direct and proximate result of Defendant's actions and omissions, Wyoming Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

C. STRICT LIABILITY - MANUFACTURING DEFECT

COUNT 102
Strict Liability – Manufacturing Defendant
Alabama

2142. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2143. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Subclass.

2144. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2145. Defendant is strictly liable under the Alabama Extended Manufacturer's Liability Doctrine (Al. Civ. Pr. § 6-5-501, *et seq.*) and Alabama common law for manufacturing the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2146. The manufacturing defect harmed Alabama Subclass Members.

2147. The Recalled BIOCELL Implants were expected to and did reach Alabama Subclass Members without a substantial change in condition and were properly implanted in Alabama Subclass Members without any alteration after they left Defendant's control. Any changes that may have been made to the Recalled BIOCELL Implants were reasonably foreseeable to Defendant.

2148. Alabama Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2149. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2150. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2151. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2152. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2153. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2154. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2155. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2156. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Alabama Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2157. If Defendant had followed its own manufacturing specifications, injury to Alabama Subclass Members would not have occurred.

2158. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Alabama Subclass Members and others without knowledge of the hazards involved in such use.

2159. As a direct and proximate result of Defendant's acts and omissions, Alabama Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 103
Strict Liability – Manufacturing Defendant
Alaska

2160. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2161. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

2162. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2163. Defendant is strictly liable under the common law of Alaska because Defendant placed the Recalled BIOCELL Implants in the market knowing that the Recalled BIOCELL Implants were to be used without inspection for defects.

2164. Further, the Recalled BIOCELL Implants had a manufacturing defect that caused injury to Alaska Subclass Members.

2165. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2166. The Recalled BIOCELL Implants were expected to and did reach Alaska Subclass Members without a substantial change in condition and were properly implanted in Alaska Subclass Members without any alteration after they left Defendant's control. In the alternative,

any changes that were made to the Recalled BIOCELL Implants received by Alaska Subclass Members were reasonably foreseeable to Defendant.

2167. Alaska Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2168. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2169. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2170. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant

surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2171. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2172. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2173. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2174. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2175. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Alaska Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2176. If Defendant had followed its own manufacturing specifications, injury to the Plaintiffs would not have occurred.

2177. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Alaska Subclass Members and others without knowledge of the hazards involved in such use.

2178. As a direct and proximate result of Defendant's acts and omissions, Alaska Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 104_
STRICT LIABILITY – MANUFACTURING DEFECT
American Samoa

2179. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2180. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Subclass.

2181. Under American Samoa law, Defendant is strictly liability for injuries caused to American Samoa Subclass Members.

2182. Defendant manufactured the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2183. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2184. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2185. The Recalled BIOCELL Implants were expected to and did reach American Samoa Subclass Members without a substantial change in condition and were properly implanted in

American Samoa Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants America Samoa Subclass Members received were reasonably foreseeable to Defendant.

2186. American Samoa Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2187. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2188. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2189. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability

of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2190. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2191. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2192. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2193. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2194. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2195. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2196. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in American Samoa Subclass Members without knowledge of the hazards involved in such use.

2197. As a direct and proximate result of Defendant's acts and omissions, American Samoa Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 105
STRICT LIABILITY – MANUFACTURING DEFECT
Arizona

2198. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2199. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arizona Subclass.

2200. Under Arizona law including Arizona's product liability statue A.R.S § 12-680, *et seq*. and Arizona common law, Defendant is strictly liable for injuries caused to Arizona Subclass Members.

2201. Defendant manufactured the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2202. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2203. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2204. The Recalled BIOCELL Implants were expected to and did reach Arizona Subclass Members without a substantial change in condition and were properly implanted in Arizona Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Arizona Subclass Members received were reasonably foreseeable to Defendant.

2205. Arizona Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2206. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2207. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2208. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation.

Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2209. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2210. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2211. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2212. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

g. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

h. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

i. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

j. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

k. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

l. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2213. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Arizona Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2214. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2215. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Arizona Subclass Members and others without knowledge of the hazards involved in such use.

2216. As a direct and proximate result of Defendant's acts and omissions, Arizona Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 106
STRICT LIABILITY – MANUFACTURING DEFECT
Arkansas

2217. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2218. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Subclass.

2219. Under the Arkansas Product Liability Act, Ark. Code Ann. § 16–116–101, *et seq.* and Arkansas common law, Defendant is strictly liable for personal injury, death, or property damage caused to Arkansas Subclass Members, and caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of the Recalled BIOCELL Implants.

2220. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2221. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2222. The Recalled BIOCELL Implants were expected to and did reach Arkansas Subclass Members without a substantial change in condition and were properly implanted in Arkansas Subclass Members without any alteration after they left Defendant's control. Any changes that were made to the Recalled BIOCELL Implants Arkansas Subclass Members received were reasonably foreseeable to Defendant.

2223. Arkansas Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2224. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2225. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2226. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation.

Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2227. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2228. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2229. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2230. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2231. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Arkansas Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2232. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2233. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Arkansas Subclass Members and others without knowledge of the hazards involved in such use.

2234. As a direct and proximate result of Defendant's acts and omissions, Arkansas Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 107
STRICT LIABILITY – MANUFACTURING DEFECT
California

2235. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2236. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass.

2237. Under California law including California Health & Safety Code § 108040, *et seq*., and California common law, Defendant is strictly liable for manufacturing defects.

2238. The Recalled BIOCELL Implants manufactured, marketed and sold by Defendant contained a manufacturing defect when they left Defendant's possession, California Subclass Members were harmed, and the defect in the Recalled BIOCELL Implants was a substantial factor in causing the harm to California Subclass Members.

2239. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2240. The Recalled BIOCELL Implants were expected to and did reach California Subclass Members without a substantial change in condition and were properly implanted in

California Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants California Subclass Members received were reasonably foreseeable to Defendant.

2241. California Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2242. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2243. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2244. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability

of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2245. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2246. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2247. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2248. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2249. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2250. If Defendant had followed its own manufacturing specifications, injury to California Subclass Members would not have occurred.

2251. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in California Subclass Members and others without knowledge of the hazards involved in such use.

2252. As a direct and proximate result of Defendant's acts and omissions, California Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 108
STRICT LIABILITY – MANUFACTURING DEFECT
Colorado

2253. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2254. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

2255. Defendant is strictly liable under Colorado common law and the Colorado Product Liability Act, Colo. Rev. Stat. §§ 13–21–401 *et seq.*, as a "manufacturer" engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2256. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Colorado Subclass Members.

2257. The manufacturing defect caused injury to Colorado Subclass Members, and the manufacturing defect existed at the time of manufacture and sale.

2258. The Recalled BIOCELL Implants were expected to and did reach Colorado Subclass Members without a substantial change in condition.

2259. Colorado Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2260. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2261. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2262. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2263. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2264. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2265. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2266. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2267. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2268. If Defendant had followed its own manufacturing specifications, injury to Colorado Subclass Members would not have occurred.

2269. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Colorado Subclass Members and others without knowledge of the hazards involved in such use.

2270. As a direct and proximate result of Defendant's acts and omissions, Colorado Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 109
STRICT LIABILITY - MANUFACTURING DEFECT
District of Columbia

2271. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2272. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the District of Columbia Subclass.

2273. Under the common law of the District of Columbia, Defendant is strictly liable because Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2274. Further, the Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to District of Columbia Subclass Members, the manufacturing defect caused injury to District of Columbia Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach District of Columbia Subclass Members without a substantial change in condition.

2275. District of Columbia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2276. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2277. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2278. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2279. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2280. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2281. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2282. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2283. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and

unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2284. If Defendant had followed its own manufacturing specifications, injury to District of Columbia Subclass Members would not have occurred.

2285. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in District of Columbia Subclass Members and others without knowledge of the hazards involved in such use.

2286. As a direct and proximate result of Defendant's acts and omissions, District of Columbia Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 110
STRICT LIABILITY - MANUFACTURING DEFECT
Florida

2287. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2288. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass.

2289. Defendant is strictly liable under the common law of the Florida.

2290. Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2291. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Florida Subclass Members.

2292. The defect was the proximate cause of the injury and/or damages suffered by Florida Subclass Members.

2293. The Recalled BIOCELL Implants had a manufacturing defect that existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Florida Subclass Members without a substantial change in condition.

2294. Florida Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2295. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2296. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2297. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation.

Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2298. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2299. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2300. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2301. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2302. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2303. If Defendant had followed its own manufacturing specifications, injury to Florida Subclass Members would not have occurred.

2304. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Florida Subclass Members and others without knowledge of the hazards involved in such use.

2305. As a direct and proximate result of Defendant's acts and omissions, Florida Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 111
STRICT LIABILITY - MANUFACTURING DEFECT
Georgia

2306. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2307. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Subclass.

2308. Under Georgia law including Georgia's product liability statute (Ga. Code Ann. § 51-1-11.1) and Georgia common law, Defendant is strictly liable for manufacturing the Recalled BIOCELL Implants,

2309. The Recalled BIOCELL Implants were not merchantable and reasonably suited for their intended use when Defendant sold them, and the defective Recalled BIOCELL Implants proximately caused the injuries suffered by Georgia Subclass Members.

2310. The Recalled BIOCELL Implants were expected to and did reach Georgia Subclass Members without a substantial change in condition.

2311. Georgia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2312. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2313. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2314. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2315. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2316. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2317. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2318. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2319. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Georgia Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2320. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2321. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Georgia Subclass Members and others without knowledge of the hazards involved in such use.

2322. As a direct and proximate result of Defendant's acts and omissions, Georgia Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and

have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 112_
STRICT LIABILITY – MANUFACTURING DEFECT
Guam

2323. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2324. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass.

2325. Under the law of Guam, Defendant is strictly liable for injuries caused to Guam Subclass Members.

2326. Defendant manufactured the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2327. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2328. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2329. The Recalled BIOCELL Implants were expected to and did reach Guam Subclass Members without a substantial change in condition and were properly implanted in Guam Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Guam Subclass Members received were reasonably foreseeable to Defendant.

2330. Guam Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in

violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2331. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2332. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2333. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2334. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2335. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2336. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2337. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2338. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Guam Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2339. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2340. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Guam Subclass Members and others without knowledge of the hazards involved in such use.

2341. As a direct and proximate result of Defendant's acts and omissions, Guam Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have

incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 113
STRICT LIABILITY - MANUFACTURING DEFECT
Hawaii

2342. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2343. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Subclass.

2344. Defendant is strictly liable under the common law of Hawaii because Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2345. The Recalled BIOCELL Implants contained an unreasonably dangerous condition that harmed Hawaii Subclass Members.

2346. Further, due to the manufacturing defect, the Recalled BIOCELL Implants did not meet the reasonable expectations of the ordinary consumer as to its safety.

2347. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2348. The Recalled BIOCELL Implants were expected to and did reach Hawaii Subclass Members without a substantial change in condition and were properly implanted in Hawaii Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Hawaii Subclass Members received were reasonably foreseeable to Defendant.

2349. Hawaii Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in

violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2350. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2351. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2352. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2353. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2354. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2355. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2356. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2357. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Hawaii Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2358. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2359. If Defendant had followed its own manufacturing specifications, injury to Hawaii Subclass Members would not have occurred.

2360. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Hawaii Subclass Members and others without knowledge of the hazards involved in such use.

2361. As a direct and proximate result of Defendant's acts and omissions, Hawaii Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT __
STRICT LIABILITY - MANUFACTURING DEFECT
Idaho

2362. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2363. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Subclass.

2364. Under the Idaho Product Liability Reform Act (I.C. § 6-1401, *et seq*.) and Idaho common law, Defendant is strictly liable as a "manufacturer" because Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2365. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to Idaho Subclass Members, the manufacturing defect caused injury to Idaho Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Idaho Subclass Members without a substantial change in condition.

2366. Idaho Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2367. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2368. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2369. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2370. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2371. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2372. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2373. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2374. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Idaho Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2375. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2376. If Defendant had followed its own manufacturing specifications, injury to Idaho Subclass Members would not have occurred.

2377. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Idaho Subclass Members and others without knowledge of the hazards involved in such use.

2378. As a direct and proximate result of Defendant's acts and omissions, Idaho Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 114
STRICT LIABILITY - MANUFACTURING DEFECT
Illinois

2379. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2380. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Subclass.

2381. Under Illinois' product liability statute (735 Ill. Comp. Stat. Ann. 5/2-2101) and Illinois common law, Defendant is strictly liable as a "manufacturer" because Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2382. Defendant manufactured and sold the Recalled BIOCELL Implants, which contained a manufacturing defect that was unreasonably dangerous to Illinois Subclass Members, the manufacturing defect caused injury to Illinois Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Illinois Subclass Members without a substantial change in condition.

2383. Illinois Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2384. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2385. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2386. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2387. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2388. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2389. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2390. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2391. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2392. If Defendant had followed its own manufacturing specifications, injury to Illinois Subclass Members would not have occurred.

2393. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Illinois Subclass Members and others without knowledge of the hazards involved in such use.

2394. As a direct and proximate result of Defendant's acts and omissions, Illinois Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 115
STRICT LIABILITY - MANUFACTURING DEFECT
Indiana

2395. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2396. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass.

2397. The Indiana Product Liability Act (Ind. Code Ann. § 34–20–1–1, *et seq.*) governs all actions brought by a user or consumer against a manufacturer for physical harm caused by a product.

2398. At all relevant times, Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2399. Defendant manufactured and sold the Recalled BIOCELL Implants, which contained a manufacturing defect that was unreasonably dangerous to Indiana Subclass Members, the manufacturing defect caused injury to Indiana Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Indiana Subclass Members without a substantial change in condition.

2400. Indiana Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2401. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2402. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2403. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2404. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2405. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2406. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and

applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2407. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove

all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2408. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Indiana Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2409. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2410. If Defendant had followed its own manufacturing specifications, injury to Indiana Subclass Members would not have occurred.

2411. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Indiana Subclass Members and others without knowledge of the hazards involved in such use.

2412. The Recalled BIOCELL Implants were defective as set forth in Ind. Code Ann. § 34-20-4-1 because, at the time the implants were conveyed by Allergan, they were in a condition: (1) not contemplated by reasonable persons among those considered expected users or consumers of the product; and (2) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.

2413. As a direct and proximate result of Defendant's acts and omissions, Indiana Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 116
STRICT LIABILITY - MANUFACTURING DEFECT
Iowa

2414. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2415. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass.

2416. Under Iowa law including Iowa's product liability statute (Iowa Code §§ 668.12, 613.18) and Iowa common law, Defendant is strictly liable for manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2417. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Iowa Subclass Members, the manufacturing defect caused injury to Iowa Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Iowa Subclass Members without a substantial change in condition.

2418. Iowa Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2419. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2420. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2421. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2422. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2423. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2424. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2425. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2426. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Iowa Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2427. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2428. If Defendant had followed its own manufacturing specifications, injury to Iowa Subclass Members would not have occurred.

2429. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Iowa Subclass Members and others without knowledge of the hazards involved in such use.

2430. As a direct and proximate result of Defendant's acts and omissions, Iowa Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 117
STRICT LIABILITY - MANUFACTURING DEFECT
Kansas

2431. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2432. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Subclass.

2433. Under the Kansas Product Liability Law (K.S.A. § 60-3301, *et seq*.) and Kansas common law, Defendant is strictly liable as a "manufacturer" because Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2434. Further, Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Kansas Subclass Members, the manufacturing defect caused injury to Kansas Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Kansas Subclass Members without a substantial change in condition.

2435. Kansas Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2436. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2437. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2438. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2439. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2440. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2441. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2442. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2443. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Kansas Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2444. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2445. If Defendant had followed its own manufacturing specifications, injury to Kansas Subclass Members would not have occurred.

2446. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Kansas Subclass Members and others without knowledge of the hazards involved in such use.

2447. As a direct and proximate result of Defendant's acts and omissions, Kansas Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 118
STRICT LIABILITY – MANUFACTURING DEFECT
Kentucky

2448. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2449. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Subclass.

2450. The Kentucky Product Liability Act (K.R.S. § 411.300, *et seq.*), governs all product liability actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture of any product.

2451. Defendant is strictly liable under Kentucky law because Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2452. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Kentucky Subclass Members, the manufacturing defect caused injury to Kentucky Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Kentucky Subclass Members without a substantial change in condition.

2453. Kentucky Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2454. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2455. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2456. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2457. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2458. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2459. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2460. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2461. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Kentucky Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2462. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2463. If Defendant had followed its own manufacturing specifications, injury to Kentucky Subclass Members would not have occurred.

2464. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Kentucky Subclass Members and others without knowledge of the hazards involved in such use.

2465. As a direct and proximate result of Defendant's acts and omissions, Kentucky Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 119
STRICT LIABILITY – MANUFACTURING DEFECT
Maine

2466. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2467. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass.

2468. Under Maine's product liability statute (Me. Rev. Stat. Ann. tit. 14, § 221, *et seq*.) and Maine common law, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to Maine Subclass Members.

2469. Defendant is strictly liable for the physical harm thereby caused to Maine Subclass Members, whom Defendant might reasonably have expected to use or be affected by the goods.

2470. Defendant is engaged in the business of manufacturing and selling the Recalled BIOCELL Implants, which were expected to and did reach the Maine Subclass Members without significant change in the condition in which the Recalled BIOCELL Implants were sold.

2471. Maine Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2472. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2473. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2474. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted

in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2475. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2476. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2477. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2478. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2479. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Maine Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms;

(b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2480. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2481. If Defendant had followed its own manufacturing specifications, injury to Maine Subclass Members would not have occurred.

2482. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Maine Subclass Members and others without knowledge of the hazards involved in such use.

2483. As a direct and proximate result of Defendant's acts and omissions, Maine Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 120
STRICT LIABILITY – MANUFACTURING DEFECT
Maryland

2484. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2485. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Subclass.

2486. At all relevant times, Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2487. Defendant is strictly liable under Maryland common law. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to Maryland Subclass

Members, the manufacturing defect caused injury to Maryland Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Maryland Subclass Members without a substantial change in condition.

2488. Maryland Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2489. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2490. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2491. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing

Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2492. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2493. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2494. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2495. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2496. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2497. If Defendant had followed its own manufacturing specifications, injury to Maryland Subclass Members would not have occurred.

2498. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Maryland Subclass Members and others without knowledge of the hazards involved in such use.

2499. As a direct and proximate result of Defendant's acts and omissions, Maryland Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 121
STRICT LIABILITY – MANUFACTURING DEFECT
Massachusetts

2500. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2501. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

2502. At all relevant times, Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2503. Under Massachusetts common law, Defendant is strictly liable for harm caused to Massachusetts Subclass Members because a defect emerged in the manufacturing of the Recalled BIOCELL Implants that made the product unreasonably dangerous.

2504. Further, the Recalled BIOCELL Implants did not substantially change from their original condition in any way that impacted the product's performance.

2505. Massachusetts Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2506. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2507. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2508. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2509. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2510. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2511. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2512. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2513. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Massachusetts Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2514. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2515. If Defendant had followed its own manufacturing specifications, injury to Massachusetts Subclass Members would not have occurred.

2516. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Massachusetts Subclass Members and others without knowledge of the hazards involved in such use.

2517. As a direct and proximate result of Defendant's acts and omissions, Massachusetts Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 122_
STRICT LIABILITY - MANUFACTURING DEFECT
Minnesota

2518. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2519. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass.

2520. At all relevant times, Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2521. Under Minnesota's product liability statute (Minn. Stat. § 544.41, *et seq*.), Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants.

2522. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Minnesota Subclass Members, the manufacturing defect caused injury to Minnesota Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach the consumer without a substantial change in condition.

2523. Minnesota Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2524. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2525. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2526. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective

manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2527. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2528. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2529. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2530. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2531. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Minnesota Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms;

(b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2532. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2533. If Defendant had followed its own manufacturing specifications, injury to Minnesota Subclass Members would not have occurred.

2534. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Minnesota Subclass Members and others without knowledge of the hazards involved in such use.

2535. As a direct and proximate result of Defendant's acts and omissions, Minnesota Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 123
STRICT LIABILITY - MANUFACTURING DEFECT
Mississippi

2536. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2537. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Subclass.

2538. Under Mississippi's product liability statute (Miss. Code Ann. § 11–1–63, *et seq*.), Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants that caused harm to Mississippi Subclass Members.

2539. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Mississippi Subclass Members.

2540. The defective and unreasonably dangerous condition of the Recalled BIOCELL Implants proximately caused the damages for which recovery is sought.

2541. The Recalled BIOCELL Implants were expected to and did reach Mississippi Subclass Members without a substantial change in condition.

2542. Mississippi Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2543. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2544. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2545. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing

process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2546. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2547. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2548. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2549. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2550. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Mississippi Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2551. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2552. If Defendant had followed its own manufacturing specifications, injury to Mississippi Subclass Members would not have occurred.

2553. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Mississippi Subclass Members and others without knowledge of the hazards involved in such use.

2554. As a direct and proximate result of Defendant's acts and omissions, Mississippi Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 124
STRICT LIABILITY - MANUFACTURING DEFECT
Missouri

2555. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2556. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Subclass.

2557. Defendant is strictly liable under Missouri common law and Missouri's product liability statute, Mo. Rev. Stat. § 537.760.

2558. Defendant is engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2559. Missouri Subclass Members used the Recalled BIOCELL Implants in a manner that was reasonably anticipated, and the Recalled BIOCELL Implants were in a defective and unreasonably dangerous condition when put to their reasonably anticipated use.

2560. Missouri Subclass Members were damaged as a direct result of the manufacturing defect that existed when the Recalled BIOCELL Implants were sold.

2561. The Recalled BIOCELL Implants were expected to and did reach the Missouri Subclass Members without a substantial change in condition.

2562. Missouri Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2563. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2564. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2565. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant

surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2566. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2567. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2568. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2569. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2570. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2571. If Defendant had followed its own manufacturing specifications, injury to Missouri Subclass Members would not have occurred.

2572. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Missouri Subclass Members and others without knowledge of the hazards involved in such use.

2573. As a direct and proximate result of Defendant's acts and omissions, Missouri Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 125
STRICT LIABILITY - MANUFACTURING DEFECT
Montana

2574. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2575. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass.

2576. Defendant is strictly liable under Montana common law and Montana's product liability statute, Mont. Code Ann. § 27-1-719.

2577. Defendant manufactured and sold the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to Montana Subclass Members. This defective condition caused harm to Montana Subclass Members, who were the ultimate users.

2578. Defendant is engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2579. The Recalled BIOCELL Implants were expected to and did reach Montana Subclass Members without a substantial change in the condition in which the Recalled BIOCELL Implants were sold.

2580. Montana Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2581. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2582. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2583. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2584. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2585. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2586. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2587. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2588. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2589. If Defendant had followed its own manufacturing specifications, injury to Montana Subclass Members would not have occurred.

2590. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Montana Subclass Members and others without knowledge of the hazards involved in such use.

2591. As a direct and proximate result of Defendant's acts and omissions, Montana Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 126
STRICT LIABILITY - MANUFACTURING DEFECT
Nebraska

2592. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2593. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass.

2594. Defendant is strictly liable under Nebraska common law and Nebraska's product liability statute (Neb. Rev. Stat. § 25-21,181), as Defendant is both manufacturers and sellers of the Recalled BIOCELL Implants.

2595. Defendant manufactured and sold the Recalled BIOCELL Implants containing a manufacturing defect that was unreasonably dangerous to Nebraska Subclass Members, the manufacturing defect caused injury to Nebraska Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Nebraska Subclass Members without a substantial change in condition.

2596. Nebraska Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2597. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2598. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2599. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated,

unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2600. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2601. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2602. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2603. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2604. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Nebraska Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms;

(b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2605. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2606. If Defendant had followed its own manufacturing specifications, injury to Nebraska Subclass Members would not have occurred.

2607. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Nebraska Subclass Members and others without knowledge of the hazards involved in such use.

2608. As a direct and proximate result of Defendant's acts and omissions, Nebraska Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 127
STRICT LIABILITY - MANUFACTURING DEFECT
Nevada

2609. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2610. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Subclass.

2611. Defendant is strictly liable under Nevada common law.

2612. Defendant manufactured and sold the Recalled BIOCELL Implants.

2613. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to Nevada Subclass Members.

2614. The manufacturing defect existed at the time of manufacture and sale.

2615. The Recalled BIOCELL Implants were used in a manner which was reasonably foreseeable by Defendant.

2616. The manufacturing defect was a proximate cause of the injury suffered by Nevada Subclass Members.

2617. Nevada Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2618. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2619. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2620. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation.

Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2621. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2622. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2623. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2624. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2625. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Nevada Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2626. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2627. If Defendant had followed its own manufacturing specifications, injury to Nevada Subclass Members would not have occurred.

2628. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Nevada Subclass Members and others without knowledge of the hazards involved in such use.

2629. As a direct and proximate result of Defendant's acts and omissions, Nevada Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 128
STRICT LIABILITY - MANUFACTURING DEFECT
New Hampshire

2630. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2631. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Subclass.

2632. Defendant is strictly liable under New Hampshire common law and New Hampshire's product liability statute (N.H. Rev. Stat. Ann. § 507-D:1) for manufacturing and selling the Recalled BIOCELL Implants that caused personal injury and/or damage to New Hampshire Subclass Members.

2633. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to New Hampshire Subclass Members.

2634. The manufacturing defect caused injury to New Hampshire Subclass Members.

2635. The manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached New Hampshire Subclass Members without a substantial change in condition.

2636. New Hampshire Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2637. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2638. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2639. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2640. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2641. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2642. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2643. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2644. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, New Hampshire Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2645. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2646. If Defendant had followed its own manufacturing specifications, injury to New Hampshire Subclass Members would not have occurred.

2647. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in New Hampshire Subclass Members and others without knowledge of the hazards involved in such use.

2648. As a direct and proximate result of Defendant's acts and omissions, New Hampshire Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 129
STRICT LIABILITY - MANUFACTURING DEFECT
New Mexico

2649. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2650. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass.

2651. Defendant is strictly liable under New Mexico common law.

2652. Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2653. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to New Mexico Subclass Members.

2654. The unreasonably dangerous condition of the Recalled BIOCELL Implants injured New Mexico Subclass Members.

2655. The unreasonably dangerous condition existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached New Mexico Subclass Members without a substantial change in condition.

2656. The Recalled BIOCELL Implants were expected to and did reach New Mexico Subclass Members without a substantial change in condition and were properly implanted in New

Mexico Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants New Mexico Subclass Members received were reasonably foreseeable to Defendant.

2657. New Mexico Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2658. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2659. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2660. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability

of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2661. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2662. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2663. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2664. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2665. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, New Mexico Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2666. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2667. If Defendant had followed its own manufacturing specifications, injury to New Mexico Subclass Members would not have occurred.

2668. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in New Mexico Subclass Members and others without knowledge of the hazards involved in such use.

2669. As a direct and proximate result of Defendant's acts and omissions, New Mexico Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 130_
STRICT LIABILITY - MANUFACTURING DEFECT
New York

2670. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2671. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Subclass.

2672. Under the common law of New York, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants to New York Subclass Members.

2673. Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to New York Subclass Members.

2674. The Recalled BIOCELL Implants injured New York Subclass Members.

2675. The unreasonably dangerous condition of the Recalled BIOCELL Implants existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached New York Subclass Members without a substantial change in condition.

2676. The Recalled BIOCELL Implants were expected to and did reach New York Subclass Members without a substantial change in condition and were properly implanted in New York Subclass Members without any alteration after they left Defendant's control. In the

alternative, any changes that were made to the Recalled BIOCELL Implants New York Subclass Members received were reasonably foreseeable to Defendant.

2677. New York Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2678. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2679. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2680. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant

surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2681. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2682. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2683. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2684. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2685. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2686. If Defendant had followed its own manufacturing specifications, injury to New York Subclass Members would not have occurred.

2687. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in New York Subclass Members and others without knowledge of the hazards involved in such use.

2688. As a direct and proximate result of Defendant's acts and omissions, New York Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 131
STRICT LIABILITY - MANUFACTURING DEFECT
North Dakota

2689. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2690. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Subclass.

2691. Defendant is strictly liable under North Dakota common law and North Dakota's product liability statute (N.D. Cent. Code § 28-01.3-04), as a "manufacturer" engaged in assembling, producing, and/or otherwise preparing a product prior to the sale of the product to a user or consumer.

2692. Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to North Dakota Subclass Members.

2693. The manufacturing defect caused harm to North Dakota Subclass Members, and the manufacturing defect existed at the time of manufacture and sale.

2694. The Recalled BIOCELL Implants were expected to and did reach North Dakota Subclass Members without a substantial change in condition.

2695. North Dakota Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2696. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2697. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2698. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2699. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2700. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2701. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2702. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2703. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, North Dakota Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2704. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2705. If Defendant had followed its own manufacturing specifications, injury to North Dakota Subclass Members would not have occurred.

2706. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in North Dakota Subclass Members and others without knowledge of the hazards involved in such use.

2707. As a direct and proximate result of Defendant's acts and omissions, North Dakota Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and

have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 132
STRICT LIABILITY – MANUFACTURING DEFECT
Northern Mariana Islands

2708. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2709. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass.

2710. Under Northern Mariana Island law, Defendant is strictly liable for injuries caused to Northern Mariana Islands Subclass Members.

2711. Defendant manufactured the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2712. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2713. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2714. The Recalled BIOCELL Implants were expected to and did reach Northern Mariana Islands Subclass Members without a substantial change in condition and were properly implanted in Northern Mariana Islands Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Northern Mariana Islands Subclass Members received were reasonably foreseeable to Defendant.

2715. Northern Mariana Islands Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been

defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2716. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2717. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2718. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2719. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2720. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2721. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2722. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

m. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

n. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

o. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

p. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

q. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

r. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2723. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Northern Mariana Islands Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2724. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2725. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Northern Mariana Islands Subclass Members and others without knowledge of the hazards involved in such use.

2726. As a direct and proximate result of Defendant's acts and omissions, Northern Mariana Subclass have sustained physical injury, have a significantly increased risk of BIA-

ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 133
STRICT LIABILITY - MANUFACTURING DEFECT
Ohio

2727. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2728. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Subclass.

2729. Defendant is strictly liable under Ohio common law and Ohio's product liability statute (Ohio Rev. Code §§ 2307.71(A)(9)), as "manufacturers" engaged in a business to formulate, produce, create, make, construct, and/ or assemble a product.

2730. Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to Ohio Subclass Members.

2731. The manufacturing defect caused injury to Ohio Subclass Members, and the manufacturing defect existed at the time of manufacture and sale.

2732. The Recalled BIOCELL Implants were expected to and did reach Ohio Subclass Members without a substantial change in condition.

2733. Ohio Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2734. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2735. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2736. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2737. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2738. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2739. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2740. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid

particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2741. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2742. If Defendant had followed its own manufacturing specifications, injury to Ohio Subclass Members would not have occurred.

2743. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Ohio Subclass Members and others without knowledge of the hazards involved in such use.

2744. As a direct and proximate result of Defendant's acts and omissions, Ohio Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 134
STRICT LIABILITY - MANUFACTURING DEFECT
Oklahoma

2745. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2746. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Subclass.

2747. Under Oklahoma law, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants to Oklahoma Subclass Members.

2748. Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to Oklahoma Subclass Members.

2749. The Recalled BIOCELL Implants injured Oklahoma Subclass Members.

2750. The Recalled BIOCELL Implants were expected to and did reach Oklahoma Subclass Members without a substantial change in condition and were properly implanted in Oklahoma Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Oklahoma Subclass Members received were reasonably foreseeable to Defendant.

2751. Oklahoma Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2752. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2753. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2754. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated,

unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2755. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2756. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2757. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2758. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2759. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Oklahoma Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms;

(b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2760. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2761. If Defendant had followed its own manufacturing specifications, injury to Oklahoma Subclass Members would not have occurred.

2762. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Oklahoma Subclass Members and others without knowledge of the hazards involved in such use.

2763. As a direct and proximate result of Defendant's acts and omissions, Oklahoma Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT __
STRICT LIABILITY - MANUFACTURING DEFECT
Oregon

2764. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2765. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Subclass.

2766. Under Oregon common law and Oregon's product liability statute (Or. Rev. Stat. § 30.920), Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to Oregon Subclass Members.

2767. Defendant is engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

2768. The Recalled BIOCELL Implants were expected to and did reach Oregon Subclass Members without substantial change in condition in which the Recalled BIOCELL Implants were sold.

2769. The Recalled BIOCELL Implants caused injury and/or damage to Oregon Subclass Members.

2770. Oregon Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2771. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2772. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2773. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant

materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2774. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2775. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2776. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2777. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2778. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Oregon Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2779. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous,

defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2780. If Defendant had followed its own manufacturing specifications, injury to Oregon Subclass Members would not have occurred.

2781. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Oregon Subclass Members and others without knowledge of the hazards involved in such use.

2782. As a direct and proximate result of Defendant's acts and omissions, Oregon Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 135
STRICT LIABILITY - MANUFACTURING DEFECT
Pennsylvania

2783. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2784. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass.

2785. Defendant is strictly liable under Pennsylvania common law for manufacturing and selling the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to Pennsylvania Subclass Members.

2786. The Recalled BIOCELL Implants caused injury to Pennsylvania Subclass Members.

2787. The unreasonably dangerous condition of the Recalled BIOCELL Implants existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached Pennsylvania Subclass Members without a substantial change in condition.

2788. Pennsylvania Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2789. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2790. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2791. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2792. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2793. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2794. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2795. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2796. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2797. If Defendant had followed its own manufacturing specifications, injury to Pennsylvania Subclass Members would not have occurred.

2798. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Pennsylvania Subclass Members and others without knowledge of the hazards involved in such use.

2799. As a direct and proximate result of Defendant's acts and omissions, Pennsylvania Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur

damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 136
STRICT LIABILITY - MANUFACTURING DEFECT
Puerto Rico

2800. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2801. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Subclass.

2802. Under Puerto Rican law, Defendant are strictly liable for manufacturing and selling the Recalled BIOCELL Implants to Puerto Rico Subclass Members.

2803. Defendant manufactured and sold the Recalled BIOCELL Implants containing a defect that made the product unreasonably dangerous to Puerto Rico Subclass Members.

2804. Defendant placed the Recalled BIOCELL Implants on the market, knowing that the product was to be used without inspection for defects, and proved to have a defect that caused injury to Puerto Rico Subclass Members.

2805. The defect was the direct and proximate cause of the injuries suffered by Puerto Rico Subclass Members.

2806. The unreasonably dangerous condition of the Recalled BIOCELL Implants existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached Puerto Rico Subclass Members without a substantial change in condition.

2807. The Recalled BIOCELL Implants were expected to and did reach Puerto Rico Subclass Members without a substantial change in condition and were properly implanted in Puerto Rico Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Puerto Rico Subclass Members received were reasonably foreseeable to Defendant.

2808. Puerto Rico Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2809. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2810. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2811. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2812. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2813. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2814. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2815. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2816. As the direct and proximate result of Defendant's acts and omissions, Puerto Rico Subclass Members have sustained permanent injury in an amount to be determined at trial.

2817. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, severe inflammation, tissue damage, seromas, and BIA-ALCL.

2818. If Defendant had followed its own manufacturing specifications, injury to Puerto Rico Subclass Members would not have occurred.

2819. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Puerto Rico Subclass Members and others without knowledge of the hazards involved in such use.

COUNT 137
STRICT LIABILITY - MANUFACTURING DEFECT
Rhode Island

2820. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2821. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass.

2822. Under Rhode Island common law, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants to Rhode Island Subclass Members.

2823. The Recalled BIOCELL Implants left Defendant's control containing a manufacturing defect that harmed Rhode Island Subclass Members.

2824. The manufacturing defect was an unreasonably dangerous condition and was the proximate cause of the harm suffered by Rhode Island Subclass Members.

2825. Rhode Island Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2826. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2827. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2828. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted

in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2829. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2830. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2831. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2832. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2833. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Rhode Island Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2834. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous,

defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2835. If Defendant had followed its own manufacturing specifications, injury to Rhode Island Subclass Members would not have occurred.

2836. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Rhode Island Subclass Members and others without knowledge of the hazards involved in such use.

2837. As a direct and proximate result of Defendant's acts and omissions, Rhode Island Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 138
STRICT LIABILITY - MANUFACTURING DEFECT
South Carolina

2838. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2839. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass.

2840. Defendant is strictly liable under South Carolina common law and South Carolina's product liability statute (S.C. Code Ann. § 15-73-10(1)) for manufacturing and selling the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to South Carolina Subclass Members.

2841. The Recalled BIOCELL Implants caused physical harm to South Carolina Subclass Members, who were the ultimate consumers.

2842. South Carolina Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively

manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2843. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2844. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2845. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2846. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2847. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2848. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2849. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2850. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, South Carolina Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2851. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2852. If Defendant had followed its own manufacturing specifications, injury to South Carolina Subclass Members would not have occurred.

2853. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in South Carolina Subclass Members and others without knowledge of the hazards involved in such use.

2854. As a direct and proximate result of Defendant's acts and omissions, South Carolina Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 139
STRICT LIABILITY - MANUFACTURING DEFECT
South Dakota

2855. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2856. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Subclass.

2857. Defendant is strictly liable under South Dakota common law and South Dakota's product liability statute (S.D. Codified Laws § 20-9-9) for manufacturing the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to South Dakota Subclass Members.

2858. South Dakota Subclass Members were harmed by the unreasonably dangerous condition of the Recalled BIOCELL Implants.

2859. South Dakota Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2860. The unreasonably dangerous condition of the Recalled BIOCELL Implants existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached South Dakota Subclass Members without a substantial change in condition.

2861. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2862. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2863. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2864. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2865. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2866. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2867. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2868. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2869. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2870. If Defendant had followed its own manufacturing specifications, injury to South Dakota Subclass Members would not have occurred.

2871. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in South Dakota Subclass Members and others without knowledge of the hazards involved in such use.

2872. As a direct and proximate result of Defendant's acts and omissions, South Dakota Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 140
STRICT LIABILITY - MANUFACTURING DEFECT
Tennessee

2873. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2874. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass.

2875. Defendant is strictly liable under Tennessee's product liability statute (Tenn. Code Ann. § 29-28-105) for manufacturing, designing, fabricating, producing, compounding, processing, or assembling the Recalled BIOCELL Implants in a defective and/or unreasonably dangerous condition.

2876. Tennessee Subclass Members were harmed by the defective and/or unreasonably dangerous condition of the Recalled BIOCELL Implants.

2877. The Recalled BIOCELL Implants were in a defective and/or unreasonably dangerous condition at the time the Recalled BIOCELL Implants left Defendant's control.

2878. Tennessee Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2879. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2880. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2881. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2882. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2883. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2884. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2885. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2886. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Tennessee Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2887. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2888. If Defendant had followed its own manufacturing specifications, injury to Tennessee Subclass Members would not have occurred.

2889. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Tennessee Subclass Members and others without knowledge of the hazards involved in such use.

2890. As a direct and proximate result of Defendant's acts and omissions, Tennessee Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 141
STRICT LIABILITY - MANUFACTURING DEFECT
Texas

2891. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2892. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass.

2893. Under Texas law, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants to Texas Subclass Members.

2894. Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to Texas Subclass Members.

2895. The Recalled BIOCELL Implants injured Texas Subclass Members.

2896. The unreasonably dangerous condition of the Recalled BIOCELL Implants existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached Texas Subclass Members without a substantial change in condition.

2897. The Recalled BIOCELL Implants were expected to and did reach Texas Subclass Members without a substantial change in condition and were properly implanted in Texas Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants Texas Subclass Members received were reasonably foreseeable to Defendant.

2898. Texas Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2899. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2900. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2901. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2902. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2903. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2904. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2905. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting

in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2906. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Texas Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2907. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2908. If Defendant had followed its own manufacturing specifications, injury to Texas Subclass Members would not have occurred.

2909. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Texas Subclass Members and others without knowledge of the hazards involved in such use.

2910. As a direct and proximate result of Defendant's acts and omissions, Texas Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 142
STRICT LIABILITY - MANUFACTURING DEFECT
Utah

2911. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2912. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass.

2913. Defendant is strictly liable under Utah common law and Utah's product liability statute (Utah Code Ann. § 78B-6-702) for manufacturing the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2914. The Recalled BIOCELL Implants were dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of the Recalled BIOCELL Implants, considering the Recalled BIOCELL Implants' characteristics, propensities, risks, dangers, and uses together with any actual knowledge, training, or experience possessed by Utah Subclass Members.

2915. Utah Subclass Members were harmed by the unreasonably dangerous condition of the Recalled BIOCELL Implants.

2916. The Recalled BIOCELL Implants were in an unreasonably dangerous condition at the time the Recalled BIOCELL Implants left Defendant's control and did not substantially change in condition before reaching Utah Subclass Members.

2917. Utah Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2918. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2919. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2920. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2921. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2922. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2923. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2924. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2925. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2926. If Defendant had followed its own manufacturing specifications, injury to Utah Subclass Members would not have occurred.

2927. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Utah Subclass Members and others without knowledge of the hazards involved in such use.

2928. As a direct and proximate result of Defendant's acts and omissions, Utah Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 143
STRICT LIABILITY - MANUFACTURING DEFECT
Vermont

2929. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2930. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Subclass.

2931. Under Vermont common law, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants.

2932. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to Vermont Subclass Members, the manufacturing defect caused injury to Vermont Subclass Members, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach Vermont Subclass Members without a substantial change in condition.

2933. Vermont Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2934. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2935. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2936. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective

manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2937. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2938. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2939. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2940. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2941. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Vermont Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms;

(b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2942. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, severe inflammation, tissue damage, seromas, and BIA-ALCL.

2943. If Defendant had followed its own manufacturing specifications, injury to Vermont Subclass Members would not have occurred.

2944. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Vermont Subclass Members and others without knowledge of the hazards involved in such use.

2945. As a direct and proximate result of Defendant's acts and omissions, Vermont Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 144
STRICT LIABILITY – MANUFACTURING DEFECT
U.S. Virgin Islands

2946. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2947. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the U.S. Virgin Islands Subclass.

2948. Under U.S. Virgin Islands law, Defendant is strictly liable for injuries caused to U.S. Virgin Islands Subclass Members.

2949. Defendant manufactured the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2950. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

2951. At the time the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use, due to non-compliance with applicable rules and regulations, and/or because Defendant did not take the proper measures in manufacturing its product against foreseeable risk, as set forth in detail above.

2952. The Recalled BIOCELL Implants were expected to and did reach U.S. Virgin Islands Subclass Members without a substantial change in condition and were properly implanted in U.S. Virgin Islands Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants U.S. Virgin Islands Subclass Members received were reasonably foreseeable to Defendant.

2953. U.S. Virgin Islands Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2954. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2955. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2956. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2957. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2958. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2959. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and

applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2960. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2961. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, U.S. Virgin Islands Subclass Members would

not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2962. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2963. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in U.S. Virgin Islands Subclass Members and others without knowledge of the hazards involved in such use.

2964. As a direct and proximate result of Defendant's acts and omissions, U.S. Virgin Islands Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 145
STRICT LIABILITY - MANUFACTURING DEFECT
West Virginia

2965. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2966. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

2967. Under the common law of West Virginia, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2968. The defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached West Virginia Subclass Members without a substantial change in condition.

2969. West Virginia Subclass Members were harmed by the unreasonably dangerous condition of the Recalled BIOCELL Implants.

2970. The Recalled BIOCELL Implants were expected to and did reach West Virginia Subclass Members without a substantial change in condition and were properly implanted in West Virginia Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants West Virginia Subclass Members received were reasonably foreseeable to Defendant.

2971. West Virginia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2972. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2973. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2974. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective

manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2975. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2976. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2977. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2978. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2979. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation,

cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

2980. If Defendant had followed its own manufacturing specifications, injury to West Virginia Subclass Members would not have occurred.

2981. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in West Virginia Subclass Members and others without knowledge of the hazards involved in such use.

2982. As a direct and proximate result of Defendant's acts and omissions, West Virginia Subclass have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 146
STRICT LIABILITY - MANUFACTURING DEFECT
Wisconsin

2983. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

2984. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Subclass.

2985. Defendant is strictly liable under Wisconsin's product liability statute (Wis. Stat. § 895.047) for manufacturing the Recalled BIOCELL Implants in an unreasonably dangerous condition.

2986. The manufacturing of the Recalled BIOCELL Implants departed from Defendant's intended design.

2987. The defective condition existed at the time the Recalled BIOCELL Implants left Defendant's control.

2988. The Recalled BIOCELL Implants reached Wisconsin Subclass Members without substantial change in condition in which the Recalled BIOCELL Implants were sold.

2989. Wisconsin Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

2990. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

2991. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

2992. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant

surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

2993. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

2994. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

2995. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

2996. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

2997. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Wisconsin Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

2998. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

2999. If Defendant had followed its own manufacturing specifications, injury to Wisconsin Subclass Members would not have occurred.

3000. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Wisconsin Subclass Members and others without knowledge of the hazards involved in such use.

3001. As a direct and proximate result of Defendant's acts and omissions, Wisconsin Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 147
STRICT LIABILITY - MANUFACTURING DEFECT
Wyoming

3002. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3003. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass.

3004. Under Wyoming common law, Defendant is strictly liable for manufacturing and selling the Recalled BIOCELL Implants to Wyoming Subclass Members.

3005. Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to Wyoming Subclass Members.

3006. The Recalled BIOCELL Implants injured Wyoming Subclass Members.

3007. The unreasonably dangerous condition of the Recalled BIOCELL Implants existed at the time of manufacture and sale, and the Recalled BIOCELL Implants reached Wyoming Subclass Members without a substantial change in condition.

3008. The Recalled BIOCELL Implants were expected to and did reach Wyoming Subclass Members without a substantial change in condition and were properly implanted in Wyoming Subclass Members without any alteration after they left Defendant's control. In the

alternative, any changes that were made to the Recalled BIOCELL Implants Wyoming Subclass Members received were reasonably foreseeable to Defendant.

3009. Wyoming Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3010. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3011. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3012. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated, unstandardized methods to reveal and release the salt embedded in the surface. This defective manual process deviated from the intended design and manufacturing specifications and resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant

surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3013. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to the state laws set forth herein, based upon Defendant's violation of the applicable federal regulations.

3014. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

3015. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3016. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, device inspection, and corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3017. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Wyoming Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3018. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including, but not limited to, those stated above.

3019. If Defendant had followed its own manufacturing specifications, injury to Wyoming Subclass Members would not have occurred.

3020. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in Wyoming Subclass Members and others without knowledge of the hazards involved in such use.

3021. As a direct and proximate result of Defendant's acts and omissions, Wyoming Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

D. NEGLIGENCE – MANUFACTURING DEFECT

COUNT 148
NEGLIGENCE – MANUFACTURING DEFECT
Alabama

3022. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3023. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Subclass.

3024. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3025. Under Alabama common law, Defendant owed a foreseeable, legal duty to the Alabama Subclass Members.

3026. Defendant breached that duty manufacturing, selling, marketing, and promoting the Recalled BIOCELL Implants, proximately causing the injury to the Alabama Subclass Members.

3027. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants that contained a defective condition unreasonably dangerous to Alabama Subclass Members.

3028. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3029. The Recalled BIOCELL Implants were expected to and did reach the Alabama Subclass Members without a substantial change in condition and were properly implanted in the Alabama Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Alabama Subclass Members received were reasonably foreseeable to Defendant.

3030. The Alabama Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3031. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3032. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3033. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles,

implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3034. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3035. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3036. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3037. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3038. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Alabama Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3039. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous,

defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3040. If Defendant had followed its own manufacturing specifications, injury to the Alabama Subclass Members would not have occurred.

3041. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Alabama Subclass Members and others without knowledge of the hazards involved in such use.

3042. As a direct and proximate result of Defendant's acts and omissions, the Alabama Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 149
NEGLIGENCE – MANUFACTURING DEFECT
Alaska

3043. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3044. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

3045. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3046. Under the common law of Alaska, Defendant owed a duty to the Arizona Subclass Members to exercise the care of a reasonably prudent manufacturer, seller, and/or distributor under the circumstances.

3047. Defendant breached its duty of care to the Arizona Subclass Members by manufacturing and selling the Recalled BIOCELL Implants, proximately causing the Arizona Subclass Members' injuries.

3048. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Alaska Subclass Members.

3049. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3050. The Recalled BIOCELL Implants were expected to and did reach the Alaska Subclass Members without a substantial change in condition and were properly implanted in Plaintiffs and the Alaska Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Alaska Subclass Members received were reasonably foreseeable to Defendant.

3051. The Alaska Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3052. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3053. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3054. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3055. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3056. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3057. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3058. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3059. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Alaska Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms;

(b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3060. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3061. If Defendant had followed its own manufacturing specifications, injury to the Alaska Subclass Members would not have occurred.

3062. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Alaska Subclass Members and others without knowledge of the hazards involved in such use.

3063. As a direct and proximate result of Defendant's acts and omissions, the Alaska Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 150
NEGLIGENCE – MANUFACTURING DEFECT
American Samoa

3064. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3065. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Subclass.

3066. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3067. Defendant owed a duty of care to the American Samoa Subclass Members. It breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants.

3068. Defendant failed to exercise the care of a reasonably prudent manufacturer, seller, and/or distributor under the circumstances. It did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the American Samoa Subclass Members.

3069. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3070. Defendant's conduct was a direct and proximate cause of the injuries suffered by the American Samoa Subclass Members.

3071. The Recalled BIOCELL Implants were expected to and did reach the American Samoa Subclass Members without a substantial change in condition and were properly implanted in the American Samoa Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the American Samoa Subclass Members received were reasonably foreseeable to Defendant.

3072. The American Samoa Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3073. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3074. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3075. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3076. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3077. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3078. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3079. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3080. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the American Samoa Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles

in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3081. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3082. If Defendant had followed its own manufacturing specifications, injury to the American Samoa Subclass Members would not have occurred.

3083. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the American Samoa Subclass Members and others without knowledge of the hazards involved in such use.

3084. As a direct and proximate result of Defendant's acts and omissions, the American Samoa Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 151
NEGLIGENCE – MANUFACTURING DEFECT
Arizona

3085. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3086. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arizona Subclass.

3087. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3088. Under the common law of Arizona, Defendant owed a duty of care to the Arizona Subclass Members.

3089. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Arizona Subclass Members.

3090. Defendant's breach was the direct and proximate cause of the injuries suffered by the Arizona Subclass Members.

3091. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3092. The Recalled BIOCELL Implants were expected to and did reach the Arizona Subclass Members without a substantial change in condition and were properly implanted in Arizona Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Arizona Subclass Members received were reasonably foreseeable to Defendant.

3093. The Arizona Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3094. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3095. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3096. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3097. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3098. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3099. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3100. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3101. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Arizona Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3102. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3103. If Defendant had followed its own manufacturing specifications, injury to the Arizona Subclass Members would not have occurred.

3104. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Arizona Subclass Members and others without knowledge of the hazards involved in such use.

3105. As a direct and proximate result of Defendant's acts and omissions, the Arizona Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 152
NEGLIGENCE – MANUFACTURING DEFECT
Arkansas

3106. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3107. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Subclass.

3108. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3109. Under the common law of Aransas, Defendant owed a duty of care to the Arkansas Subclass Members.

3110. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Arkansas Subclass Members.

3111. That defect was the direct and proximate cause of the injuries suffered by the Arkansas Subclass Members.

3112. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3113. The Recalled BIOCELL Implants were expected to and did reach the Arkansas Subclass Members without a substantial change in condition and were properly implanted in the Arkansas Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Arkansas Subclass Members received were reasonably foreseeable to Defendant.

3114. The Arkansas Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3115. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3116. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3117. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3118. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3119. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3120. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3121. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3122. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Arkansas Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3123. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3124. If Defendant had followed its own manufacturing specifications, injury to the Arkansas Subclass Members would not have occurred.

3125. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Arkansas Subclass Members and others without knowledge of the hazards involved in such use.

3126. As a direct and proximate result of Defendant's acts and omissions, the Arkansas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 153
NEGLIGENCE – MANUFACTURING DEFECT
California

3127. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3128. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass.

3129. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3130. Under the common law of California, Defendant owed a duty of care to the California Subclass Members.

3131. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the California Subclass Members.

3132. Defendant's breach was the direct and proximate cause of the injuries suffered by the California Subclass Members.

3133. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3134. The Recalled BIOCELL Implants were expected to and did reach the California Subclass Members without a substantial change in condition and were properly implanted in the California Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the California Subclass Members received were reasonably foreseeable to Defendant.

3135. Plaintiffs and the California Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3136. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3137. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3138. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3139. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3140. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3141. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3142. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3143. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the California Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3144. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3145. If Defendant had followed its own manufacturing specifications, injury to the California Subclass Members would not have occurred.

3146. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the California Subclass Members and others without knowledge of the hazards involved in such use.

3147. As a direct and proximate result of Defendant's acts and omissions, the California Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 154
NEGLIGENCE – MANUFACTURING DEFECT
Colorado

3148. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3149. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

3150. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3151. Under Colorado common law, Defendant owed a duty of care to the Colorado Subclass Members. It breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Colorado Subclass Members.

3152. Defendant's breach was the direct and proximate cause of the injuries suffered by the Colorado Subclass Members.

3153. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3154. The Recalled BIOCELL Implants were expected to and did reach the Colorado Subclass Members without a substantial change in condition and were properly implanted in the Colorado Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Colorado Subclass Members received were reasonably foreseeable to Defendant.

3155. The Colorado Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3156. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3157. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3158. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3159. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3160. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3161. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3162. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3163. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Colorado Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3164. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3165. If Defendant had followed its own manufacturing specifications, injury to the Colorado Subclass Members would not have occurred.

3166. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted the Colorado Subclass Members and others without knowledge of the hazards involved in such use.

3167. As a direct and proximate result of Defendant's acts and omissions, the Colorado Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 155
NEGLIGENCE – MANUFACTURING DEFECT
Delaware

3168. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3169. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Delaware Subclass.

3170. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

3171. Under the common law of Delaware, Defendant owed a duty to the Delaware Subclass Members.

3172. Defendant breached that duty when it failed to exercise the care of a reasonably prudent manufacturer under all circumstances and failed to take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Delaware Subclass Members.

3173. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3174. Defendant's conduct was a direct and proximate cause of the injuries suffered by the Delaware Subclass Members.

3175. The Recalled BIOCELL Implants were expected to and did reach the Delaware Subclass Members without a substantial change in condition and were properly implanted in the Delaware Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Delaware Subclass Members received were reasonably foreseeable to Defendant.

3176. The Delaware Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3177. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3178. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3179. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3180. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3181. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3182. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3183. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting

in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3184. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Delaware Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3185. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3186. If Defendant had followed its own manufacturing specifications, injury to the Delaware Subclass Members would not have occurred.

3187. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Delaware Subclass Members and others without knowledge of the hazards involved in such use.

3188. As a direct and proximate result of Defendant's acts and omissions, the Delaware Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 156
NEGLIGENCE – MANUFACTURING DEFECT
District of Columbia

3189. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3190. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the District of Columbia Subclass.

3191. Under District of Columbia law, Defendant owed a duty of care to the District of Columbia Subclass Members when manufacturing and selling the Recalled BIOCELL Implants.

3192. Defendant breached that duty of care by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the District of Columbia Subclass Members.

3193. Defendant's breach was the direct and proximate cause of the injuries suffered by the District of Columbia Subclass Members.

3194. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3195. The Recalled BIOCELL Implants were expected to and did reach the District of Columbia Subclass Members without a substantial change in condition and were properly implanted in the District of Columbia Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the District of Columbia Subclass Members received were reasonably foreseeable to Defendant.

3196. The District of Columbia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3197. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3198. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3199. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3200. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3201. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3202. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3203. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting

in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3204. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the District of Columbia Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3205. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3206. If Defendant had followed its own manufacturing specifications, injury to the District of Columbia Subclass Members would not have occurred.

3207. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the District of Columbia Subclass Members and others without knowledge of the hazards involved in such use.

3208. As a direct and proximate result of Defendant's acts and omissions, the District of Columbia Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 157
NEGLIGENCE – MANUFACTURING DEFECT
Florida

3209. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3210. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass.

3211. Under Florida law, Defendant owed a duty of care to the Florida Subclass Members when manufacturing and selling the Recalled BIOCELL Implants.

3212. Defendant breached that duty of care by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or were unreasonably dangerous to the Florida Subclass Members.

3213. Defendant's breach was the proximate cause of the injuries suffered by the Florida Subclass Members.

3214. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3215. The Recalled BIOCELL Implants were expected to and did reach the Florida Subclass Members without a substantial change in condition and were properly implanted in the Florida Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Florida Subclass Members received were reasonably foreseeable to Defendant.

3216. The Florida Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3217. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3218. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3219. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3220. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state law set forth herein.

3221. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3222. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3223. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3224. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Florida Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3225. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3226. If Defendant had followed its own manufacturing specifications, injury to the Florida Subclass Members would not have occurred.

3227. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Florida Subclass Members and others without knowledge of the hazards involved in such use.

3228. As a direct and proximate result of Defendant's acts and omissions, the Florida Subclass Members have significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 158
NEGLIGENCE – MANUFACTURING DEFECT
Georgia

3229. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3230. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Subclass.

3231. Under Georgia law, Defendant owed a duty of care to the Georgia Subclass Members. It breached that duty of care by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or were in an unreasonably dangerous condition.

3232. Defendant's conduct was a direct and proximate cause of the injuries suffered by the Georgia Subclass Members.

3233. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3234. The Recalled BIOCELL Implants were expected to and did reach the Georgia Subclass Members without a substantial change in condition and were properly implanted in the Georgia Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Georgia Subclass Members received were reasonably foreseeable to Defendant.

3235. The Georgia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3236. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3237. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3238. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3239. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations.

3240. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3241. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3242. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3243. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Georgia Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies,

including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3244. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3245. If Defendant had followed its own manufacturing specifications, injury to the Georgia Subclass Members would not have occurred.

3246. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Georgia Subclass Members and others without knowledge of the hazards involved in such use.

3247. As a direct and proximate result of Defendant's acts and omissions, the Georgia Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 159
NEGLIGENCE – MANUFACTURING DEFECT
Guam

3248. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3249. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass.

3250. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3251. Under the common law of Guam, Defendant failed to exercise the care of a reasonably prudent manufacturer, seller, and/or distributor under the circumstances.

3252. Defendant breached the duty of care owed to the Guam Subclass Members by manufacturing and selling the Recalled BIOCELL Implants.

3253. Defendant's conduct was a direct and proximate cause of the injuries suffered by the Guam Subclass Members.

3254. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Guam Subclass Members.

3255. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3256. The Recalled BIOCELL Implants were expected to and did reach the Guam Subclass Members without a substantial change in condition and were properly implanted in the Guam Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Guam Subclass Members received were reasonably foreseeable to Defendant.

3257. The Guam Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3258. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3259. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3260. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3261. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as parallel state law claims pursuant to the state laws set forth herein.

3262. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3263. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3264. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3265. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Guam Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3266. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3267. If Defendant had followed its own manufacturing specifications, injury to the Guam Subclass Members would not have occurred.

3268. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Guam Subclass Members and others without knowledge of the hazards involved in such use.

3269. As a direct and proximate result of Defendant's acts and omissions, the Guam Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 160
NEGLIGENCE – MANUFACTURING DEFECT
Hawaii

3270. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3271. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Subclass.

3272. Under Hawaii common law, Defendant had a duty, or obligation, recognized by the law, requiring Defendant to conform to the standard of conduct of a reasonable manufacturer, seller, and/or distributor.

3273. Defendant failed to conform to that standard and breached its duty to the Hawaii Subclass Members by manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or were unreasonably dangerous to the Hawaii Subclass Members.

3274. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3275. The Defendant's acts and omissions directly and proximately caused injury to the Hawaii Subclass Members.

3276. The Recalled BIOCELL Implants were expected to and did reach the Hawaii Subclass Members without a substantial change in condition and were properly implanted in the Hawaii Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Hawaii Subclass Members received were reasonably foreseeable to Defendant.

3277. The Hawaii Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3278. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3279. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3280. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3281. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as parallel state law claims pursuant to the state laws set forth herein.

3282. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3283. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3284. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3285. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Hawaii Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3286. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3287. If Defendant had followed its own manufacturing specifications, injury to the Hawaii Subclass Members would not have occurred.

3288. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Hawaii Subclass Members and others without knowledge of the hazards involved in such use.

3289. As a direct and proximate result of Defendant's acts and omissions, the Guam Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 161
NEGLIGENCE – MANUFACTURING DEFECT
Idaho

3290. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3291. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Subclass.

3292. Under Idaho common law, Defendant had a duty, recognized by the law, requiring Defendant to conform to the standard of conduct of a reasonable manufacturer, seller, and/or distributor.

3293. Defendant failed to conform to this standard of care by manufacturing and selling the Recalled BIOCELL Implants that contained a defect and/or were unreasonably dangerous to the Idaho Subclass Members.

3294. Defendant's breach directly and proximately caused the injuries suffered by the Idaho Subclass Members, which caused actual loss and/or damage.

3295. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3296. The Recalled BIOCELL Implants were expected to and did reach the Idaho Subclass Members without a substantial change in condition and were properly implanted in the Idaho Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Idaho Subclass Members received were reasonably foreseeable to Defendant.

3297. The Idaho Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3298. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3299. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3300. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3301. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as parallel state law claims pursuant to the state laws set forth herein.

3302. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3303. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3304. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3305. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Idaho Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3306. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3307. If Defendant had followed its own manufacturing specifications, injury to the Idaho Subclass Members would not have occurred.

3308. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Idaho Subclass Members and others without knowledge of the hazards involved in such use.

3309. As a direct and proximate result of Defendant's acts and omissions, the Idaho Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 162
NEGLIGENCE – MANUFACTURING DEFECT
Illinois

3310. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3311. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Subclass.

3312. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3313. Under the common law of Illinois, Defendant owed a duty of care to the Illinois Subclass Members.

3314. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Illinois Subclass Members.

3315. Defendant's breach was the direct and proximate cause of the injuries suffered by the Illinois Subclass Members.

3316. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3317. The Recalled BIOCELL Implants were expected to and did reach the Illinois Subclass Members without a substantial change in condition and were properly implanted in the Illinois Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Illinois Subclass Members received were reasonably foreseeable to Defendant.

3318. The Illinois Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3319. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3320. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3321. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3322. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as parallel state law claims pursuant to the state laws set forth herein.

3323. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3324. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3325. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3326. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Illinois Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3327. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3328. If Defendant had followed its own manufacturing specifications, injury to the Illinois Subclass Members would not have occurred.

3329. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Illinois Subclass Members and others without knowledge of the hazards involved in such use.

3330. As a direct and proximate result of Defendant's acts and omissions, the Illinois Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 163
NEGLIGENCE – MANUFACTURING DEFECT
Indiana

3331. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3332. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass.

3333. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3334. Under Indiana law, Defendant breached the duty of care owed to the Indiana Subclass Members in manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to any user or consumer.

3335. Defendant's breach was the direct and proximate cause of the injuries suffered by the Indiana Subclass Members.

3336. Further, the Indiana Subclass Members were foreseeable users and/or consumers, and the Recalled BIOCELL Implants reached the Indiana Subclass Members in the condition in which they were sold.

3337. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, and Defendant did not take reasonable measures against foreseeable risks.

3338. When the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3339. The Recalled BIOCELL Implants were expected to and did reach the Indiana Subclass Members without a substantial change in condition and were properly implanted in the Indiana Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Indiana Subclass Members received were reasonably foreseeable to Defendant.

3340. The Indiana Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in

violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3341. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3342. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3343. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3344. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3345. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3346. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3347. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3348. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Indiana Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3349. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3350. If Defendant had followed its own manufacturing specifications, injury to the Indiana Subclass Members would not have occurred.

3351. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Indiana Subclass Members and others without knowledge of the hazards involved in such use.

3352. As a direct and proximate result of Defendant's acts and omissions, the Indiana Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 164
NEGLIGENCE – MANUFACTURING DEFECT
Iowa

3353. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3354. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass.

3355. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3356. Under the common law of Iowa, Defendant failed to exercise the care of a reasonably prudent manufacturer, seller, and/or distributor under the circumstances.

3357. Defendant owed a duty of care to the Iowa Subclass Members in manufacturing and selling the Recalled BIOCELL Implants.

3358. Defendant breached that duty because it failed to take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Iowa Subclass Members.

3359. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3360. Defendant's acts and omissions directly and proximately caused the Iowa Subclass Members injury.

3361. The Recalled BIOCELL Implants were expected to and did reach the Iowa Subclass Members without a substantial change in condition and were properly implanted in the Iowa Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Iowa Subclass Members received were reasonably foreseeable to Defendant.

3362. The Iowa Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3363. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3364. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3365. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3366. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3367. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3368. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3369. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3370. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Iowa Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3371. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3372. If Defendant had followed its own manufacturing specifications, injury to the Iowa Subclass Members would not have occurred.

3373. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Iowa Subclass Members and others without knowledge of the hazards involved in such use.

3374. As a direct and proximate result of Defendant's acts and omissions, the Iowa Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 165
NEGLIGENCE – MANUFACTURING DEFECT
Kansas

3375. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3376. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Subclass.

3377. Under Kansas common law, Defendant had a duty to the Kansas Subclass Members, recognized by the law, requiring Defendant to conform to the standard of conduct of a reasonable manufacturer, seller, and/or distributor.

3378. Defendant failed to conform to the standard required by manufacturing and selling the Recalled BIOCELL Implants that contained a defect and/or were unreasonably dangerous to the Kansas Subclass Members and breached its duty to the Kansas Subclass Members.

3379. The Defendant's breach directly and proximately caused the injuries suffered by the Kansas Subclass Members, which caused actual loss and/or damage.

3380. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3381. The Recalled BIOCELL Implants were expected to and did reach the Kansas Subclass Members without a substantial change in condition and were properly implanted in the Kansas Subclass Members without any alteration after they left Defendant's control. In the

alternative, any changes that were made to the Recalled BIOCELL Implants that the Kansas Subclass Members received were reasonably foreseeable to Defendant.

3382. The Kansas Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3383. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3384. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3385. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles

on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3386. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as parallel state law claims pursuant to the state laws set forth herein.

3387. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3388. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3389. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3390. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Kansas Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3391. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3392. If Defendant had followed its own manufacturing specifications, injury to the Kansas Subclass Members would not have occurred.

3393. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Kansas Subclass Members and others without knowledge of the hazards involved in such use.

3394. As a direct and proximate result of Defendant's acts and omissions, the Kansas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 166
NEGLIGENCE – MANUFACTURING DEFECT
Kentucky

3395. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3396. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Subclass.

3397. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3398. Under the common law of Kentucky, Defendant owed a duty of care to the Kentucky Subclass Members.

3399. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Kentucky Subclass Members.

3400. Defendant's breach was the direct and proximate cause of the injuries suffered by the Kentucky Subclass Members.

3401. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3402. The Recalled BIOCELL Implants were expected to and did reach the Kentucky Subclass Members without a substantial change in condition and were properly implanted in the Kentucky Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Kentucky Subclass Members received were reasonably foreseeable to Defendant.

3403. The Kentucky Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3404. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3405. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3406. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3407. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3408. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3409. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3410. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3411. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Kentucky Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3412. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3413. If Defendant had followed its own manufacturing specifications, injury to the Kentucky Subclass Members would not have occurred.

3414. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Kentucky Subclass Members and others without knowledge of the hazards involved in such use.

3415. As a direct and proximate result of Defendant's acts and omissions, the Kentucky Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 167
NEGLIGENCE – MANUFACTURING DEFECT
Maine

3416. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3417. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass.

3418. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3419. Under the common law of Maine, Defendant owed a duty of care to the Maine Subclass Members.

3420. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Maine Subclass Members.

3421. Defendant's breach was the direct and proximate cause of the injuries suffered by the Maine Subclass Members.

3422. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3423. The Recalled BIOCELL Implants were expected to and did reach the Maine Subclass Members without a substantial change in condition and were properly implanted in the Maine Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Maine Subclass Members received were reasonably foreseeable to Defendant.

3424. The Maine Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3425. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3426. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3427. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3428. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3429. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3430. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3431. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3432. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Maine Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3433. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3434. If Defendant had followed its own manufacturing specifications, injury to the Maine Subclass Members would not have occurred.

3435. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Maine Subclass Members and others without knowledge of the hazards involved in such use.

3436. As a direct and proximate result of Defendant's acts and omissions, the Maine Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 168
NEGLIGENCE – MANUFACTURING DEFECT
Maryland

3437. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3438. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Subclass.

3439. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3440. Under the common law of Maryland, Defendant owed a duty of care to the Maryland Subclass Members.

3441. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Maryland Subclass Members.

3442. Defendant's breach was the direct and proximate cause of the injuries suffered by the Maryland Subclass Members.

3443. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3444. The Recalled BIOCELL Implants were expected to and did reach the Maryland Subclass Members without a substantial change in condition and were properly implanted in the Maryland Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Maryland Subclass Members received were reasonably foreseeable to Defendant.

3445. The Maryland Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3446. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3447. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3448. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3449. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3450. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3451. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3452. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3453. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Maryland Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3454. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3455. If Defendant had followed its own manufacturing specifications, injury to the Maryland Subclass Members would not have occurred.

3456. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Maryland Subclass Members and others without knowledge of the hazards involved in such use.

3457. As a direct and proximate result of Defendant's acts and omissions, the Maryland Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 169
NEGLIGENCE – MANUFACTURING DEFECT
Massachusetts

3458. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3459. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

3460. Under Massachusetts common law, Defendant had a duty to the Massachusetts Subclass Members, recognized by the law, requiring Defendant to conform to the standard of conduct of a reasonable manufacturer, seller, and/or distributor.

3461. Defendant failed to conform to the standard required by manufacturing and selling the Recalled BIOCELL Implants that contained a defect and/or were unreasonably dangerous to the Massachusetts Subclass Members.

3462. The Defendant's breach directly and proximately caused the injuries suffered by the Massachusetts Subclass Members, which caused actual loss and/or damage.

3463. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3464. The Recalled BIOCELL Implants were expected to and did reach the Massachusetts Subclass Members without a substantial change in condition and were properly implanted in the Massachusetts Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Massachusetts Subclass Members received were reasonably foreseeable to Defendant.

3465. The Massachusetts Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3466. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3467. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3468. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3469. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3470. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3471. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3472. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3473. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Massachusetts Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3474. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3475. If Defendant had followed its own manufacturing specifications, injury to the Massachusetts Subclass Members would not have occurred.

3476. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Massachusetts Subclass Members and others without knowledge of the hazards involved in such use.

3477. As a direct and proximate result of Defendant's acts and omissions, the Massachusetts Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 170
NEGLIGENCE - MANUFACTURING DEFECT
Michigan

3478. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3479. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Michigan Subclass.

3480. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing and promoting the Recalled BIOCELL Implants.

3481. Under Michigan's product liability statute (M.C.L. § 600.2946), Defendant is liable for harm caused by the manufacturing defect contained in the Recalled BIOCELL Implants.

3482. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants that contained a defective condition unreasonably dangerous to the Michigan Subclass Members.

3483. The Recalled BIOCELL Implants were not reasonably safe at the time the Recalled BIOCELL Implants left Defendant's control, and according to generally accepted production practices at the time the Recalled BIOCELL Implants left Defendant's control, a practical and technically feasible alternative production practice was available that would have prevented the

harm without significantly impairing the usefulness or desirability of the Recalled BIOCELL Implants to the Michigan Subclass Members and without creating equal or greater risk of harm to others.

3484. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3485. The Recalled BIOCELL Implants were expected to and did reach the Michigan Subclass Members without a substantial change in condition and were properly implanted in the Michigan Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Michigan Subclass Members received were reasonably foreseeable to Defendant.

3486. The Michigan Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3487. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3488. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3489. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3490. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3491. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3492. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3493. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3494. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Michigan Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related

symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3495. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3496. If Defendant had followed its own manufacturing specifications, injury to the Michigan Subclass Members would not have occurred.

3497. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Michigan Subclass Members and others without knowledge of the hazards involved in such use.

3498. As a direct and proximate result of Defendant's acts and omissions, the Michigan Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 171
NEGLIGENCE – MANUFACTURING DEFECT
Minnesota

3499. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3500. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass.

3501. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3502. Under the common law of Minnesota, Defendant owed a duty of care to the Minnesota Subclass Members.

3503. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Minnesota Subclass Members.

3504. Defendant's breach was the direct and proximate cause of the injuries suffered by the Minnesota Subclass Members.

3505. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3506. The Recalled BIOCELL Implants were expected to and did reach the Minnesota Subclass Members without a substantial change in condition and were properly implanted in the Minnesota Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Minnesota Subclass Members received were reasonably foreseeable to Defendant.

3507. The Minnesota Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3508. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3509. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3510. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3511. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3512. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3513. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3514. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3515. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Minnesota Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their

bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3516. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3517. If Defendant had followed its own manufacturing specifications, injury to the Minnesota Subclass Members would not have occurred.

3518. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Minnesota Subclass Members and others without knowledge of the hazards involved in such use.

3519. As a direct and proximate result of Defendant's acts and omissions, the Minnesota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 172
NEGLIGENCE – MANUFACTURING DEFECT
Mississippi

3520. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3521. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Subclass.

3522. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3523. Under Mississippi law, Defendant are liable for negligence that resulted from the manufacturing and selling of the Recalled BIOCELL Implants.

3524. The Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to the Mississippi Subclass Members, and which caused harm to the Mississippi Subclass Members.

3525. Defendant's conduct was a breach of the duty it owed to the Mississippi Subclass Members and the direct and proximate cause of the harm suffered by the Mississippi Subclass Members.

3526. Further, the defective and unreasonably dangerous condition of the Recalled BIOCELL Implants proximately caused the damages for which recovery is sought.

3527. The Recalled BIOCELL Implants were expected to and did reach the Mississippi Subclass Members without a substantial change in condition.

3528. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3529. The Recalled BIOCELL Implants were properly implanted in the Mississippi Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Mississippi Subclass Members received were reasonably foreseeable to Defendant.

3530. The Mississippi Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3531. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3532. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3533. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3534. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3535. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3536. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3537. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting

in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3538. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Mississippi Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3539. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3540. If Defendant had followed its own manufacturing specifications, injury to the Mississippi Subclass Members would not have occurred.

3541. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Mississippi Subclass Members and others without knowledge of the hazards involved in such use.

3542. As a direct and proximate result of Defendant's acts and omissions, the Mississippi Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 173
NEGLIGENCE – MANUFACTURING DEFECT
Missouri

3543. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3544. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Subclass.

3545. Under Missouri common law, Defendant had a duty to the Missouri Subclass Members, recognized by the law, requiring Defendant to conform to the standard of conduct of a reasonable manufacturer, seller, and/or distributor.

3546. Defendant failed to conform to the standard required by manufacturing and selling the Recalled BIOCELL Implants that contained a defect and/or were unreasonably dangerous to the Missouri Subclass Members.

3547. The Defendant's breach directly and proximately caused the injuries suffered by the Missouri Subclass Members, which caused actual loss and/or damage.

3548. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3549. The Recalled BIOCELL Implants were expected to and did reach the Missouri Subclass Members without a substantial change in condition and were properly implanted in the Missouri Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Missouri Subclass Members received were reasonably foreseeable to Defendant.

3550. The Missouri Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3551. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3552. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3553. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3554. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3555. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3556. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3557. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting

in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3558. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Missouri Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3559. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3560. If Defendant had followed its own manufacturing specifications, injury to the Missouri Subclass Members would not have occurred.

3561. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Missouri Subclass Members and others without knowledge of the hazards involved in such use.

3562. As a direct and proximate result of Defendant's acts and omissions, the Missouri Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 174
NEGLIGENCE – MANUFACTURING DEFECT
Montana

3563. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3564. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass.

3565. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3566. Under Montana law, Defendant owed a duty of care to the Montana Subclass Members to act as a reasonable manufacturer under the same or similar circumstances.

3567. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Montana Subclass Members.

3568. Defendant's breach was the direct and proximate cause of the injuries suffered by the Montana Subclass Members.

3569. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3570. The Recalled BIOCELL Implants were expected to and did reach the Montana Subclass Members without a substantial change in condition and were properly implanted in the Montana Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Montana Subclass Members received were reasonably foreseeable to Defendant.

3571. The Montana Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3572. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3573. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3574. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3575. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3576. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable

PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3577. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3578. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting

in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3579. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Montana Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3580. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3581. If Defendant had followed its own manufacturing specifications, injury to the Montana Subclass Members would not have occurred.

3582. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Montana Subclass Members and others without knowledge of the hazards involved in such use.

3583. As a direct and proximate result of Defendant's acts and omissions, the Montana Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 175
NEGLIGENCE – MANUFACTURING DEFECT
Nebraska

3584. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3585. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass.

3586. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3587. Under Nebraska law, Defendant engaged in conduct that was not reasonable in view of the foreseeable risk of injury to the Nebraska Subclass Members.

3588. Defendant owed a duty of care to the Nebraska Subclass Members.

3589. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Nebraska Subclass Members.

3590. Defendant's breach was the direct and proximate cause of the injuries suffered by the Nebraska Subclass Members.

3591. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3592. The Recalled BIOCELL Implants were expected to and did reach the Nebraska Subclass Members without a substantial change in condition and were properly implanted in the Nebraska Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Nebraska Subclass Members received were reasonably foreseeable to Defendant.

3593. The Nebraska Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently

manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3594. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3595. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3596. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3597. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3598. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3599. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3600. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3601. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Nebraska Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3602. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3603. If Defendant had followed its own manufacturing specifications, injury to the Nebraska Subclass Members would not have occurred.

3604. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Nebraska Subclass Members and others without knowledge of the hazards involved in such use.

3605. As a direct and proximate result of Defendant's acts and omissions, the Nebraska Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 176
NEGLIGENCE – MANUFACTURING DEFECT
Nevada

3606. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3607. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Subclass.

3608. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3609. Under Nevada common law, Defendant owed a duty of care to the Nevada Subclass Members.

3610. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Nevada Subclass Members.

3611. Defendant's breach was the direct and proximate cause of the injuries suffered by the Nevada Subclass Members.

3612. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3613. The Recalled BIOCELL Implants were expected to and did reach the Nevada Subclass Members without a substantial change in condition and were properly implanted in the Nevada Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Nevada Subclass Members received were reasonably foreseeable to Defendant.

3614. The Nevada Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in

violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3615. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3616. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3617. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3618. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3619. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3620. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3621. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3622. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Nevada Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3623. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3624. If Defendant had followed its own manufacturing specifications, injury to the Nevada Subclass Members would not have occurred.

3625. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Nevada Subclass Members and others without knowledge of the hazards involved in such use.

3626. As a direct and proximate result of Defendant's acts and omissions, the Nevada Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 177
NEGLIGENCE – MANUFACTURING DEFECT
New Hampshire

3627. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3628. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Subclass.

3629. Under New Hampshire law, Defendant had a duty to the New Hampshire Subclass Members, recognized by the law, requiring Defendant to conform to the standard of conduct of a reasonable manufacturer, seller, and/or distributor.

3630. Defendant failed to conform to this standard of conduct by manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3631. The Defendant's breach directly and proximately caused the injuries suffered by the New Hampshire Subclass Members, which caused actual loss and/or damage.

3632. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3633. The Recalled BIOCELL Implants were expected to and did reach the New Hampshire Subclass Members without a substantial change in condition and were properly implanted in the New Hampshire Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the New Hampshire Subclass Members received were reasonably foreseeable to Defendant.

3634. The New Hampshire Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently

manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3635. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3636. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3637. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3638. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3639. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3640. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3641. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3642. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the New Hampshire Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3643. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3644. If Defendant had followed its own manufacturing specifications, injury to the New Hampshire Subclass Members would not have occurred.

3645. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the New Hampshire Subclass Members and others without knowledge of the hazards involved in such use.

3646. As a direct and proximate result of Defendant's acts and omissions, the New Hampshire Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the

Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 178
NEGLIGENCE – MANUFACTURING DEFECT
New Mexico

3647. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3648. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass.

3649. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3650. Under New Mexico law, Defendant owed a duty of care to the New Mexico Subclass Members.

3651. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the New Mexico Subclass Members.

3652. Defendant's breach was the direct and proximate cause of the injuries suffered by the New Mexico Subclass Members.

3653. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3654. The Recalled BIOCELL Implants were expected to and did reach the New Mexico Subclass Members without a substantial change in condition and were properly implanted in the New Mexico Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the New Mexico Subclass Members received were reasonably foreseeable to Defendant.

3655. The New Mexico Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3656. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3657. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3658. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3659. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3660. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3661. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3662. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3663. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the New Mexico Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3664. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3665. If Defendant had followed its own manufacturing specifications, injury to the New Mexico Subclass Members would not have occurred.

3666. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the New Mexico Subclass Members and others without knowledge of the hazards involved in such use.

3667. As a direct and proximate result of Defendant's acts and omissions, the New Mexico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 179
NEGLIGENCE – MANUFACTURING DEFECT
New York

3668. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3669. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Subclass.

3670. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3671. Under New York law, Defendant owed a duty of care to the New York Subclass Members.

3672. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the New York Subclass Members.

3673. Defendant's breach was the direct and proximate cause of the injuries suffered by the New York Subclass Members.

3674. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3675. The Recalled BIOCELL Implants were expected to and did reach the New York Subclass Members without a substantial change in condition and were properly implanted in the New York Subclass Members without any alteration after they left Defendant's control. In the

alternative, any changes that were made to the Recalled BIOCELL Implants that the New York Subclass Members received were reasonably foreseeable to Defendant.

3676. The New York Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3677. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3678. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3679. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles

on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3680. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3681. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3682. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3683. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3684. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the New York Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3685. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3686. If Defendant had followed its own manufacturing specifications, injury to the New York Subclass Members would not have occurred.

3687. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the New York Subclass Members and others without knowledge of the hazards involved in such use.

3688. As a direct and proximate result of Defendant's acts and omissions, the New Mexico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 180
NEGLIGENCE - MANUFACTURING DEFECT
North Carolina

3689. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3690. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Carolina Subclass.

3691. Under the North Carolina product liability statute (N.C. Gen. Stat. §§ 99B–1(3)), Defendant is liable for negligently manufacturing the Recalled BIOCELL Implants.

3692. The Recalled BIOCELL Implants were manufactured and sold in a defective condition unreasonably dangerous to the North Carolina Subclass Members.

3693. The North Carolina Subclass Members were injured because Defendant manufactured the Recalled BIOCELL Implants in an unreasonable manner.

3694. Defendant did not take reasonable measures against foreseeable risks, and the Recalled BIOCELL Implants were not fit for their foreseeable use.

3695. The Recalled BIOCELL Implants were expected to and did reach the North Carolina Subclass Members without a substantial change in condition and were properly implanted in the North Carolina Subclass Members without any alteration after they left Defendant's control.

In the alternative, any changes that were made to the Recalled BIOCELL Implants that the North Carolina Subclass Members received were reasonably foreseeable to Defendant.

3696. The North Carolina Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3697. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3698. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3699. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles

on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3700. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3701. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3702. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3703. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3704. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3705. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3706. If Defendant had followed its own manufacturing specifications, injury to the North Carolina Subclass Members would not have occurred.

3707. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the North Carolina Subclass Members and others without knowledge of the hazards involved in such use.

3708. As a direct and proximate result of Defendant's acts and omissions, the North Carolina Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 181
NEGLIGENCE – MANUFACTURING DEFECT
North Dakota

3709. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3710. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Subclass.

3711. Under North Dakota law, Defendant had a duty, recognized by the law, requiring Defendant to conform to the standard of reasonable care.

3712. Defendant failed to conform to this standard of care by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3713. The Defendant's breach directly and proximately caused the injuries suffered by the North Dakota Subclass Members, which caused actual loss and/or damage.

3714. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3715. The Recalled BIOCELL Implants were expected to and did reach the North Dakota Subclass Members without a substantial change in condition and were properly implanted in the

North Dakota Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the North Dakota Subclass Members received were reasonably foreseeable to Defendant.

3716. The North Dakota Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3717. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3718. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3719. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles

on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3720. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3721. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3722. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3723. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3724. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the North Dakota Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3725. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3726. If Defendant had followed its own manufacturing specifications, injury to the North Dakota Subclass Members would not have occurred.

3727. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the North Dakota Subclass Members and others without knowledge of the hazards involved in such use.

3728. As a direct and proximate result of Defendant's acts and omissions, the North Dakota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 182
NEGLIGENCE – MANUFACTURING DEFECT
Northern Mariana Islands

3729. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3730. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass.

3731. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3732. Under the common law of Northern Mariana Islands, Defendant failed to exercise the care of a reasonably prudent manufacturer, seller, and/or distributor under the circumstances.

3733. Defendant breached the duty of care owed to the Northern Mariana Islands Subclass Members by manufacturing and selling the Recalled BIOCELL Implants.

3734. Defendant's breach directly and proximately caused injury to the Northern Mariana Islands Subclass.

3735. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Northern Mariana Islands Subclass Members.

3736. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3737. The Recalled BIOCELL Implants were expected to and did reach the Northern Mariana Islands Subclass Members without a substantial change in condition and were properly implanted in the Northern Mariana Islands Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Northern Mariana Islands Subclass Members received were reasonably foreseeable to Defendant.

3738. The Northern Mariana Islands Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3739. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3740. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3741. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process

resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3742. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3743. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3744. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3745. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3746. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Northern Mariana Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3747. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous,

defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3748. If Defendant had followed its own manufacturing specifications, injury to the Northern Mariana Islands Subclass Members would not have occurred.

3749. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Northern Mariana Islands Subclass Members and others without knowledge of the hazards involved in such use.

3750. As a direct and proximate result of Defendant's acts and omissions, the Northern Mariana Islands Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures

COUNT 183
NEGLIGENCE – MANUFACTURING DEFECT
Ohio

3751. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3752. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Subclass.

3753. At all relevant times Defendant was "manufacturers" engaged in a business to formulate, produce, create, make, construct, and/ or assemble a product.

3754. Under Ohio law, Defendant owed a duty of care to the Ohio Subclass Members.

3755. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Ohio Subclass Members.

3756. Defendant's breach was the direct and proximate cause of the injuries suffered by the Ohio Subclass Members.

3757. Further, Defendant manufactured and sold the Recalled BIOCELL Implants in an unreasonably dangerous condition to the Ohio Subclass Members.

3758. The manufacturing defect caused injury to the Ohio Subclass Members, and the manufacturing defect existed at the time of manufacture and sale.

3759. The Recalled BIOCELL Implants were expected to and did reach the Ohio Subclass Members without a substantial change in condition.

3760. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3761. The Recalled BIOCELL Implants were expected to and did reach the Ohio Subclass Members without a substantial change in condition and were properly implanted in the Ohio Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Ohio Subclass Members received were reasonably foreseeable to Defendant.

3762. The Ohio Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3763. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3764. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3765. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3766. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3767. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3768. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3769. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3770. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Ohio Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3771. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3772. If Defendant had followed its own manufacturing specifications, injury to the Ohio Subclass Members would not have occurred.

3773. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Ohio Subclass Members and others without knowledge of the hazards involved in such use.

3774. As a direct and proximate result of Defendant's acts and omissions, the Ohio Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 184
NEGLIGENCE – MANUFACTURING DEFECT
Oklahoma

3775. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3776. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Subclass.

3777. Under Oklahoma law, Defendant owed a duty to the Oklahoma Subclass Members to use ordinary care.

3778. Defendant breached this duty by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3779. Defendant's breach was the direct and proximate cause of the injuries suffered by Plaintiffs and the Oklahoma Subclass Members.

3780. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3781. The Recalled BIOCELL Implants were expected to and did reach the Oklahoma Subclass Members without a substantial change in condition and were properly implanted in the Oklahoma Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Oklahoma Subclass Members received were reasonably foreseeable to Defendant.

3782. The Oklahoma Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3783. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3784. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3785. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3786. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3787. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3788. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3789. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3790. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Oklahoma Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their

bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3791. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3792. If Defendant had followed its own manufacturing specifications, injury to the Oklahoma Subclass Members would not have occurred.

3793. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Oklahoma Subclass Members and others without knowledge of the hazards involved in such use.

3794. As a direct and proximate result of Defendant's acts and omissions, the Oklahoma Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 185
NEGLIGENCE – MANUFACTURING DEFECT
Oregon

3795. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3796. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Subclass.

3797. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3798. Under Oregon law, Defendant owed a duty of care to the Oregon Subclass Members.

3799. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Oregon Subclass Members.

3800. Defendant's breach was the direct and proximate cause of the injuries suffered by the Oregon Subclass Members.

3801. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3802. The Recalled BIOCELL Implants were expected to and did reach the Oregon Subclass Members without a substantial change in condition and were properly implanted in the Oregon Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Oregon Subclass Members received were reasonably foreseeable to Defendant.

3803. The Oregon Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3804. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles

were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3805. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3806. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3807. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3808. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3809. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3810. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3811. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Oregon Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3812. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3813. If Defendant had followed its own manufacturing specifications, injury to the Oregon Subclass Members would not have occurred.

3814. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Oregon Subclass Members and others without knowledge of the hazards involved in such use.

3815. As a direct and proximate result of Defendant's acts and omissions, the Oregon Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 186
NEGLIGENCE – MANUFACTURING DEFECT
Pennsylvania

3816. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3817. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass .

3818. Under Pennsylvania law, Defendant owed a duty to the Pennsylvania Subclass Members to exercise reasonable care.

3819. Defendant breached this duty by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3820. Defendant's breach was the direct and proximate cause of the injuries suffered by the Pennsylvania Subclass Members.

3821. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3822. The Recalled BIOCELL Implants were expected to and did reach the Pennsylvania Subclass Members without a substantial change in condition and were properly implanted in the Pennsylvania Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Pennsylvania Subclass Members received were reasonably foreseeable to Defendant.

3823. The Pennsylvania Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3824. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3825. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3826. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3827. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3828. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3829. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3830. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3831. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Pennsylvania Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their

bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3832. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3833. If Defendant had followed its own manufacturing specifications, injury to the Pennsylvania Subclass Members would not have occurred.

3834. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Pennsylvania Subclass Members and others without knowledge of the hazards involved in such use.

3835. As a direct and proximate result of Defendant's acts and omissions, the Pennsylvania Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 187
NEGLIGENCE – MANUFACTURING DEFECT
Puerto Rico

3836. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3837. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Subclass.

3838. Under Puerto Rico law, Defendant owed a duty of care to the Puerto Rico Subclass Members to prevent harm by conforming to a reasonable standard of conduct.

3839. Defendant breached this duty by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3840. Defendant also failed to exercise due diligence to avoid foreseeable risks.

3841. Defendant's breach was the direct and proximate cause of the injuries suffered by Plaintiffs and the Puerto Rico Subclass Members.

3842. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3843. The Recalled BIOCELL Implants were expected to and did reach the Puerto Rico Subclass Members without a substantial change in condition and were properly implanted in the Puerto Rico Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Puerto Rico Subclass Members received were reasonably foreseeable to Defendant.

3844. The Puerto Rico Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3845. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3846. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3847. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3848. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3849. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3850. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3851. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3852. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Puerto Rico Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their

bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3853. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3854. If Defendant had followed its own manufacturing specifications, injury to the Puerto Rico Subclass Members would not have occurred.

3855. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Puerto Rico Subclass Members and others without knowledge of the hazards involved in such use.

3856. As a direct and proximate result of Defendant's acts and omissions, the Puerto Rico Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 188
NEGLIGENCE – MANUFACTURING DEFECT
Rhode Island

3857. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3858. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass.

3859. Under Rhode Island law, Defendant owed a duty of care to the Rhode Island Subclass Members.

3860. Defendant breached this duty by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3861. Defendant's breach was the direct and proximate cause of the injuries suffered by the Rhode Island Subclass Members.

3862. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3863. The Recalled BIOCELL Implants were expected to and did reach the Rhode Island Subclass Members without a substantial change in condition and were properly implanted in the Rhode Island Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Rhode Island Subclass Members received were reasonably foreseeable to Defendant.

3864. The Rhode Island Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3865. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3866. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3867. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3868. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3869. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3870. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3871. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3872. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Rhode Island Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related

symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3873. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3874. If Defendant had followed its own manufacturing specifications, injury to the Rhode Island Subclass Members would not have occurred.

3875. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Rhode Island Subclass Members and others without knowledge of the hazards involved in such use.

3876. As a direct and proximate result of Defendant's acts and omissions, the Rhode Island Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 189
NEGLIGENCE – MANUFACTURING DEFECT
South Carolina

3877. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3878. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass.

3879. Under South Carolina law, Defendant owed a duty to the South Carolina Subclass Members to exercise due care.

3880. Defendant breached this duty by negligently manufacturing and selling the Recalled BIOCELL Implants, which contained a defect and/or unreasonably dangerous condition.

3881. Defendant's breach was the direct and proximate cause of the injuries suffered by the South Carolina Subclass Members.

3882. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3883. The Recalled BIOCELL Implants were expected to and did reach the South Carolina Subclass Members without a substantial change in condition and were properly implanted in the South Carolina Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the South Carolina Subclass Members received were reasonably foreseeable to Defendant.

3884. The South Carolina Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3885. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3886. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3887. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated

methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3888. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3889. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3890. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3891. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3892. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the South Carolina Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related

symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3893. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3894. If Defendant had followed its own manufacturing specifications, injury to the South Carolina Subclass Members would not have occurred.

3895. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the South Carolina Subclass Members and others without knowledge of the hazards involved in such use.

3896. As a direct and proximate result of Defendant's acts and omissions, the South Carolina Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 190
NEGLIGENCE – MANUFACTURING DEFECT
South Dakota

3897. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3898. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Subclass.

3899. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3900. The law of South Dakota imposes upon Defendant a legal obligation of reasonable conduct for the benefit of the South Dakota Subclass Members.

3901. Defendant breached this obligation and/or duty by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the South Dakota Subclass Members.

3902. Defendant's breach was the direct and proximate cause of the injuries suffered by the South Dakota Subclass Members.

3903. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3904. The Recalled BIOCELL Implants were expected to and did reach the South Dakota Subclass Members without a substantial change in condition and were properly implanted in the South Dakota Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the South Dakota Subclass Members received were reasonably foreseeable to Defendant.

3905. The South Dakota Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3906. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3907. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3908. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3909. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3910. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3911. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and

unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3912. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3913. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the South Dakota Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their

bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3914. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3915. If Defendant had followed its own manufacturing specifications, injury to the South Dakota Subclass Members would not have occurred.

3916. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the South Dakota Subclass Members and others without knowledge of the hazards involved in such use.

3917. As a direct and proximate result of Defendant's acts and omissions, the South Dakota Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 191
NEGLIGENCE – MANUFACTURING DEFECT
Tennessee

3918. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3919. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass.

3920. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3921. Under Tennessee law, Defendant are liable in this product liability action because the Recalled BIOCELL Implants were in a defective condition and/or unreasonably dangerous at the time it left Defendant's control.

3922. The defective condition of the Recalled BIOCELL Implants rendered the product unsafe for normal or anticipatable handling and consumption.

3923. The unreasonably dangerous condition of the Recalled BIOCELL Implants made the product dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.

3924. Defendant knew of the Recalled BIOCELL Implants' dangerous condition and nonetheless put it on the market, failing to act as a reasonably prudent manufacturer or seller.

3925. The defect contained in the Recalled BIOCELL Implants was the direct and proximate cause of the injuries suffered by the Tennessee Subclass Members.

3926. Further, Defendant had a duty of care to the Tennessee Subclass Members.

3927. Defendant breached that duty of care as a result of the manufacturing and selling of the Recalled BIOCELL Implants.

3928. Defendant's breach was a direct and proximate cause of the injuries suffered by the Tennessee Subclass Members.

3929. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3930. The Recalled BIOCELL Implants were expected to and did reach the Tennessee Subclass Members without a substantial change in condition and were properly implanted in the

Tennessee Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Tennessee Subclass Members received were reasonably foreseeable to Defendant.

3931. The Tennessee Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3932. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3933. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3934. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles

on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3935. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3936. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3937. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3938. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3939. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Tennessee Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3940. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3941. If Defendant had followed its own manufacturing specifications, injury to the Tennessee Subclass Members would not have occurred.

3942. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Tennessee Subclass Members and others without knowledge of the hazards involved in such use.

3943. As a direct and proximate result of Defendant's acts and omissions, the Tennessee Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 192
NEGLIGENCE – MANUFACTURING DEFECT
Texas

3944. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3945. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass.

3946. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3947. Under Texas law, Defendant owed a duty of care to the Texas Subclass Members.

3948. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Texas Subclass Members.

3949. Defendant's breach was the factual and proximate cause of the injuries suffered by the Texas Subclass Members.

3950. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3951. The Recalled BIOCELL Implants were expected to and did reach the Texas Subclass Members without a substantial change in condition and were properly implanted in the Texas Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Texas Subclass Members received were reasonably foreseeable to Defendant.

3952. The Texas Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3953. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3954. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3955. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3956. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3957. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3958. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3959. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3960. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Texas Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3961. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3962. If Defendant had followed its own manufacturing specifications, injury to the Texas Subclass Members would not have occurred.

3963. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Texas Subclass Members and others without knowledge of the hazards involved in such use.

3964. As a direct and proximate result of Defendant's acts and omissions, the Texas Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 193
NEGLIGENCE – MANUFACTURING DEFECT
U.S. Virgin Islands

3965. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3966. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

3967. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3968. Under the common law of U.S. Virgin Islands, Defendant failed to exercise the care of a reasonably prudent manufacturer, seller, and/or distributor under the circumstances.

3969. Defendant breached the duty of care owed to the U.S. Virgin Islands Subclass Members by manufacturing and selling the Recalled BIOCELL Implants.

3970. Defendant did not take reasonable measures in the manufacturing and sale of the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the U.S. Virgin Islands Subclass Members.

3971. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3972. The Recalled BIOCELL Implants were expected to and did reach the U.S. Virgin Islands Subclass Members without a substantial change in condition and were properly implanted in the U.S. Virgin Islands Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the U.S. Virgin Islands Subclass Members received were reasonably foreseeable to Defendant.

3973. The U.S. Virgin Islands Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3974. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3975. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3976. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3977. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3978. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

3979. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

3980. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

g. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

h. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

i. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

j. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

k. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

l. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

3981. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the U.S. Virgin Islands Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

3982. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

3983. If Defendant had followed its own manufacturing specifications, injury to the U.S. Virgin Islands Subclass Members would not have occurred.

3984. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the U.S. Virgin Islands Subclass Members and others without knowledge of the hazards involved in such use.

3985. As a direct and proximate result of Defendant's acts and omissions, the U.S. Virgin Islands Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 194
NEGLIGENCE – MANUFACTURING DEFECT
Utah

3986. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

3987. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass.

3988. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

3989. Under Utah law, Defendant owed a duty of care to the Utah Subclass Members.

3990. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Utah Subclass Members.

3991. Defendant's breach was the factual and proximate cause of the injuries suffered by the Utah Subclass Members.

3992. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

3993. The Recalled BIOCELL Implants were expected to and did reach the Utah Subclass Members without a substantial change in condition and were properly implanted in the Utah Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Utah Subclass Members received were reasonably foreseeable to Defendant.

3994. The Utah Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

3995. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

3996. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

3997. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

3998. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

3999. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

4000. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

4001. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

4002. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Utah Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

4003. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

4004. If Defendant had followed its own manufacturing specifications, injury to the Utah Subclass Members would not have occurred.

4005. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Utah Subclass Members and others without knowledge of the hazards involved in such use.

4006. As a direct and proximate result of Defendant's acts and omissions, the Utah Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 195
NEGLIGENCE – MANUFACTURING DEFECT
Vermont

4007. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4008. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Subclass.

4009. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

4010. Under Vermont law, Defendant owed a duty of reasonable care to the Vermont Subclass Members.

4011. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Vermont Subclass Members.

4012. Defendant's breach was the factual and proximate cause of the injuries suffered by the Vermont Subclass Members.

4013. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

4014. The Recalled BIOCELL Implants were expected to and did reach the Vermont Subclass Members without a substantial change in condition and were properly implanted in the Vermont Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Vermont Subclass Members received were reasonably foreseeable to Defendant.

4015. The Vermont Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

4016. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

4017. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

4018. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

4019. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

4020. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

4021. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

4022. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

4023. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Vermont Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

4024. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

4025. If Defendant had followed its own manufacturing specifications, injury to the Vermont Subclass Members would not have occurred.

4026. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Vermont Subclass Members and others without knowledge of the hazards involved in such use.

4027. As a direct and proximate result of Defendant's acts and omissions, the Vermont Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 196
NEGLIGENCE - MANUFACTURING DEFECT
Virginia

4028. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4029. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virginia Subclass.

4030. Under the common law of Virginia, Defendant had a duty to the Virginia Subclass Members to exercise the care of a reasonably prudent manufacturer.

4031. Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants.

4032. Defendant did not take reasonable measures in manufacturing the Recalled BIOCELL Implants that had a defective condition unreasonably dangerous to the Virginia Subclass Members, breaching its duty to the Virginia Subclass Members.

4033. Further, Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for the product's foreseeable.

4034. The Recalled BIOCELL Implants were expected to and did reach the Virginia Subclass Members without a substantial change in condition and were properly implanted in the

Virginia Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Virginia Subclass Members received were reasonably foreseeable to Defendant.

4035. The Virginia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

4036. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

4037. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

4038. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles

on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

4039. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

4040. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

4041. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

4042. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

4043. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

4044. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

4045. If Defendant had followed its own manufacturing specifications, injury to the Virginia Subclass Members would not have occurred.

4046. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Virginia Subclass Members and others without knowledge of the hazards involved in such use.

4047. As a direct and proximate result of Defendant's acts and omissions, the Virginia Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 197
NEGLIGENCE – MANUFACTURING DEFECT
West Virginia

4048. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4049. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

4050. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

4051. Defendant owed a duty of care to the West Virginia Subclass Members.

4052. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the West Virginia Subclass Members.

4053. Defendant's breach was the direct and proximate cause of the injuries suffered by the West Virginia Subclass Members.

4054. Defendant's conduct was not reasonable in view of the foreseeable risk of injury, and Defendant did not take reasonable measures against foreseeable risks, and when the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

4055. The Recalled BIOCELL Implants were expected to and did reach the West Virginia Subclass Members without a substantial change in condition and were properly implanted in the West Virginia Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the West Virginia Subclass Members received were reasonably foreseeable to Defendant.

4056. The West Virginia Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

4057. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

4058. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

4059. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good

Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

4060. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

4061. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

4062. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

4063. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

4064. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the West Virginia Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

4065. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

4066. If Defendant had followed its own manufacturing specifications, injury to the West Virginia Subclass Members would not have occurred.

4067. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the West Virginia Subclass Members and others without knowledge of the hazards involved in such use.

4068. As a direct and proximate result of Defendant's acts and omissions, the West Virginia Subclass Members have a significantly increased risk of BIA-ALCL and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 198
NEGLIGENCE – MANUFACTURING DEFECT
Wisconsin

4069. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4070. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Subclass.

4071. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

4072. Under Wisconsin law, Defendant owed a duty of care to the Wisconsin Subclass Members.

4073. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Wisconsin Subclass Members.

4074. Defendant's breach was the direct and proximate cause of the injuries suffered by the Wisconsin Subclass Members.

4075. Defendant's conduct was not reasonable in view of the foreseeable risk of injury, and Defendant did not take reasonable measures against foreseeable risks.

4076. When the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

4077. The Recalled BIOCELL Implants were expected to and did reach the Wisconsin Subclass Members without a substantial change in condition and were properly implanted in the Wisconsin Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Wisconsin Subclass Members received were reasonably foreseeable to Defendant.

4078. The Wisconsin Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

4079. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

4080. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

4081. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective

manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

4082. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

4083. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

4084. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

4085. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

4086. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Wisconsin Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

4087. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

4088. If Defendant had followed its own manufacturing specifications, injury to the Wisconsin Subclass Members would not have occurred.

4089. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Wisconsin Subclass Members and others without knowledge of the hazards involved in such use.

4090. As a direct and proximate result of Defendant's acts and omissions, the Wisconsin Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 199
NEGLIGENCE – MANUFACTURING DEFECT
Wyoming

4091. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4092. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass.

4093. At all relevant times Defendant was engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

4094. Under Wyoming law, Defendant owed a duty of care to the Wyoming Subclass Members.

4095. Defendant breached that duty of care by manufacturing and selling the Recalled BIOCELL Implants, which contained a defective condition unreasonably dangerous to the Wyoming Subclass Members.

4096. Defendant's breach was the direct and proximate cause of the injuries suffered by the Wyoming Subclass Members.

4097. Further, Defendant engaged in conduct that was not reasonable in view of the foreseeable risk of injury, and Defendant did not take reasonable measures against foreseeable risks.

4098. When the Recalled BIOCELL Implants left Defendant's control, they were unreasonably dangerous and not fit for their foreseeable use.

4099. The Recalled BIOCELL Implants were expected to and did reach the Wyoming Subclass Members without a substantial change in condition and were properly implanted in the Wyoming Subclass Members without any alteration after they left Defendant's control. In the alternative, any changes that were made to the Recalled BIOCELL Implants that the Wyoming Subclass Members received were reasonably foreseeable to Defendant.

4100. The Wyoming Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been negligently manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

4101. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

4102. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

4103. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated

methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

4104. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations and is brought as a parallel state law claim pursuant to the state laws set forth herein.

4105. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because its negligent, unsafe, highly variable process produced non-conforming, dangerous implants.

4106. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

4107. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

4108. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the Wyoming Subclass Members would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related

symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

4109. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

4110. If Defendant had followed its own manufacturing specifications, injury to the Wyoming Subclass Members would not have occurred.

4111. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Wyoming Subclass Members and others without knowledge of the hazards involved in such use.

4112. As a direct and proximate result of Defendant's acts and omissions, the Wyoming Subclass Members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

E. STRICT LIABILITY – DESIGN DEFECT

COUNT 200
Strict Product Liability—Design Defect
Alabama

4113. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4114. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Non-PMA Device Subclass.

4115. Defendant is strictly liable under the Alabama Extended Manufacturer's Liability Doctrine (Al. Civ. Pr. § 6-5-501 *et seq.*) for designing and manufacturing the Non-PMA BIOCELL Implants in an unreasonably dangerous and defective condition.

4116. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Alabama Non-PMA Device Subclass. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Alabama Non-PMA Device Subclass.

4117. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4118. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4119. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4120. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4121. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo the salt loss texturing process that the Non-PMA BIOCELL Implants undergo. Even among the

textured implants sold in the U.S., Defendant's BIOCELL line associated with the vast majority of ALCL cases.

4122. The risk benefit profile of Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market. The utility of the alternative design outweighed the utility of the design used.

4123. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4124. The use of the Non-PMA BIOCELL Implants in the Alabama Non-PMA Device Subclass was foreseeable to the Defendant.

4125. As a direct and proximate result of Defendant's actions and omissions, the Alabama Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4126. Allergan acted with willful and wanton disregard for the rights and health of the Alabama Non-PMA Device Subclass Members and other patients.

COUNT 201
Strict Product Liability—Design Defect
Alaska

4127. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4128. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Non-PMA Device Subclass.

4129. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Alaska Non-

PMA Device Subclass. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Alaska Non-PMA Device Subclass.

4130. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4131. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4132. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4133. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4134. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo the salt loss texturing process that the Non-PMA BIOCELL Implants undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line associated with the vast majority of ALCL cases.

4135. The risk benefit profile of Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4136. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4137. The use of the Non-PMA BIOCELL Implants in the Alaska Non-PMA Device Subclass was foreseeable to the Defendant.

4138. As a direct and proximate result of Defendant's actions and omissions, the Alaska Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4139. Allergan acted with willful and wanton disregard for the rights and health of the Alaska Non-PMA Device Subclass Members and other patients.

COUNT 202
Strict Product Liability—Design Defect
American Samoa

4140. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4141. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Non-PMA Device Subclass.

4142. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the American Samoa Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the American Samoa Non-PMA Device Subclass.

4143. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4144. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4145. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4146. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4147. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4148. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4149. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4150. The use of the Non-PMA BIOCELL Implants in the American Samoa Non-PMA Device Subclass Members was foreseeable to the Defendant.

4151. As a direct and proximate result of Defendant's actions and omissions, the American Samoa Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4152. Allergan acted with willful and wanton disregard for the rights and health of the American Samoa Non-PMA Device Subclass and other patients.

COUNT 203
Strict Product Liability—Design Defect
Arkansas

4153. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4154. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Non-PMA Device Subclass.

4155. Under the Arkansas Product Liability Act, Ark. Code Ann. § 16–116–202(5), Defendant is strict liability for personal injury, death, or property damage caused to the Arkansas Non-PMA Device Subclass Members, and caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of the Non-PMA BIOCELL Implants.

4156. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Arkansas

Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Arkansas Non-PMA Device Subclass.

4157. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4158. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4159. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4160. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4161. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4162. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4163. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4164. The use of the Non-PMA BIOCELL Implants in the Arkansas Non-PMA Device Subclass Members was foreseeable to the Defendant.

4165. As a direct and proximate result of Defendant's actions and omissions, the Arkansas Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4166. Allergan acted with willful and wanton disregard for the rights and health of the Arkansas Non-PMA Device Subclass and other patients.

COUNT 204
Strict Product Liability—Design Defect
California

4167. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4168. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Non-PMA Device Subclass.

4169. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the California Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the California Non-PMA Device Subclass.

4170. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4171. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4172. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4173. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4174. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4175. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4176. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4177. The use of the Non-PMA BIOCELL Implants in the California Non-PMA Device Subclass Members was foreseeable to the Defendant.

4178. As a direct and proximate result of Defendant's actions and omissions, the California Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4179. Allergan acted with willful and wanton disregard for the rights and health of the California Non-PMA Device Subclass and other patients.

COUNT 205
Strict Product Liability—Design Defect
Colorado

4180. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4181. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Non-PMA Device Subclass.

4182. Defendant is strictly liable under the Colorado Product Liability Act, Colo. Rev. Stat. §§ 13–21–401 *et seq.*, as "manufacturers" engaged in the business of manufacturing, selling, distributing, marketing and promoting the Non-PMA BIOCELL Implants.

4183. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Colorado Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Colorado Non-PMA Device Subclass.

4184. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4185. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4186. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4187. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4188. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4189. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4190. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4191. The use of the Non-PMA BIOCELL Implants in the Colorado Non-PMA Device Subclass Members was foreseeable to the Defendant.

4192. As a direct and proximate result of Defendant's actions and omissions, the Colorado Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4193. Allergan acted with willful and wanton disregard for the rights and health of the Colorado Non-PMA Device Subclass Members and other patients.

COUNT 206
Strict Product Liability—Design Defect
District of Columbia

4194. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4195. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the District of Columbia Non-PMA Device Subclass.

4196. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the District of Columbia Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the District of Columbia Non-PMA Device Subclass Members.

4197. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue

damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4198. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4199. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4200. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4201. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4202. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4203. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4204. The use of the Non-PMA BIOCELL Implants in the District of Columbia Non-PMA Device Subclass Members was foreseeable to the Defendant.

4205. As a direct and proximate result of Defendant's actions and omissions, the District of Columbia Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4206. Allergan acted with willful and wanton disregard for the rights and health of the District of Columbia Non-PMA Device Subclass Members and other patients.

COUNT 207
Strict Product Liability—Design Defect
Florida

4207. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4208. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Non-PMA Device Subclass.

4209. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Florida Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Florida Non-PMA Device Subclass Members.

4210. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4211. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4212. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4213. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4214. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4215. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4216. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4217. The use of the Non-PMA BIOCELL Implants in the Florida Non-PMA Device Subclass Members was foreseeable to the Defendant.

4218. As a direct and proximate result of Defendant's actions and omissions, the Florida Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4219. Allergan acted with willful and wanton disregard for the rights and health of the Florida Non-PMA Device Subclass Members and other patients.

COUNT 208
Strict Product Liability—Design Defect
Georgia

4220. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4221. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Non-PMA Device Subclass.

4222. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Georgia Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Georgia Non-PMA Device Subclass Members.

4223. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4224. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4225. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4226. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4227. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4228. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4229. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4230. The use of the Non-PMA BIOCELL Implants in the Georgia Non-PMA Device Subclass Members was foreseeable to the Defendant.

4231. As a direct and proximate result of Defendant's actions and omissions, the Georgia Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including

surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4232. Allergan acted with willful and wanton disregard for the rights and health of the Georgia Non-PMA Device Subclass Members and other patients.

COUNT 209
Strict Product Liability—Design Defect
Guam

4233. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4234. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Non-PMA Device Subclass.

4235. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Guam Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Guam Non-PMA Device Subclass Members.

4236. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4237. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4238. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed

primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4239. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4240. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4241. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4242. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4243. The use of the Non-PMA BIOCELL Implants in the Guam Non-PMA Device Subclass Members was foreseeable to the Defendant.

4244. As a direct and proximate result of Defendant's actions and omissions, the Guam Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4245. Allergan acted with willful and wanton disregard for the rights and health of the Guam Non-PMA Device Subclass Members and other patients.

COUNT 210
Strict Product Liability—Design Defect
Hawaii

4246. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4247. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Non-PMA Device Subclass.

4248. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Hawaii Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Hawaii Non-PMA Device Subclass Members.

4249. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4250. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4251. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found

in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4252. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4253. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4254. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4255. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4256. The use of the Non-PMA BIOCELL Implants in the Hawaii Non-PMA Device Subclass Members was foreseeable to the Defendant.

4257. As a direct and proximate result of Defendant's actions and omissions, the Hawaii Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4258. Allergan acted with willful and wanton disregard for the rights and health of the Hawaii Non-PMA Device Subclass Members and other patients.

COUNT 211
Strict Product Liability—Design Defect
Idaho

4259. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4260. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Non-PMA Device Subclass.

4261. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Idaho Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including Idaho Non-PMA Device Subclass Members.

4262. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4263. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4264. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4265. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4266. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4267. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4268. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4269. The use of the Non-PMA BIOCELL Implants in Idaho Non-PMA Device Subclass Members was foreseeable to the Defendant.

4270. As a direct and proximate result of Defendant's actions and omissions, Idaho Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4271. Allergan acted with willful and wanton disregard for the rights and health of the Idaho Non-PMA Device Subclass Members and other patients.

COUNT 212
Strict Product Liability—Design Defect
Illinois

4272. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4273. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Non-PMA Device Subclass.

4274. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Illinois Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Illinois Non-PMA Device Subclass Members.

4275. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4276. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4277. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4278. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4279. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4280. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4281. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4282. The use of the Non-PMA BIOCELL Implants in the Illinois Non-PMA Device Subclass Members was foreseeable to the Defendant.

4283. As a direct and proximate result of Defendant's actions and omissions, the Illinois Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4284. Allergan acted with willful and wanton disregard for the rights and health of the Illinois Non-PMA Device Subclass Members and other patients.

COUNT 213
Strict Product Liability—Design Defect
Indiana

4285. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4286. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Non-PMA Device Subclass.

4287. The Indiana Product Liability Act (Ind. Code Ann. § 34–20–1–1) governs all actions brought by a user or consumer against a manufacturer for physical harm caused by a product.

4288. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Indiana Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Indiana Non-PMA Device Subclass Members.

4289. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4290. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4291. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4292. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4293. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4294. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4295. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4296. The use of the Non-PMA BIOCELL Implants in the Indiana Non-PMA Device Subclass Members was foreseeable to the Defendant.

4297. As a direct and proximate result of Defendant's actions and omissions, the Indiana Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4298. Allergan acted with willful and wanton disregard for the rights and health of the Indiana Non-PMA Device Subclass Members and other patients.

COUNT 214
Strict Product Liability—Design Defect
Iowa

4299. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4300. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Non-PMA Device Subclass.

4301. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Iowa Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Iowa Non-PMA Device Subclass Members.

4302. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4303. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4304. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4305. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4306. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo

a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4307. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4308. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4309. The use of the Non-PMA BIOCELL Implants in the Iowa Non-PMA Device Subclass Members was foreseeable to the Defendant.

4310. As a direct and proximate result of Defendant's actions and omissions, the Iowa Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4311. Allergan acted with willful and wanton disregard for the rights and health of the Iowa Non-PMA Device Subclass Members and other patients.

COUNT 215
Strict Product Liability—Design Defect
Kansas

4312. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4313. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Non-PMA Device Subclass.

4314. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Kansas Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL

Implants to be implanted into members of the public, including the Kansas Non-PMA Device Subclass Members.

4315. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4316. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4317. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4318. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4319. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4320. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4321. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4322. The use of the Non-PMA BIOCELL Implants in the Kansas Non-PMA Device Subclass Members was foreseeable to the Defendant.

4323. As a direct and proximate result of Defendant's actions and omissions, the Kansas Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4324. Allergan acted with willful and wanton disregard for the rights and health of the Kansas Non-PMA Device Subclass Members and other patients.

COUNT 216
Strict Product Liability—Design Defect
Kentucky

4325. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4326. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Non-PMA Device Subclass.

4327. The Kentucky Product Liability Act (K.R.S. § 411.300), governs all product liability actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture of any product.

4328. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Kentucky Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL

Implants to be implanted into members of the public, including the Kentucky Non-PMA Device Subclass Members.

4329. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4330. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4331. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4332. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4333. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4334. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4335. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4336. The use of the Non-PMA BIOCELL Implants in the Kentucky Non-PMA Device Subclass Members was foreseeable to the Defendant.

4337. As a direct and proximate result of Defendant's actions and omissions, the Kentucky Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4338. Allergan acted with willful and wanton disregard for the rights and health of the Kentucky Non-PMA Device Subclass Members and other patients.

COUNT 217
Strict Product Liability—Design Defect
Maine

4339. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4340. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Non-PMA Device Subclass.

4341. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Maine Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Maine Non-PMA Device Subclass Members.

4342. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4343. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4344. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4345. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4346. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4347. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4348. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4349. The use of the Non-PMA BIOCELL Implants in the Maine Non-PMA Device Subclass Members was foreseeable to the Defendant.

4350. As a direct and proximate result of Defendant's actions and omissions, the Maine Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4351. Allergan acted with willful and wanton disregard for the rights and health of the Maine Non-PMA Device Subclass Members and other patients.

COUNT 218
Strict Product Liability—Design Defect
Maryland

4352. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4353. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Non-PMA Device Subclass.

4354. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Maryland Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Maryland Non-PMA Device Subclass Members.

4355. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue

damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4356. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4357. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4358. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4359. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4360. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4361. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4362. The use of the Non-PMA BIOCELL Implants in the Maryland Non-PMA Device Subclass Members was foreseeable to the Defendant.

4363. As a direct and proximate result of Defendant's actions and omissions, the Maryland Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4364. Allergan acted with willful and wanton disregard for the rights and health of the Maryland Non-PMA Device Subclass Members and other patients.

COUNT 219
Strict Product Liability—Design Defect
Massachusetts

4365. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4366. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Non-PMA Device Subclass.

4367. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Massachusetts Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Massachusetts Non-PMA Device Subclass Members.

4368. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4369. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4370. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4371. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4372. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4373. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4374. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4375. The use of the Non-PMA BIOCELL Implants in the Massachusetts Non-PMA Device Subclass Members was foreseeable to the Defendant.

4376. As a direct and proximate result of Defendant's actions and omissions, the Massachusetts Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4377. Allergan acted with willful and wanton disregard for the rights and health of the Massachusetts Non-PMA Device Subclass Members and other patients.

COUNT 210
Strict Product Liability—Design Defect
Minnesota

4378. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4379. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Non-PMA Device Subclass.

4380. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Minnesota Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including Minnesota Non-PMA Device Subclass Members.

4381. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4382. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4383. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4384. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4385. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4386. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4387. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4388. The use of the Non-PMA BIOCELL Implants in the Minnesota Non-PMA Device Subclass Members was foreseeable to the Defendant.

4389. As a direct and proximate result of Defendant's actions and omissions, Minnesota Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4390. Allergan acted with willful and wanton disregard for the rights and health of the Minnesota Non-PMA Device Subclass Members and other patients.

COUNT 211
Strict Product Liability—Design Defect
Mississippi

4391. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4392. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Non-PMA Device Subclass.

4393. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Mississippi Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Mississippi Non-PMA Device Subclass Members.

4394. Under Mississippi's product liability statute (Miss. Code Ann. § 11–1–63), Defendant is strictly liable for designing and selling the Recalled BIOCELL Implants that caused harm to the Mississippi Subclass Members.

4395. Defendant designed, manufactured, and sold the Recalled BIOCELL Implants containing a design defect that was unreasonably dangerous to Plaintiffs and the Mississippi Subclass Members.

4396. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4397. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4398. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4399. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4400. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4401. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4402. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4403. The use of the Non-PMA BIOCELL Implants in the Mississippi Non-PMA Device Subclass Members was foreseeable to the Defendant.

4404. As a direct and proximate result of Defendant's actions and omissions, the Missouri Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4405. Allergan acted with willful and wanton disregard for the rights and health of the Mississippi Non-PMA Device Subclass Members and other patients.

COUNT 212
Strict Product Liability—Design Defect
Missouri

4406. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4407. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Non-PMA Device Subclass.

4408. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Missouri Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Missouri Non-PMA Device Subclass Members.

4409. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue

damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4410. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4411. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4412. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4413. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4414. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4415. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4416. The use of the Non-PMA BIOCELL Implants in the Missouri Non-PMA Device Subclass Members was foreseeable to the Defendant.

4417. As a direct and proximate result of Defendant's actions and omissions, the Missouri Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4418. Allergan acted with willful and wanton disregard for the rights and health of the Missouri Non-PMA Device Subclass Members and other patients.

COUNT 213
Strict Product Liability—Design Defect
Montana

4419. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4420. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Non-PMA Device Subclass.

4421. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Montana Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Montana Non-PMA Device Subclass Members.

4422. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4423. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4424. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4425. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4426. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4427. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4428. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4429. The use of the Non-PMA BIOCELL Implants in the Montana Non-PMA Device Subclass Members was foreseeable to the Defendant.

4430. As a direct and proximate result of Defendant's actions and omissions, the Montana Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4431. Allergan acted with willful and wanton disregard for the rights and health of the and other patients.

COUNT 214
Strict Product Liability—Design Defect
Nebraska

4432. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4433. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Non-PMA Device Subclass.

4434. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Nebraska Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Nebraska Non-PMA Device Subclass Members.

4435. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4436. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4437. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4438. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4439. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4440. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4441. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4442. The use of the Non-PMA BIOCELL Implants in the Nebraska Non-PMA Device Subclass Members was foreseeable to the Defendant.

4443. As a direct and proximate result of Defendant's actions and omissions, the Nebraska Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses

including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4444. Allergan acted with willful and wanton disregard for the rights and health of the Nebraska Non-PMA Device Subclass Members and other patients.

COUNT 215
Strict Product Liability—Design Defect
Nevada

4445. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4446. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Non-PMA Device Subclass.

4447. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Nevada Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Nevada Non-PMA Device Subclass Members.

4448. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4449. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4450. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed

primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4451. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4452. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4453. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4454. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4455. The use of the Non-PMA BIOCELL Implants in the Nevada Non-PMA Device Subclass Members was foreseeable to the Defendant.

4456. As a direct and proximate result of Defendant's actions and omissions, the Nevada Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4457. Allergan acted with willful and wanton disregard for the rights and health of the Nevada Non-PMA Device Subclass Members and other patients.

COUNT 216
Strict Product Liability—Design Defect
New Hampshire

4458. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4459. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Non-PMA Device Subclass.

4460. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the New Hampshire Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the New Hampshire Non-PMA Device Subclass Members.

4461. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4462. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4463. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4464. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4465. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4466. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4467. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4468. The use of the Non-PMA BIOCELL Implants in the New Hampshire Non-PMA Device Subclass Members was foreseeable to the Defendant.

4469. As a direct and proximate result of Defendant's actions and omissions, the New Hampshire Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4470. Allergan acted with willful and wanton disregard for the rights and health of the New Hampshire Non-PMA Device Subclass Members and other patients.

COUNT 217
Strict Product Liability—Design Defect
New Mexico

4471. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4472. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Non-PMA Device Subclass.

4473. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the New Mexico Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the New Mexico Non-PMA Device Subclass Members.

4474. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4475. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4476. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4477. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4478. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4479. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4480. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4481. The use of the Non-PMA BIOCELL Implants in the New Mexico Non-PMA Device Subclass Members was foreseeable to the Defendant.

4482. As a direct and proximate result of Defendant's actions and omissions, the New Mexico Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4483. Allergan acted with willful and wanton disregard for the rights and health of the New Mexico Non-PMA Device Subclass Members and other patients.

COUNT 218
Strict Product Liability—Design Defect
New York

4484. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4485. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Non-PMA Device Subclass.

4486. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the New York Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the New York Non-PMA Device Subclass Members.

4487. T The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4488. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4489. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4490. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4491. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo

a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4492. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4493. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4494. The use of the Non-PMA BIOCELL Implants in the New York Non-PMA Device Subclass Members was foreseeable to the Defendant.

4495. As a direct and proximate result of Defendant's actions and omissions, the New York Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4496. Allergan acted with willful and wanton disregard for the rights and health of the New York Non-PMA Device Subclass Members and other patients.

COUNT 219
Strict Product Liability—Design Defect
North Dakota

4497. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4498. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Non-PMA Device Subclass.

4499. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the North Dakota Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL

Implants to be implanted into members of the public, including the North Dakota Non-PMA Device Subclass Members.

4500. T The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4501. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4502. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4503. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4504. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4505. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4506. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4507. The use of the Non-PMA BIOCELL Implants in the North Dakota Non-PMA Device Subclass Members was foreseeable to the Defendant.

4508. As a direct and proximate result of Defendant's actions and omissions, the North Dakota Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4509. Allergan acted with willful and wanton disregard for the rights and health of the North Dakota Non-PMA Device Subclass Members and other patients.

COUNT 220
Strict Product Liability—Design Defect
Northern Mariana Islands

4510. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4511. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Non-PMA Device Subclass.

4512. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Northern Mariana Islands Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Northern Mariana Islands Non-PMA Device Subclass Members.

4513. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4514. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4515. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4516. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4517. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4518. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4519. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4520. The use of the Non-PMA BIOCELL Implants in the Northern Mariana Islands Non-PMA Device Subclass Members was foreseeable to the Defendant.

4521. As a direct and proximate result of Defendant's actions and omissions, the Northern Mariana Islands Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4522. Allergan acted with willful and wanton disregard for the rights and health of the Northern Mariana Islands Non-PMA Device Subclass Members and other patients.

COUNT 221
Strict Product Liability—Design Defect
Ohio

4523. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4524. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Non-PMA Device Subclass.

4525. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Ohio Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Ohio Non-PMA Device Subclass Members.

4526. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue

damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4527. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4528. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4529. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4530. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4531. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4532. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4533. The use of the Non-PMA BIOCELL Implants in the Ohio Non-PMA Device Subclass Members was foreseeable to the Defendant.

4534. As a direct and proximate result of Defendant's actions and omissions, the Ohio Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4535. Allergan acted with willful and wanton disregard for the rights and health of the Ohio Non-PMA Device Subclass Members and other patients.

COUNT 222
Strict Product Liability—Design Defect
Oklahoma

4536. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4537. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Non-PMA Device Subclass.

4538. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Oklahoma Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Oklahoma Non-PMA Device Subclass Members.

4539. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4540. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4541. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4542. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4543. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4544. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4545. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4546. The use of the Non-PMA BIOCELL Implants in the Oklahoma Non-PMA Device Subclass Members was foreseeable to the Defendant.

4547. As a direct and proximate result of Defendant's actions and omissions, the Oklahoma Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4548. Allergan acted with willful and wanton disregard for the rights and health of the Oklahoma Non-PMA Device Subclass Members and other patients.

COUNT 223
Strict Product Liability—Design Defect
Oregon

4549. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4550. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Non-PMA Device Subclass.

4551. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Oregon Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Oregon Non-PMA Device Subclass Members.

4552. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4553. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4554. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4555. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4556. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4557. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4558. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4559. The use of the Non-PMA BIOCELL Implants in the Oregon Non-PMA Device Subclass Members was foreseeable to the Defendant.

4560. As a direct and proximate result of Defendant's actions and omissions, the Oregon Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4561. Allergan acted with willful and wanton disregard for the rights and health of the Oregon Non-PMA Device Subclass Members and other patients.

COUNT 224
Strict Product Liability—Design Defect
Pennsylvania

4562. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4563. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Non-PMA Device Subclass.

4564. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Pennsylvania Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Pennsylvania Non-PMA Device Subclass Members.

4565. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4566. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4567. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4568. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4569. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4570. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4571. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4572. The use of the Non-PMA BIOCELL Implants in the Pennsylvania Non-PMA Device Subclass Members was foreseeable to the Defendant.

4573. As a direct and proximate result of Defendant's actions and omissions, the Pennsylvania Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4574. Allergan acted with willful and wanton disregard for the rights and health of the Pennsylvania Non-PMA Device Subclass Members and other patients.

COUNT 225
Strict Product Liability—Design Defect
Puerto Rico

4575. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4576. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Non-PMA Device Subclass.

4577. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Puerto Rico Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Puerto Rico Non-PMA Device Subclass Members.

4578. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4579. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4580. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4581. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4582. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4583. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4584. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4585. The use of the Non-PMA BIOCELL Implants in the Puerto Rico Non-PMA Device Subclass Members was foreseeable to the Defendant.

4586. As a direct and proximate result of Defendant's actions and omissions, the Puerto Rico Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4587. Allergan acted with willful and wanton disregard for the rights and health of the Puerto Rico Non-PMA Device Subclass Members and other patients.

COUNT 226
Strict Product Liability—Design Defect
Rhode Island

4588. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4589. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Non-PMA Device Subclass.

4590. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Rhode Island Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Rhode Island Non-PMA Device Subclass Members.

4591. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4592. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4593. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4594. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4595. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4596. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4597. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4598. The use of the Non-PMA BIOCELL Implants in the Rhode Island Non-PMA Device Subclass Members was foreseeable to the Defendant.

4599. As a direct and proximate result of Defendant's actions and omissions, the Rhode Island Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4600. Allergan acted with willful and wanton disregard for the rights and health of the Rhode Island Non-PMA Device Subclass Members and other patients.

COUNT 227
Strict Product Liability—Design Defect
South Carolina

4601. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4602. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Non-PMA Device Subclass.

4603. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the South Carolina Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the South Carolina Non-PMA Device Subclass Members.

4604. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4605. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4606. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4607. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4608. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4609. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4610. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4611. The use of the Non-PMA BIOCELL Implants in the South Carolina Non-PMA Device Subclass Members was foreseeable to the Defendant.

4612. As a direct and proximate result of Defendant's actions and omissions, the South Carolina Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4613. Allergan acted with willful and wanton disregard for the rights and health of the South Carolina Non-PMA Device Subclass Members and other patients.

COUNT 228
Strict Liability - Design Defect
South Dakota

4614. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4615. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Non-PMA Device Subclass.

4616. Defendant is strictly liable under South Dakota's product liability statute (S.D. Codified Laws § 20-9-9) for designing the Recalled BIOCELL Implants in a defective condition unreasonably dangerous to the South Dakota Non-PMA Device Subclass Members.

4617. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4618. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4619. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4620. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4621. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4622. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4623. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4624. The use of the Non-PMA BIOCELL Implants in the South Dakota Non-PMA Device Subclass Members was foreseeable to the Defendant.

4625. As a direct and proximate result of Defendant's actions and omissions, the South Dakota Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses

including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4626. Allergan acted with willful and wanton disregard for the rights and health of the South Dakota Non-PMA Device Subclass Members and other patients.

COUNT 229
Strict Product Liability—Design Defect
Tennessee

4627. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4628. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Non-PMA Device Subclass.

4629. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Tennessee Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Tennessee Non-PMA Device Subclass Members.

4630. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4631. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4632. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed

primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4633. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4634. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4635. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4636. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4637. The use of the Non-PMA BIOCELL Implants in the Tennessee Non-PMA Device Subclass Members was foreseeable to the Defendant.

4638. As a direct and proximate result of Defendant's actions and omissions, the Tennessee Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4639. Allergan acted with willful and wanton disregard for the rights and health of the Tennessee Non-PMA Device Subclass Members and other patients.

COUNT 230
Strict Product Liability—Design Defect
Texas

4640. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4641. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Non-PMA Device Subclass.

4642. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Texas Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Texas Non-PMA Device Subclass Members.

4643. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4644. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4645. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found

in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4646. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4647. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4648. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4649. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4650. The use of the Non-PMA BIOCELL Implants in the Texas Non-PMA Device Subclass Members was foreseeable to the Defendant.

4651. As a direct and proximate result of Defendant's actions and omissions, the Texas Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4652. Allergan acted with willful and wanton disregard for the rights and health of the Texas Non-PMA Device Subclass Members and other patients.

COUNT 231
Strict Product Liability—Design Defect
U.S. Virgin Islands

4653. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4654. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the U.S. Virgin Islands Non-PMA Device Subclass.

4655. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the U.S. Virgin Islands Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the U.S. Virgin Islands Non-PMA Device Subclass Members.

4656. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4657. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4658. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4659. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4660. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4661. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4662. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4663. The use of the Non-PMA BIOCELL Implants in the U.S. Virgin Islands Non-PMA Device Subclass Members was foreseeable to the Defendant.

4664. As a direct and proximate result of Defendant's actions and omissions, the U.S. Virgin Islands Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4665. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

COUNT 232
Strict Product Liability—Design Defect
Utah

4666. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4667. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Non-PMA Device Subclass.

4668. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Utah Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Utah Non-PMA Device Subclass Members.

4669. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4670. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4671. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4672. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4673. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4674. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4675. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4676. The use of the Non-PMA BIOCELL Implants in the Utah Non-PMA Device Subclass Members was foreseeable to the Defendant.

4677. As a direct and proximate result of Defendant's actions and omissions, the Utah Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4678. Allergan acted with willful and wanton disregard for the rights and health of the Utah Non-PMA Device Subclass Members and other patients.

COUNT 233
Strict Product Liability—Design Defect
Vermont

4679. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4680. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Non-PMA Device Subclass.

4681. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Vermont Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Vermont Non-PMA Device Subclass Members.

4682. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4683. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4684. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4685. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4686. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo

a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4687. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4688. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4689. The use of the Non-PMA BIOCELL Implants in the Vermont Non-PMA Device Subclass Members was foreseeable to the Defendant.

4690. As a direct and proximate result of Defendant's actions and omissions, the Vermont Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4691. Allergan acted with willful and wanton disregard for the rights and health of the Vermont Non-PMA Device Subclass Members and other patients.

COUNT 234
Strict Product Liability—Design Defect
West Virginia

4692. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4693. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Non-PMA Device Subclass.

4694. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the West Virginia Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL

Implants to be implanted into members of the public, including the West Virginia Non-PMA Device Subclass Members.

4695. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4696. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4697. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4698. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4699. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4700. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4701. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4702. The use of the Non-PMA BIOCELL Implants in the West Virginia Non-PMA Device Subclass Members was foreseeable to the Defendant.

4703. As a direct and proximate result of Defendant's actions and omissions, the West Virginia Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4704. Allergan acted with willful and wanton disregard for the rights and health of the West Virginia Non-PMA Device Subclass Members and other patients.

COUNT 235
Strict Product Liability—Design Defect
Wisconsin

4705. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4706. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Non-PMA Device Subclass.

4707. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Wisconsin Non-PMA Device Subclass Members. Defendant knew and Non-PMA for the Recalled BIOCELL Implants to be implanted into members of the public, including the Wisconsin Non-PMA Device Subclass Members.

4708. The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing

an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4709. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4710. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4711. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4712. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4713. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4714. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4715. The use of the Non-PMA BIOCELL Implants in the Wisconsin Non-PMA Device Subclass Members was foreseeable to the Defendant.

4716. As a direct and proximate result of Defendant's actions and omissions, the Wisconsin Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4717. Allergan acted with willful and wanton disregard for the rights and health of the Wisconsin Non-PMA Device Subclass Members and other patients.

COUNT 236
Strict Product Liability—Design Defect
Wyoming

4718. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4719. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Non-PMA Device Subclass.

4720. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Wyoming Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Wyoming Non-PMA Device Subclass Members.

4721. T The design of the Non-PMA BIOCELL Implants, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, cellular and subcellular damage, tissue damage, seromas, BIA-ALCL, the accumulation of foreign and adulterated silicone particles, and other related injuries.

4722. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4723. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4724. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

4725. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4726. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

4727. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4728. The use of the Non-PMA BIOCELL Implants in the Wyoming Non-PMA Device Subclass Members was foreseeable to the Defendant.

4729. As a direct and proximate result of Defendant's actions and omissions, the Wyoming Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

4730. Allergan acted with willful and wanton disregard for the rights and health of the Wyoming Non-PMA Device Subclass Members and other patients.

F. NEGLIGENCE – DESIGN DEFECT

COUNT 237
Negligence—Design Defect
Alabama

4731. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4732. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Non-PMA Device Subclass.

4733. Defendant is strictly liable under the Alabama Extended Manufacturer's Liability Doctrine (Al. Civ. Pr. § 6-5-501 *et seq.*) and the common law for designing and manufacturing the Non-PMA BIOCELL Implants in an unreasonably dangerous and defective condition.

4734. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Alabama Non-PMA Device Subclass. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Alabama Non-PMA Device Subclass.

4735. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Alabama Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features

of the design were unreasonably dangerous and proximately caused harm to the Alabama Non-PMA Device Subclass Members

4736. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4737. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4738. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4739. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo the salt loss texturing process that the Non-PMA BIOCELL Implants undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line associated with the vast majority of ALCL cases.

4740. The risk benefit profile of Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market. The utility of the alternative design outweighed the utility of the design used.

4741. The use of the Non-PMA BIOCELL Implants in the Alabama Non-PMA Device Subclass was foreseeable to the Defendant.

4742. As a direct and proximate result of Defendant's actions and omissions, the Alabama Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 238
Negligence—Design Defect
Alaska

4743. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4744. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Non-PMA Device Subclass.

4745. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Alaska Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Alaska Non-PMA Device Subclass Members.

4746. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Alaska Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Alaska Non-PMA Device Subclass Members.

4747. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4748. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4749. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4750. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4751. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4752. The Non-PMA BIOCELL Implants products did not perform as an ordinary consumer would expect.

4753. The use of the Non-PMA BIOCELL Implants in the Alaska Non-PMA Device Subclass Members was foreseeable to the Defendant.

4754. As a direct and proximate result of Defendant's actions and omissions, the Alaska Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including

surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 239
Negligence—Design Defect
American Samoa

4755. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4756. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Non-PMA Device Subclass.

4757. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the American Samoa Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the American Samoa Non-PMA Device Subclass Members.

4758. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the American Samoa Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the American Samoa Non-PMA Device Subclass Members.

4759. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4760. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found

in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4761. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4762. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4763. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4764. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4765. The use of the Non-PMA BIOCELL Implants in the American Samoa Non-PMA Device Subclass Members was foreseeable to the Defendant.

4766. As a direct and proximate result of Defendant's actions and omissions, the American Samoa Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 240
Negligence—Design Defect
Arkansas

4767. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4768. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Non-PMA Device Subclass.

4769. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Arkansas Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Arkansas Non-PMA Device Subclass Members.

4770. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Arkansas Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Arkansas Non-PMA Device Subclass Members.

4771. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4772. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4773. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4774. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4775. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4776. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4777. The use of the Non-PMA BIOCELL Implants in the Arkansas Non-PMA Device Subclass Members was foreseeable to the Defendant.

4778. As a direct and proximate result of Defendant's actions and omissions, the Arkansas Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 241
Negligence—Design Defect
California

4779. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4780. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Non-PMA Device Subclass.

4781. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the California

Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the California Non-PMA Device Subclass Members.

4782. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the California Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the California Non-PMA Device Subclass Members.

4783. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4784. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4785. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4786. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured

implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4787. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4788. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4789. The use of the Non-PMA BIOCELL Implants in the California Non-PMA Device Subclass Members was foreseeable to the Defendant.

4790. As a direct and proximate result of Defendant's actions and omissions, the California Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 242
Negligence—Design Defect
Colorado

4791. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4792. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Non-PMA Device Subclass.

4793. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Colorado Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Colorado Non-PMA Device Subclass Members.

4794. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Colorado Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL

Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Colorado Non-PMA Device Subclass Members.

4795. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4796. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4797. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4798. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4799. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4800. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4801. The use of the Non-PMA BIOCELL Implants in the Colorado Non-PMA Device Subclass Members was foreseeable to the Defendant.

4802. As a direct and proximate result of Defendant's actions and omissions, the Colorado Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 243
Negligence—Design Defect
Delaware

4803. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4804. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Delaware Non-PMA Device Subclass.

4805. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Delaware Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Delaware Non-PMA Device Subclass Members.

4806. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed the Delaware Non-PMA Device Subclass Members a duty to design Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Delaware Non-PMA Device Subclass Members.

4807. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4808. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4809. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4810. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4811. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4812. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4813. The use of the Non-PMA BIOCELL Implants in the Delaware Non-PMA Device Subclass Members was foreseeable to the Defendant.

4814. As a direct and proximate result of Defendant's actions and omissions, the Delaware Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 244
Negligence—Design Defect
District of Columbia

4815. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4816. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the District of Columbia Non-PMA Device Subclass.

4817. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the District of Columbia Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the District of Columbia Non-PMA Device Subclass Members.

4818. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed the District of Columbia Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the District of Columbia Non-PMA Device Subclass Members.

4819. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4820. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4821. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4822. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4823. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4824. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4825. The use of the Non-PMA BIOCELL Implants in the District of Columbia Non-PMA Device Subclass Members was foreseeable to the Defendant.

4826. As a direct and proximate result of Defendant's actions and omissions, the District of Columbia Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 245
Negligence—Design Defect
Florida

4827. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4828. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Non-PMA Device Subclass.

4829. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Florida Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Florida Non-PMA Device Subclass Members.

4830. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Florida Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Florida Non-PMA Device Subclass Members.

4831. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4832. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4833. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4834. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4835. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4836. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4837. The use of the Non-PMA BIOCELL Implants in the Florida Non-PMA Device Subclass Members was foreseeable to the Defendant.

4838. As a direct and proximate result of Defendant's actions and omissions, the Florida Non-PMA Device Subclass Members have significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses, including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 246
Negligence—Design Defect
Georgia

4839. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4840. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Non-PMA Device Subclass.

4841. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL that were implanted into the Georgia Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Georgia Non-PMA Device Subclass Members.

4842. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Georgia Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Georgia Non-PMA Device Subclass Members.

4843. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4844. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4845. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4846. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4847. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4848. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4849. The use of the Non-PMA BIOCELL Implants in the Georgia Non-PMA Device Subclass Members was foreseeable to the Defendant.

4850. As a direct and proximate result of Defendant's actions and omissions, the Georgia Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 247
Negligence—Design Defect
Guam

4851. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4852. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Non-PMA Device Subclass.

4853. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Guam Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Guam Non-PMA Device Subclass Members.

4854. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Guam Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Guam Non-PMA Device Subclass.

4855. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4856. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4857. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4858. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated

solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4859. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4860. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4861. The use of the Non-PMA BIOCELL Implants in the Guam Non-PMA Device Subclass Members was foreseeable to the Defendant.

4862. As a direct and proximate result of Defendant's actions and omissions, the Guam Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 248
Negligence—Design Defect
Hawaii

4863. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4864. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into the Hawaii Non-PMA Device Subclass Members. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including the Hawaii Non-PMA Device Subclass Members.

4865. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed the Hawaii Non-PMA Device Subclass Members a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Hawaii Non-PMA Device Subclass Members.

4866. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4867. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4868. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4869. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4870. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4871. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4872. The use of the Non-PMA BIOCELL Implants in the Hawaii Non-PMA Device Subclass Members was foreseeable to the Defendant.

4873. As a direct and proximate result of Defendant's actions and omissions, the Hawaii Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 249
Negligence—Design Defect
Idaho

4874. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4875. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Non-PMA Device Subclass.

4876. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Idaho Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Idaho Non-PMA Device Subclass Members.

4877. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4878. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4879. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4880. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4881. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4882. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4883. The use of the Non-PMA BIOCELL Implants in the Idaho Non-PMA Device Subclass Members was foreseeable to the Defendant.

4884. As a direct and proximate result of Defendant's actions and omissions, the Idaho Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 250
Negligence—Design Defect
Illinois

4885. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4886. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Non-PMA Device Subclass.

4887. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Illinois Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Illinois Non-PMA Device Subclass Members.

4888. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4889. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4890. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4891. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4892. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4893. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4894. The use of the Non-PMA BIOCELL Implants in the Illinois Non-PMA Device Subclass Members was foreseeable to the Defendant.

4895. As a direct and proximate result of Defendant's actions and omissions, the Illinois Non-PMA Device Subclass Members have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 251
Negligence—Design Defect
Indiana

4896. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4897. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Non-PMA Device Subclass.

4898. The Indiana Product Liability Act (Ind. Code Ann. § 34–20–1–1) governs all actions brought by a user or consumer against a manufacturer for physical harm caused by a product.

4899. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Indiana Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Indiana Non-PMA Device Subclass Members.

4900. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4901. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4902. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4903. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured

implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4904. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4905. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4906. The use of the Non-PMA BIOCELL Implants in the Indiana Non-PMA Device Subclass Members was foreseeable to the Defendant.

4907. As a direct and proximate result of Defendant's actions and omissions, the Indiana Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 252
Negligence—Design Defect
Iowa

4908. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4909. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Non-PMA Device Subclass.

4910. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Iowa Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCELL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Iowa Non-PMA Device Subclass Members.

4911. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4912. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4913. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4914. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4915. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4916. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4917. The use of the Non-PMA BIOCELL Implants in the Iowa Non-PMA Device Subclass Members was foreseeable to the Defendant.

4918. As a direct and proximate result of Defendant's actions and omissions, the Iowa Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 253
Negligence—Design Defect
Kansas

4919. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4920. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Non-PMA Device Subclass.

4921. Defendant negligently designed its Non-PMA BIOCELL Implants. Defendant owed the Kansas Non-PMA Device Subclass Members a duty to design its Non-PMA BIOCEL Implants in a reasonable manner. Defendant breached its duty by designing its Non-PMA BIOCELL Implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Kansas Non-PMA Device Subclass Members.

4922. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4923. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4924. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the Non-PMA BIOCELL Implants.

4925. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4926. The risk benefit profile of the Non-PMA BIOCELL products was unreasonable, and the products should not have been sold in the market.

4927. The Non-PMA BIOCELL Implants did not perform as an ordinary consumer would expect.

4928. The use of the Non-PMA BIOCELL Implants in the Kansas Non-PMA Device Subclass Members was foreseeable to the Defendant.

4929. As a direct and proximate result of Defendant's actions and omissions, the Kansas Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 254
Negligence—Design Defect
Kentucky

4930. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4931. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Non-PMA Device Subclass.

4932. The Kentucky Product Liability Act (K.R.S. § 411.300), governs all product liability actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture of any product.

4933. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed the Kentucky Non-PMA Device Subclass Members a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Kentucky Non-PMA Device Subclass Members.

4934. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4935. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4936. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

4937. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss

texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4938. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

4939. The BIOCELL products did not perform as an ordinary consumer would expect.

4940. The use of the Recalled BIOCELL Implants in the Kentucky Non-PMA Device Subclass Members was foreseeable to the Defendant.

4941. As a direct and proximate result of Defendant's actions and omissions, the Kentucky Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 255
Negligence—Design Defect
Maine

4942. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4943. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Non-PMA Device Subclass.

4944. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

4945. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4946. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4947. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

4948. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4949. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

4950. The BIOCELL products did not perform as an ordinary consumer would expect.

4951. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

4952. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 256
Negligence—Design Defect
Maryland

4953. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4954. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Non-PMA Device Subclass.

4955. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

4956. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4957. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4958. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

4959. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4960. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

4961. The BIOCELL products did not perform as an ordinary consumer would expect.

4962. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

4963. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 257
Negligence—Design Defect
Massachusetts

4964. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4965. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Non-PMA Device Subclass.

4966. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

4967. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4968. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4969. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

4970. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4971. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

4972. The BIOCELL products did not perform as an ordinary consumer would expect.

4973. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

4974. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 258
Negligence—Design Defect
Michigan

4975. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4976. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Michigan Non-PMA Device Subclass.

4977. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

4978. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4979. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4980. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

4981. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4982. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

4983. The BIOCELL products did not perform as an ordinary consumer would expect.

4984. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

4985. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 259
Negligence—Design Defect
Minnesota

4986. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4987. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Non-PMA Device Subclass.

4988. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

4989. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

4990. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

4991. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

4992. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

4993. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

4994. The BIOCELL products did not perform as an ordinary consumer would expect.

4995. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

4996. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 260
Negligence—Design Defect
Mississippi

4997. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

4998. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Non-PMA Device Subclass.

4999. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Non-PMA BIOCELL Implants that were implanted into the Mississippi Non-PMA Device Subclass Members. Defendant knew and intended for the Non-PMA BIOCELL Implants to be implanted into members of the public, including the Mississippi Non-PMA Device Subclass Members.

5000. Under Mississippi's product liability statute (Miss. Code Ann. § 11–1–63), Defendant is liable for designing and selling the Recalled BIOCELL Implants that caused harm to the Mississippi Subclass Members.

5001. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to the Mississippi Non-PMA Device Subclass Members.

5002. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Non-PMA BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5003. The dangers of the Non-PMA BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5004. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with Non-PMA BIOCELL Implants.

5005. "Smooth" breast implants were on the market at the times in which Allergan's Non-PMA BIOCELL Implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5006. The risk benefit profile of the Non-PMA BIOCELL Implants was unreasonable, and the products should not have been sold in the market.

5007. The use of the Non-PMA BIOCELL Implants in the Mississippi Non-PMA Device Subclass Members was foreseeable to the Defendant.

5008. As a direct and proximate result of Defendant's actions and omissions, the Mississippi Non-PMA Device Subclass Members have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 260
Negligence—Design Defect
Missouri

5009. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5010. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Non-PMA Device Subclass.

5011. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5012. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5013. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5014. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5015. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss

texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5016. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5017. The BIOCELL products did not perform as an ordinary consumer would expect.

5018. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5019. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 262
Negligence—Design Defect
Montana

5020. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5021. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Non-PMA Device Subclass.

5022. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5023. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5024. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5025. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5026. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5027. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5028. The BIOCELL products did not perform as an ordinary consumer would expect.

5029. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5030. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 263
Negligence—Design Defect
Nebraska

5031. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5032. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Non-PMA Device Subclass.

5033. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5034. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5035. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5036. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5037. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5038. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5039. The BIOCELL products did not perform as an ordinary consumer would expect.

5040. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5041. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 264
Negligence—Design Defect
Nevada

5042. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5043. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Non-PMA Device Subclass.

5044. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5045. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5046. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5047. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5048. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5049. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5050. The BIOCELL products did not perform as an ordinary consumer would expect.

5051. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5052. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 265
Negligence—Design Defect
New Hampshire

5053. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5054. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Non-PMA Device Subclass.

5055. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5056. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5057. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5058. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5059. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5060. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5061. The BIOCELL products did not perform as an ordinary consumer would expect.

5062. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5063. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 266
Negligence—Design Defect
New Mexico

5064. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5065. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Non-PMA Device Subclass.

5066. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5067. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5068. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5069. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5070. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5071. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5072. The BIOCELL products did not perform as an ordinary consumer would expect.

5073. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5074. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 267
Negligence—Design Defect
New York

5075. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5076. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Non-PMA Device Subclass.

5077. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5078. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5079. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5080. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5081. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss

texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5082. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5083. The BIOCELL products did not perform as an ordinary consumer would expect.

5084. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5085. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 268
Negligence—Design Defect
North Carolina

5086. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5087. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Carolina Non-PMA Device Subclass.

5088. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5089. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5090. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5091. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5092. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5093. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5094. The BIOCELL products did not perform as an ordinary consumer would expect.

5095. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5096. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 269
Negligence—Design Defect
North Dakota

5097. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5098. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Non-PMA Device Subclass.

5099. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5100. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5101. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5102. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5103. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5104. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5105. The BIOCELL products did not perform as an ordinary consumer would expect.

5106. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5107. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 270
Negligence—Design Defect
Northern Mariana Islands

5108. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5109. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Non-PMA Device Subclass.

5110. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5111. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5112. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5113. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5114. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5115. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5116. The BIOCELL products did not perform as an ordinary consumer would expect.

5117. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5118. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 271
Negligence—Design Defect
Ohio

5119. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5120. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Non-PMA Device Subclass.

5121. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5122. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5123. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5124. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5125. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5126. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5127. The BIOCELL products did not perform as an ordinary consumer would expect.

5128. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5129. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 272
Negligence—Design Defect
Oklahoma

5130. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5131. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Non-PMA Device Subclass.

5132. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5133. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5134. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5135. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5136. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5137. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5138. The BIOCELL products did not perform as an ordinary consumer would expect.

5139. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5140. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 273
Negligence—Design Defect
Oregon

5141. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5142. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Non-PMA Device Subclass.

5143. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5144. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5145. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5146. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5147. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5148. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5149. The BIOCELL products did not perform as an ordinary consumer would expect.

5150. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5151. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 274
Negligence—Design Defect
Pennsylvania

5152. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5153. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Non-PMA Device Subclass.

5154. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5155. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5156. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5157. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5158. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5159. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5160. The BIOCELL products did not perform as an ordinary consumer would expect.

5161. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5162. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL

and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 275
Negligence—Design Defect
Puerto Rico

5163. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5164. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Non-PMA Device Subclass.

5165. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5166. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5167. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5168. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5169. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5170. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5171. The BIOCELL products did not perform as an ordinary consumer would expect.

5172. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5173. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 276
Negligence—Design Defect
Rhode Island

5174. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5175. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Non-PMA Device Subclass.

5176. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5177. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5178. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5179. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5180. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5181. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5182. The BIOCELL products did not perform as an ordinary consumer would expect.

5183. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5184. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 277
Negligence—Design Defect
South Carolina

5185. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5186. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Non-PMA Device Subclass.

5187. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5188. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5189. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5190. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5191. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5192. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5193. The BIOCELL products did not perform as an ordinary consumer would expect.

5194. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5195. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 278
Negligence—Design Defect
South Dakota

5196. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5197. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Non-PMA Device Subclass.

5198. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5199. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5200. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5201. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5202. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5203. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5204. The BIOCELL products did not perform as an ordinary consumer would expect.

5205. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5206. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 279
Negligence—Design Defect
Tennessee

5207. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5208. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Non-PMA Device Subclass.

5209. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5210. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5211. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5212. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5213. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with

the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5214. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5215. The BIOCELL products did not perform as an ordinary consumer would expect.

5216. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5217. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 280
Negligence—Design Defect
Texas

5218. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5219. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Non-PMA Device Subclass.

5220. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5221. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5222. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5223. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5224. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5225. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5226. The BIOCELL products did not perform as an ordinary consumer would expect.

5227. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5228. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical

costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 281
Negligence—Design Defect
U.S. Virgin Islands

5229. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5230. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the U.S. Virgin Islands Non-PMA Device Subclass.

5231. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5232. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5233. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5234. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5235. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5236. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5237. The BIOCELL products did not perform as an ordinary consumer would expect.

5238. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5239. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 282
Negligence—Design Defect
Utah

5240. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5241. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Non-PMA Device Subclass.

5242. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA

textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5243. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5244. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5245. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5246. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5247. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5248. The BIOCELL products did not perform as an ordinary consumer would expect.

5249. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5250. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 283
Negligence—Design Defect
Vermont

5251. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5252. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Non-PMA Device Subclass.

5253. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5254. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5255. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5256. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5257. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5258. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5259. The BIOCELL products did not perform as an ordinary consumer would expect.

5260. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5261. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 284
Negligence—Design Defect
Virginia

5262. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5263. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virginia Non-PMA Device Subclass.

5264. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable

manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5265. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5266. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5267. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5268. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5269. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5270. The BIOCELL products did not perform as an ordinary consumer would expect.

5271. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5272. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 285
Negligence—Design Defect
West Virginia

5273. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5274. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Non-PMA Device Subclass.

5275. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5276. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5277. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5278. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5279. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5280. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5281. The BIOCELL products did not perform as an ordinary consumer would expect.

5282. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5283. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have a significantly increased risk of developing BIA-ALCL and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 286
Negligence—Design Defect
Wisconsin

5284. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5285. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Non-PMA Device Subclass.

5286. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA

textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5287. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5288. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5289. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5290. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5291. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5292. The BIOCELL products did not perform as an ordinary consumer would expect.

5293. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5294. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 287
Negligence—Design Defect
Wyoming

5295. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5296. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Non-PMA Device Subclass.

5297. Defendant negligently designed its Recalled BIOCELL Implants. Defendant owed Plaintiffs a duty to design its BIOCELL textured expanders and non-PMA implants in a reasonable manner. Defendant breached its duty by designing its BIOCELL expanders and non-PMA textured implants in an unreasonable manner, such that its texturing process and other features of the design were unreasonably dangerous and proximately caused harm to Plaintiffs.

5298. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5299. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5300. Safer alternative designs of implants and expanders existed and were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5301. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5302. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5303. The BIOCELL products did not perform as an ordinary consumer would expect.

5304. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5305. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

G. STATE PRODUCT LIABILITY ACTS (EXCLUSIVE REMEDIES)

COUNT 288
Connecticut – Strict Liability – Failure To Warn
Violation of Conn. Product Liability Act, General Statutes, 52-572m et seq.

5306. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5307. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Connecticut Subclass.

5308. Under the Connecticut Product Liability Act, General Statutes, 52-572m *et seq.,* Defendant is strictly liable because Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants, and the Recalled BIOCELL Implants were defective in that adequate warnings were not provided.

5309. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5310. The Recalled BIOCELL Implants that were implanted into Plaintiffs were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

5311. Under Connecticut law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Plaintiffs about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

5312. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as manufacturers of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

5313. Defendant failed to adequately warn the FDA, medical professionals, and Plaintiffs about the true risk of using its Recalled BIOCELL Implants, including:

a. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

b. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

c. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

d. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Plaintiffs received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

5314. Rather than disclose the truth, Defendant, in violation of its duties to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

5315. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of

developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

5316. Plaintiffs and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Plaintiffs, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

5317. The Recalled BIOCELL Implants presented a substantial risk to Plaintiffs and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Plaintiffs and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

5318. The inadequate warnings were a substantial factor in bringing about Plaintiffs' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019

recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

5319. If, as mandated by Connecticut law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Plaintiffs and their physicians, and Plaintiffs and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Plaintiffs would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

5320. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have sustained physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 289
Connecticut – Strict Liability – Manufacturing Defect
Violation of Conn. Product Liability Act, General Statutes, 52-572m et seq.

5321. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5322. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Connecticut Subclass.

5323. Under the Connecticut Product Liability Act, General Statutes, 52-572m *et seq.,* Defendant is strictly liable because Defendant was engaged in the business of manufacturing and selling the Recalled BIOCELL Implants, the Recalled BIOCELL Implants contained a manufacturing defect that was unreasonably dangerous to the Connecticut Subclass Members, the manufacturing defect caused the injury for which Plaintiffs and Class members seek compensation, the manufacturing defect existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach the Connecticut Subclass Members without a substantial change in condition.

5324. Plaintiffs and the Connecticut Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

5325. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

5326. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

5327. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated

methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

5328. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to state law, based upon Defendant's violation of the applicable federal regulations.

5329. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

5330. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

5331. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

5332. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous,

defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to (a) the accumulation of foreign and adulterated silicone particles in patients' bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) a significantly increased risk of BIA-ALCL; or (c) costly, invasive surgeries to explant the Recalled BIOCELL Implants.

5333. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Connecticut Subclass Members and others without knowledge of the hazards involved in such use.

5334. As a direct and proximate result of Defendant's acts and omissions, the Connecticut Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 290
Connecticut – Strict Liability – Design Defect
Violation of Conn. Product Liability Act, General Statutes, 52-572m et seq.

5335. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5336. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Connecticut Non-PMA Device Subclass.

5337. Under the Connecticut Product Liability Act, General Statutes, 52-572m *et seq.,* Defendant is strictly liable because Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5338. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5339. The design of the BIOCELL textured implants and tissue expanders, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, tissue damage, seromas, BIA-ALCL, and other related injuries.

5340. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5341. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5342. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5343. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5344. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5345. The BIOCELL products did not perform as an ordinary consumer would expect.

5346. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5347. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

5348. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

COUNT 291
Louisiana – Strict Liability – Failure To Warn
Violation of Louisiana Product Liability Act, La. Rev. Stat. Ann. § 9:2800.51, *et seq*.

5349. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5350. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Louisiana Subclass.

5351. Under the Louisiana Product Liability Act (La. Rev. Stat. Ann. § 9:2800.51, *et seq*), Defendant is strictly liable for harm caused to the Louisiana Subclass Members by the Recalled BIOCELL implants, which were unreasonably dangerous because an adequate warning about the product was not provided.

5352. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs.

Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5353. The Recalled BIOCELL Implants that were implanted into Plaintiffs were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

5354. Under Louisiana law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Plaintiffs about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

5355. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as manufacturers of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

5356. Defendant failed to adequately warn the FDA, medical professionals, and Plaintiffs about the true risk of using its Recalled BIOCELL Implants, including:

5357. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

5358. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

5359. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

5360. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Plaintiffs received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

5361. Rather than disclose the truth, Defendant, in violation of its duties to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

5362. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite

opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

5363. Plaintiffs and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Plaintiffs, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

5364. The Recalled BIOCELL Implants presented a substantial risk to Plaintiffs and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Plaintiffs and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

5365. The inadequate warnings were a substantial factor in bringing about Plaintiffs' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

5366. If, as mandated by Louisiana law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the

information would have been known to Plaintiffs and their physicians, and Plaintiffs and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Plaintiffs would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

5367. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 292
Louisiana – Strict Liability – Manufacturing Defect
Violation of Louisiana Product Liability Act, La. Rev. Stat. Ann. § 9:2800.51, *et seq*.

5368. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5369. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Louisiana Subclass.

5370. Defendant is engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

5371. Under the Louisiana Product Liability Act (La. Rev. Stat. Ann. § 9:2800.51, *et seq*), Defendant is strictly liable for harm caused to the Louisiana Subclass Members by the Recalled

BIOCELL implants, which contained a manufacturing defect that rendered the product unreasonably dangerous.

5372. Such harm suffered by the Louisiana Subclass Members arose from a reasonably anticipated use of the Recalled BIOCELL Implants.

5373. Further, the Recalled BIOCELL Implants contained a manufacturing defect that existed at the time of manufacture and sale, and the Recalled BIOCELL Implants were expected to and did reach the Louisiana Subclass Members without a substantial change in condition.

5374. Plaintiffs and the Louisiana Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

5375. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

5376. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

5377. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective

manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

5378. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to state law, based upon Defendant's violation of the applicable federal regulations.

5379. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

5380. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

5381. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

5382. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants..

5383. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

5384. If Defendant had followed its own manufacturing specifications, injury to the Louisiana Subclass Members would not have occurred.

5385. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Louisiana Subclass Members and others without knowledge of the hazards involved in such use.

5386. As a direct and proximate result of Defendant's acts and omissions, the Louisiana Subclass have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 293
Louisiana – Strict Liability – Design Defect
Violation of Louisiana Product Liability Act, La. Rev. Stat. Ann. § 9:2800.51, *et seq*.

5387. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5388. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Louisiana Non-PMA Device Subclass.

5389. Defendant is engaged in the business of manufacturing, selling, distributing, marketing, and promoting the Recalled BIOCELL Implants.

5390. Under the Louisiana Product Liability Act (La. Rev. Stat. Ann. § 9:2800.51, *et seq*), Defendant is strictly liable for harm caused to the Louisiana Subclass Members by the Recalled BIOCELL implants, which were defectively designed in such a way that rendered the product unreasonably dangerous.

5391. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5392. The design of the BIOCELL textured implants and tissue expanders, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, tissue damage, seromas, BIA-ALCL, and other related injuries.

5393. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5394. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5395. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5396. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5397. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5398. The BIOCELL products did not perform as an ordinary consumer would expect.

5399. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5400. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

5401. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

COUNT 294
New Jersey – Strict Liability - Failure To Warn
Violation of New Jersey Product Liability Act, N.J.S.A. 2A:58C-1 et seq.

5402. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5403. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Jersey Subclass.

5404. Defendant is strictly liable under the New Jersey Product Liability Act (N.J.S.A. 2A:58C-1 et seq.).

5405. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5406. The Recalled BIOCELL Implants that were implanted into Plaintiffs were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

5407. Under New Jersey law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Plaintiffs about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

5408. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as manufacturers of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

5409. Defendant failed to adequately warn the FDA, medical professionals, and Plaintiffs about the true risk of using its Recalled BIOCELL Implants, including:

a. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;
b. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and
c. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.
d. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Plaintiffs received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated

with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

5410. Rather than disclose the truth, Defendant, in violation of its duties to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

5411. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

5412. Plaintiffs and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for

implantation. Plaintiffs, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

5413. The Recalled BIOCELL Implants presented a substantial risk to Plaintiffs and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Plaintiffs and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

5414. The inadequate warnings were a substantial factor in bringing about Plaintiffs' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

5415. If, as mandated by New Jersey law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Plaintiffs and their physicians, and Plaintiffs and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the

implants. Accordingly, Plaintiffs would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

5416. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 295
New Jersey – Strict Liability - Manufacturing Defect
Violation of New Jersey Product Liability Act, N.J.S.A. 2A:58C-1 et seq.

5417. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5418. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Jersey Subclass.

5419. Defendant is strictly liable under the New Jersey Product Liability Act (N.J.S.A. 2A:58C-1 et seq.).

5420. Defendant manufactured and sold the Recalled BIOCELL Implants.

5421. The Recalled BIOCELL Implants were not reasonably fit, suitable, or safe for the product's intended purpose because the Recalled BIOCELL Implants deviated from Defendant's manufacturing specifications, formulae, and/or performance standards.

5422. The manufacturing defect caused harm to the New Jersey Subclass Members.

5423. Plaintiffs and the New Jersey Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been

defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

5424. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

5425. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

5426. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

5427. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to state law, based upon Defendant's violation of the applicable federal regulations.

5428. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

5429. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

5430. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

5431. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

5432. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

5433. If Defendant had followed its own manufacturing specifications, injury to the New Jersey Subclass Members would not have occurred.

5434. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the New Jersey Subclass Members and others without knowledge of the hazards involved in such use.

5435. As a direct and proximate result of Defendant's acts and omissions, the New Jersey Subclass members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 296
New Jersey – Strict Liability – Design Defect
Violation of New Jersey Product Liability Act, N.J.S.A. 2A:58C-1 et seq.

5436. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5437. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Jersey Non-PMA Device Subclass.

5438. Defendant is strictly liable under the New Jersey Product Liability Act (N.J.S.A. 2A:58C-1 et seq.).

5439. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5440. The design of the BIOCELL textured implants and tissue expanders, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, tissue damage, seromas, BIA-ALCL, and other related injuries.

5441. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5442. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed

primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5443. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5444. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5445. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5446. The BIOCELL products did not perform as an ordinary consumer would expect.

5447. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5448. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

5449. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

COUNT 297
Washington – Strict Liability – Failure To Warn
Violation of Washington Product Liability Act, RCW § 7.72.010 et seq.

5450. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5451. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Washington Subclass.

5452. Defendant is strictly liable under the Washington Product Liability Act (RCW § 7.72.010 et seq.) because (i) adequate warnings or instructions were not provided with the Recalled BIOCELL Implants, and (ii) adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. Wash. Rev. Code § 7.72.030.

5453. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5454. The Recalled BIOCELL Implants that were implanted into Plaintiffs were defective, unreasonably dangerous and adulterated upon manufacture, having been manufactured in violation of applicable standards, specifications, good manufacturing practices, and in non-conformance with applicable PMA requirements and FDA standards.

5455. Under Washington law, Defendant had a duty to adequately warn and disclose to the FDA, medical professionals, and Plaintiffs about the dangers and true risks of the Recalled BIOCELL Implants, which Defendant knew, or, in the exercise of ordinary care, should have known, at the time the Recalled BIOCELL Implants left Defendant's control.

5456. Pursuant to 21 C.F.R. §§ 803.50 and 814.84, as manufacturers of Class III medical devices, Defendant had a continuing duty to report post-approval information to the FDA concerning the devices—including information that was reasonably known to Defendant—such as adverse events, new clinical investigations and studies, and reports in scientific literature.

5457. Defendant failed to adequately warn the FDA, medical professionals, and Plaintiffs about the true risk of using its Recalled BIOCELL Implants, including:

a. The greatly increased risk of BIA-ALCL, which was significantly greater than the risk posed by implants from competitors;

b. That the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements; and

c. The existing warnings were misleading and minimized the risk of developing BIA-ALCL.

d. The true risks of the Recalled BIOCELL Implants, including the significantly greater risk of developing BIA-ALCL, were known or knowable in light of what was generally accepted in the scientific and medical community. At the time Plaintiffs received their implants, Defendant was aware of the significantly greater risk of BIA-ALCL associated with the implants and that implants were defectively manufactured. Defendant obtained this knowledge from, among other sources, adverse event reports, performing extensive decades-long clinical studies, reviewing scientific studies and literature, reports from international medical associations and governmental entities, and consumer complaints.

5458. Rather than disclose the truth, Defendant, in violation of their duties to disclose under state law, attempted to conceal the true facts by not reporting all adverse events to the FDA, manipulating the FDA's system for reporting adverse events, not revealing that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and other FDA

requirements, and otherwise failing to disclose the true risks of its Recalled BIOCELL Implants. Defendant also failed to revise the labels on the Recalled BIOCELL Implants to conform them to the actual risk profile of the implants that was known or readily available to Defendant.

5459. The Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they did not contain adequate warnings, including the causal connection between Defendant's implants and the substantially greater risk of developing BIA-ALCL. In addition, the Recalled BIOCELL Implants were defective and unreasonably dangerous when they left Defendant's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer would not put such a dangerous product on the market. Despite opportunities to do so, Defendant never acted to strengthen any existing warnings for the Recalled BIOCELL Implants.

5460. Plaintiffs and their physicians reasonably relied on the superior knowledge and representations of Defendant in consenting to and selecting Recalled BIOCELL Implants for implantation. Plaintiffs, ordinary consumers, and medical professionals did not, and could not have, recognized the true risks associated with the Recalled BIOCELL Implants.

5461. The Recalled BIOCELL Implants presented a substantial risk to Plaintiffs and ordinary consumers when used for their intended purpose or in a reasonably foreseeable manner. Defendant knew that the Recalled BIOCELL Implants would be implanted in Plaintiffs and patients' bodies without inspection of defects and without knowledge of the risks involved in their use.

5462. The inadequate warnings were a substantial factor in bringing about Plaintiffs' injuries which would not have occurred but for the use of the Recalled BIOCELL Implants. The FDA—through making adverse event reports public, recalls, and other means—routinely communicates important safety information to medical professionals and consumers. The FDA relies on medical device manufacturers to promptly provide accurate information regarding risks associated with their products. Consumers and medical professionals rely on FDA warnings and other information regarding the safety of FDA-approved products. As demonstrated by the 2019 recall of Defendant's implants, the FDA acts on information suggesting that a medical device poses an unreasonable safety risk to the public.

5463. If, as mandated by Washington law as well as 21 C.F.R. §§ 803.50 and 814.84, Defendant had provided the FDA with timely and accurate information revealing that the Recalled BIOCELL Implants were defective and posed a high risk of developing BIA-ALCL, the information would have been known to Plaintiffs and their physicians, and Plaintiffs and their physicians would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs and their physicians would not have used a Recalled BIOCELL Implant if they had known of the true safety risks associated with the implants. Accordingly, Plaintiffs would not have (a) been subjected to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

5464. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have sustained physical injury, have a significantly increased

risk of BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

COUNT 298
Washington – Strict Liability – Manufacturing Defect
Violation of Washington Product Liability Act, RCW § 7.72.010 et seq.

5465. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5466. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Washington Subclass.

5467. Defendant is strictly liable under the Washington Product Liability Act (RCW § 7.72.010) for manufacturing and selling the Recalled BIOCELL Implants to the Washington Subclass Members.

5468. The harm suffered by the Washington Subclass Members was proximately caused by the fact that the Recalled BIOCELL Implants were not reasonably safe in construction.

5469. The Recalled BIOCELL Implants were not reasonably safe in construction because the Recalled BIOCELL Implants deviated in a material way from Defendant's design specifications and/or performance standards.

5470. Further, the Recalled BIOCELL Implants were unsafe to an extent beyond that which would be contemplated by the ordinary consumer.

5471. Plaintiffs and the Washington Subclass Members were implanted with Recalled BIOCELL Implants that were defective and adulterated upon manufacture, having been defectively manufactured in violation of applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements.

5472. To texturize the surface of Recalled BIOCELL Implants, Defendant utilized a specific manufacturing process known as the "salt loss" process. The salt loss process involved

applying solid particles of cubic salt over the surface of the implant shell, such that the salt particles were embedded into the surface of the implant, followed by a layer of silicone. The final silicone layer was washed and scrubbed off in an effort to remove all solid particles.

5473. The intended, specified process, consistent with the approved process under the PMAs, was to "gently agitate" the shell to "ensure dissolution of all the solid particles."

5474. The final scrubbing/abrading process was performed manually, using a variable and uncontrolled process, conducted by different workers using diverse brushes and unvalidated methods to reveal and release the salt embedded in the surface. This defective manual process resulted in overly-textured implants with degraded and loosened fragments of silicone particles, implant materials, and other unintended residues on the implant surface. This defective manufacturing process was also characterized by lack of quality control, lack of testing, and lack of validation. Defendant was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. § 351 and 21 C.F.R. §§ 808.1(d)(2)(ii), 820.70(c),(e),(h), and 820.75.

5475. This cause of action is based entirely on the contention that Defendant violated federal statutes and regulations, and is brought herein as a parallel state law claim, pursuant to state law, based upon Defendant's violation of the applicable federal regulations.

5476. Defendant violated current good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those of the FDA and the applicable PMAs, because their unsafe, highly variable process produced non-conforming, dangerous implants.

5477. Defendant's deficiencies, violations of manufacturing process, and failure to comply with applicable standards, specifications, good manufacturing practices, and FDA and applicable PMA standards and specifications, resulted in defectively manufactured and unreasonably dangerous Recalled BIOCELL Implants, with loss of particles and material from the surface, proximately causing unsafe inflammation, tissue damage, seromas, and BIA-ALCL.

5478. Defendant violated current good manufacturing practices, applicable regulations and other applicable standards and specifications, including those of the FDA and the applicable PMAs by, *inter alia*:

a. Failing to govern the manufacturing methods used to manufacture, produce, and distribute the Recalled BIOCELL Implants;

b. Failing to govern the manufacturing facilities and the quality controls used for the manufacture, packaging, and storage of all finished Recalled BIOCELL Implants;

c. Failing to adopt procedures and controls relating to quality assurance, manufacturing and processing, process validation, and device inspection, corrective and preventive action;

d. Failing to establish and maintain procedures to control a product that does not conform to specified requirements as required by 21 CFR § 820.90;

e. Failing to establish and maintain procedures for implementing corrective actions and preventive actions as required by 21 CFR § 820.100; and

f. Failing to follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to remove all solid particles, resulting in implants with unwanted fragmented silicone and degraded particles on the implant surface.

5479. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, the members of the putative class would not have (a) been subject to the accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (b) sustained a significantly increased risk of BIA-ALCL; or (c) undergone a costly, invasive surgery to explant the Recalled BIOCELL Implants.

5480. Defendant knew or should have known that its manufacturing process was defective, unsafe and dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured Recalled BIOCELL Implants with a significantly increased and unreasonable risk of causing severe injuries, including but not limited to those stated above.

5481. If Defendant had followed its own manufacturing specifications, injury to the Washington Subclass Members would not have occurred.

5482. Defendant knew that the defectively manufactured Recalled BIOCELL Implants would be implanted in the Washington Subclass Members and others without knowledge of the hazards involved in such use.

5483. As a direct and proximate result of Defendant's acts and omissions, the Washington Subclass members have sustained physical injury, have a significantly increased risk of BIA-ALCL, and have incurred or will incur damages, including the cost of explanting the Recalled BIOCELL Implants and fees associated with medical monitoring and diagnostic procedures.

COUNT 299
Washington – Strict Liability – Design Defect
Violation of Washington Product Liability Act, RCW § 7.72.010 et seq.

5484. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5485. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Washington Non-PMA Device Subclass.

5486. Defendant is strictly liable under the Washington Product Liability Act (RCW § 7.72.010 et seq.).

5487. At all relevant times, Defendant designed, tested, manufactured, marketed, distributed, and sold the Recalled BIOCELL Implants that were implanted into Plaintiffs. Defendant knew and intended for the Recalled BIOCELL Implants to be implanted into members of the public, including Plaintiffs.

5488. The design of the BIOCELL textured implants and tissue expanders, including but not limited to the texturing process and features of the design, was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, tissue damage, seromas, BIA-ALCL, and other related injuries.

5489. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the Recalled BIOCELL Implants not reasonably fit, suitable, or safe for their intended purpose.

5490. The dangers of the Recalled BIOCELL Implants outweighed the benefits and rendered the products unreasonably dangerous. Indeed, the BIOCELL products were marketed primarily as having a reduced implant contracture rate over other products, but Defendant found in its own studies that there were no statistically different contracture rates among its BIOCELL products and other products.

5491. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the BIOCELL products.

5492. "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Defendant's BIOCELL line is associated with the vast majority of ALCL cases.

5493. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been sold in the market.

5494. The BIOCELL products did not perform as an ordinary consumer would expect.

5495. The use of the Recalled BIOCELL Implants in Plaintiffs was foreseeable to the Defendant.

5496. As a direct and proximate result of Defendant's actions and omissions, Plaintiffs and members of the putative class have suffered physical injury, have a significantly increased risk of developing BIA-ALCL, and have suffered and will suffer economic losses including surgical costs of removing the implants, other medical expenses, and expenses associated with ongoing medical monitoring.

5497. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

H. MEDICAL MONITORING (INDEPENDENT CAUSE OF ACTION)

COUNT 300
MEDICAL MONITORING
Colorado

5498. Plaintiffs incorporate all preceding and subsequent paragraphs.

5499. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

5500. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5501. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5502. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5503. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have ensured that its manufacturing comported with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5504. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with

textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[28]

5505. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5506. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

5507. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.

5508. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

[28] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

5509. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5510. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5511. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5512. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5513. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5514. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled BIOCELL Implants. Without a court-approved medical monitoring program as described herein,

or established by the Court, the Colorado Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 301
MEDICAL MONITORING
Florida

5515. Plaintiffs incorporate all preceding and subsequent paragraphs.

5516. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass.

5517. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5518. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5519. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5520. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have ensured that its manufacturing comported with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5521. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which

there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[29]

5522. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5523. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

5524. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled

[29] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

5525. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5526. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5527. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5528. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5529. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5530. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled

BIOCELL Implants. Without a court-approved medical monitoring program as described herein, or established by the Court, the Florida Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 302
MEDICAL MONITORING
Massachusetts

5531. Plaintiffs incorporate all preceding and subsequent paragraphs.

5532. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

5533. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has caused subcellular damage, including inflammation, that have significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5534. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5535. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5536. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including subcellular damage and the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have ensured that its manufacturing comported

with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5537. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[30]

5538. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5539. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants, on the one hand, and subcellular damage and BIA-ALCL, on the other, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

5540. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively

[30] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.

5541. The subcellular damage and latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

5542. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5543. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5544. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5545. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5546. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all

medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5547. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled BIOCELL Implants. Without a court-approved medical monitoring program as described herein, or established by the Court, the Massachusetts Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 303
MEDICAL MONITORING
Montana

5548. Plaintiffs incorporate all preceding and subsequent paragraphs.

5549. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass.

5550. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5551. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5552. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5553. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar

circumstances would have ensured that its manufacturing comported with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5554. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[31]

5555. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5556. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

[31] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

5557. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.

5558. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

5559. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5560. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5561. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5562. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5563. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be

determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5564. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled BIOCELL Implants. Without a court-approved medical monitoring program as described herein, or established by the Court, the Montana Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 304
MEDICAL MONITORING
Pennsylvania

5565. Plaintiffs incorporate all preceding and subsequent paragraphs.

5566. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass.

5567. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5568. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5569. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5570. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have ensured that its manufacturing comported with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5571. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[32]

5572. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5573. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not

[32] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

5574. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.

5575. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

5576. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5577. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5578. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5579. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5580. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5581. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled BIOCELL Implants. Without a court-approved medical monitoring program as described herein, or established by the Court, the Pennsylvania Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 305
MEDICAL MONITORING
Utah

5582. Plaintiffs incorporate all preceding and subsequent paragraphs.

5583. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass.

5584. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5585. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5586. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5587. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have ensured that its manufacturing comported with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5588. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[33]

[33] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

5589. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5590. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

5591. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.

5592. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

5593. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5594. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5595. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5596. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5597. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5598. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled BIOCELL Implants. Without a court-approved medical monitoring program as described herein, or established by the Court, the Utah Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT ____
MEDICAL MONITORING
West Virginia

5599. Plaintiffs incorporate all preceding and subsequent paragraphs.

5600. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

5601. The Plaintiffs' exposure to and implantation of the Recalled BIOCELL Implants has significantly increased their risk of developing BIA-ALCL, a serious and potentially deadly cancer.

5602. At all relevant times Defendant had a duty to, *inter alia,*

a. Monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety;

b. Provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants, including through updated product labeling; and

c. Manufacture the Recalled BIOCELL Implants in accordance with good manufacturing practices, applicable regulations, and other applicable standards and specifications, including those set forth in the applicable PMAs.

5603. Defendant breached these duties by, *inter alia,*

a. Failing to comply with applicable reporting and monitoring requirements,

b. Failing to timely, adequately, and appropriately report adverse events to the FDA, which would have reached reach Plaintiffs, the class members, and their physicians;

c. Failing to warn Plaintiffs, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL;

d. Failing to manufacture the Recalled BIOCELL implants in accordance with applicable standards, specifications, good manufacturing practices, and FDA and PMA standards and requirements, resulting in a defectively manufactured, unreasonably dangerous, and adulterated device;

e. Failing to inform Plaintiffs, the class members, and their physicians that the Recalled BIOCELL Implants were not manufactured in conformance with PMAs and FDA requirements;

f. Failing to inform Plaintiffs, the class members, and their physicians that the existing warnings were misleading and minimized the risk of developing BIA-ALCL; and

g. Continuing to manufacture, distribute and/or sell the Recalled BIOCELL Implants notwithstanding these facts.

5604. At all relevant times, Defendant knew or should have known of the danger of exposing Plaintiffs to the Recalled BIOCELL Implants, including the significantly increased risk of BIA-ALCL. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have ensured that its manufacturing comported with applicable standards, regulations, practices, and requirements and/or would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

5605. On July 24, 2019, the FDA recognized the significant risks the Recalled BIOCELL Implants pose to Plaintiffs and instituted a Class I Recall. A Class I Recall is "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." The FDA concluded that "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with

textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL."[34]

5606. At the time of the recall, 84% of the worldwide reported cases of BIA-ALCL had occurred in patients with the Recalled BIOCELL Implants, greater than any "normal background levels."

5607. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between the Recalled BIOCELL Implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL. Plaintiffs would not have selected the Recalled BIOCELL Implants or sustained a significantly increased risk of BIA-ALCL.

5608. Had Defendant manufactured the Recalled BIOCELL Implants in accordance with applicable practices, regulations, and requirements, Plaintiffs would not have received defectively manufactured, unreasonably dangerous, and adulterated medical devices and would not have sustained a significantly increased risk of BIA-ALCL.

5609. The latent injuries from which Plaintiffs suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to the Recalled BIOCELL Implants and is different from that normally recommended in the absence of exposure to this risk of harm.

[34] https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed May 25, 2020).

5610. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in diagnosing BIA-ALCL. This diagnosis will facilitate treatment and interventions that will mitigate the development of and health effects associated with BIA-ALCL.

5611. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of lymphomas, including BIA-ALCL.

5612. By monitoring and testing Plaintiffs, the risk that Plaintiffs will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

5613. Plaintiffs, therefore, seek an injunction creating a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs for BIA-ALCL. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs as frequently and appropriately as necessary.

5614. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things, (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who received Recalled Breast Implants for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all medical monitoring class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

5615. Plaintiffs have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to the Recalled BIOCELL Implants. Without a court-approved medical monitoring program as described herein,

or established by the Court, the West Virginia Subclass Members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

I. BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

COUNT 306
Breach of the Implied Warranty of Merchantability
Alabama

5616. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5617. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Subclass.

5618. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Alabama Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5619. Pursuant to Ala. Code § 7-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5620. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unsafe and unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5621. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation

in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5622. Had Plaintiffs and the Alabama Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5623. Defendant's breaches of its implied warranties under Ala. Code § 7-2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and Ala. Code § 7-2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5624. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Alabama Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5625. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Alabama Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 307
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Alaska

5626. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5627. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

5628. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Alaska Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5629. Pursuant to Alaska Stat. § 45.02.314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5630. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5631. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's

Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5632. Had Plaintiffs and the Alaska Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5633. Defendant's breaches of its implied warranties under Alaska Stat. § 45.02.314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and Alaska Stat. § 45.02.314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5634. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Alaska Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5635. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Alaska Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 308
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
American Samoa

5636. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5637. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the American Samoa Subclass.

5638. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the American Samoa Subclass

Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5639. Pursuant to ASCA 27.0701, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5640. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unsafe and unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5641. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5642. Had Plaintiffs and the American Samoa Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5643. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the American Samoa Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5644. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the American Samoa Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 309
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Colorado

5645. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5646. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

5647. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Colorado Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5648. Pursuant to Colo. Rev. Stat. § 4-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5649. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact

made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5650. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5651. Had Plaintiffs and the Colorado Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5652. Defendant's breaches of its implied warranties under Colo. Rev. Stat. § 4-2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and Colo. Rev. Stat. § 4-2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5653. Plaintiffs and the Colorado Subclass Members have provided Defendant with notice of the breach of implied warranties. Additionally, Defendant received notice of the breach of implied warranties by numerous pending lawsuits and consumer communications.

5654. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Colorado Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5655. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Colorado Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 310
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
District of Columbia

5656. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5657. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the District of Columbia Subclass.

5658. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the District of Columbia Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5659. Pursuant to D.C. Code § 28:2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5660. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact

made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5661. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5662. Had Plaintiffs and the District of Columbia Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5663. Defendant's breaches of its implied warranties under D.C. Code § 28:2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and D.C. Code § 28:2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5664. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the District of Columbia Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5665. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the District of Columbia Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 311
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Guam

5666. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5667. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass.

5668. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Guam Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5669. Pursuant to 13 G.C.A. § 2314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5670. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unsafe and unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5671. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation

in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5672. Had Plaintiffs and the Guam Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5673. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Guam Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5674. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Guam Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 312
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Indiana

5675. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5676. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass.

5677. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Indiana Subclass

Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5678. Pursuant to Ind. Code § 26-1-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5679. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5680. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5681. Had Plaintiffs and the Indiana Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5682. Defendant's breaches of its implied warranties under Ind. Code § 26-1-2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and Ind. Code § 26-1-2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5683. Plaintiffs and the Indiana Subclass Members have provided Defendant with notice of the breach of implied warranties. Additionally, Defendant received notice of the breach of implied warranties by numerous pending lawsuits and consumer communications.

5684. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Indiana Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5685. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Indiana Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 313
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Iowa

5686. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5687. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass.

5688. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Iowa Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5689. Pursuant to Iowa Code Ann. § 554.2314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5690. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5691. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5692. Had Plaintiffs and the Iowa Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5693. Plaintiffs and the Iowa Subclass Members have provided Defendant with notice of the breach of implied warranties. Additionally, Defendant received notice of the breach of implied warranties by numerous pending lawsuits and consumer communications.

5694. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Iowa Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5695. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Iowa Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 314
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Maine

5696. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5697. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass.

5698. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Mississippi Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5699. Pursuant to 11 M.R.S.A. § 2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5700. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5701. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5702. Had Plaintiffs and the Maine Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5703. Plaintiffs and the Maine Subclass Members have provided Defendant with notice of the breach of implied warranties. Additionally, Defendant received notice of the breach of implied warranties by numerous pending lawsuits and consumer communications.

5704. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Maine Subclass Members

reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5705. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Maine Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 315
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Massachusetts

5706. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5707. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

5708. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Massachusetts Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5709. Pursuant to Mass. Gen. Laws, ch. 106, § 2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5710. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5711. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5712. Defendant's Recalled BIOCELL Implants contain defects that render them unreasonably dangerous for use because they (i) contain latent flaws that render the BIOCELL products unsuitable for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury.

5713. Had Plaintiffs and the Massachusetts Subclass Members known of the unmerchantable and/or unreasonably dangerous condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5714. Defendant's breaches of its implied warranties under M.G.L.A. 106 § 2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and M.G.L.A. 106 § 2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5715. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Massachusetts Subclass

Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5716. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Massachusetts Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 316_
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Minnesota

5717. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5718. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass.

5719. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Minnesota Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5720. Pursuant to Minn. Stat. § 336.2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5721. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5722. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5723. Had Plaintiffs and the Minnesota Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5724. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Minnesota Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5725. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Minnesota Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 317
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Mississippi

5726. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5727. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Subclass.

5728. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Mississippi Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5729. Pursuant to Miss. Code Ann. § 75-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5730. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5731. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5732. Had Plaintiffs and the Mississippi Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5733. Defendant's breaches of its implied warranties under Miss. Code Ann. § 75-2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and Miss. Code Ann. § 75-2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5734. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Mississippi Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5735. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Mississippi Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 318
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Nebraska

5736. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5737. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass.

5738. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Nebraska Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5739. Pursuant to Neb. Rev. Stat. (U.C.C.) § 2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5740. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5741. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they contain latent flaws that render the unsuitable for use in the human body. As such, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body, and Defendant deviated from the standard of merchantability at the time of sale.

5742. Had Plaintiffs and the Nebraska Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5743. Defendant has refused to provide appropriate warranty relief. Plaintiffs and the Nebraska Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants were not defective.

5744. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Nebraska Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 319
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
New Mexico

5745. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5746. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass.

5747. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the New Mexico Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5748. Pursuant to N.M. Stat. Ann. § 55-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5749. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5750. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation

in the human body. Defendant's Recalled BIOCELL Implants are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5751. Defendant's Recalled BIOCELL Implants contain defects that render them unreasonably dangerous for use because they (i) contain latent flaws that render the BIOCELL products unsuitable for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury.

5752. Had Plaintiffs and the New Mexico Subclass Members known of the unmerchantable and/or unreasonably dangerous condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5753. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the New Mexico Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5754. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the New Mexico Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 320
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
North Dakota

5755. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5756. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Subclass.

5757. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the North Dakota Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5758. Pursuant to N.D. Cent. Code § 41-02-32, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5759. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5760. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's Recalled BIOCELL Implants are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's

Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5761. Had Plaintiffs and the North Dakota Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5762. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the North Dakota Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5763. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the North Dakota Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 321
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Northern Mariana Islands

5764. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5765. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass.

5766. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Northern Mariana Islands Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5767. Pursuant to 5 N. Mar. I. Code § 2314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product

was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5768. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unsafe and unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5769. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5770. Had Plaintiffs and the Northern Mariana Islands Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5771. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Northern Mariana Islands Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5772. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Northern Mariana Islands Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 322
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Puerto Rico

5773. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5774. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Subclass.

5775. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Puerto Rico Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5776. Pursuant to P.R. Laws Ann. tit. 31, § 3841, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5777. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unsafe and unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5778. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled

breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5779. Had Plaintiffs and the Puerto Rico Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5780. Defendant's breaches of its implied warranties under P.R. Laws Ann. tit. 31, § 3841 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and P.R. Laws Ann. tit. 31, § 3841 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5781. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Puerto Rico Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5782. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Puerto Rico Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 323
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
South Carolina

5783. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5784. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass.

5785. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the South Carolina Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5786. Pursuant to S.C. Code Ann. § 36-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5787. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5788. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose

unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5789. Had Plaintiffs and the South Carolina Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5790. Defendant's breaches of its implied warranties under S.C. Code Ann. § 36-2-314 parallel its violations of federal law; the Recalled BIOCELL Implants' PMA specifically mandates, and S.C. Code Ann. § 36-2-314 independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

5791. Plaintiffs and the South Carolina Subclass Members have provided Defendant with notice of the breach of implied warranties. Additionally, Defendant received notice of the breach of implied warranties by numerous pending lawsuits and consumer communications.

5792. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the South Carolina Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5793. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the South Carolina Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 324
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
South Dakota

5794. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5795. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Subclass.

5796. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the South Dakota Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5797. Pursuant to S.D. Codified Laws § 57A-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5798. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5799. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's

Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5800. Had Plaintiffs and the South Dakota Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5801. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the South Dakota Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5802. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the South Dakota Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 325
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Tennessee

5803. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5804. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass.

5805. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Tennessee Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5806. Pursuant to Tenn. Code Ann. § 47-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product

was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5807. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5808. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5809. Had Plaintiffs and the Tennessee Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5810. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Tennessee Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5811. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Tennessee Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 326
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Texas

5812. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5813. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass.

5814. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Texas Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5815. Pursuant to Tex. Bus. & Com. Code § 2.314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5816. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5817. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation

in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5818. Had Plaintiffs and the Texas Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5819. As described in detail above, Defendant violated federal FDA and PMA standards in turn causing Defendant to breach the implied warranty of merchantability.

5820. Plaintiffs and the Texas Subclass Members have provided Defendant with notice of the breach of implied warranties. Additionally, Defendant received notice of the breach of implied warranties by numerous pending lawsuits and consumer communications.

5821. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Texas Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5822. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Texas Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 327
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
U.S. Virgin Islands

5823. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5824. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the U.S. Virgin Islands Subclass.

5825. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the U.S. Virgin Islands Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5826. Pursuant to V.I. Code Ann. tit. 11A, § 2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5827. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unsafe and unfit for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5828. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's

Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5829. Had Plaintiffs and the U.S. Virgin Islands Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5830. Plaintiffs and each member of the U.S. Virgin Islands Subclass have had sufficient direct dealings with either Defendant via their website or their agents (including distributors, dealers, and sellers authorized by Defendant) to establish privity of contract between Defendant, on the one hand, and Plaintiffs and each member of the class, on the other hand.

5831. Further, Plaintiffs and each member of the U.S. Virgin Islands Subclass were third-party beneficiaries of Defendant's agreements with their distributors, dealers, and sellers for the distribution, dealing, and sale of the Recalled BIOCELL Implants to end user consumers. Specifically, Plaintiffs and class members are the intended beneficiaries of Defendant's implied warranties. Defendant's Recalled BIOCELL Implants are manufactured with the express purpose and intent of being sold to end user consumers.

5832. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the U.S. Virgin Islands Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5833. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the U.S. Virgin Islands Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 328
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
West Virginia

5834. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5835. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

5836. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the West Virginia Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5837. Pursuant to W. Va. Code § 46-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5838. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5839. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose

unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5840. Had Plaintiffs and the West Virginia Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5841. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the West Virginia Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5842. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the West Virginia Subclass Members have sustained damages in an amount to be determined at trial.

COUNT 329
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
Wyoming

5843. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5844. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass.

5845. Defendant has at all relevant times been a merchant with respect to the Recalled BIOCELL Implants that were sold to and implanted in Plaintiffs and the Wyoming Subclass Members, and was in the business of manufacturing, selling, and distributing the Recalled BIOCELL Implants.

5846. Pursuant to Wyo. Stat. Ann. § 34.1-2-314, each Recalled BIOCELL Implant manufactured, sold and distributed by Defendant included an implied warranty that the product

was merchantable, safe, and fit for the ordinary purpose for which it will be used, and measures up to the representations stated by the manufacturer.

5847. Defendant has breached the implied warranty of merchantability because the Recalled BIOCELL Implants were unfit and unsafe for their intended use, not in merchantable condition when sold, defective when sold, did not conform to the promises and affirmations of fact made on the Recalled BIOCELL Implants' labels, and/or do not possess even the most basic degree of fitness for ordinary use.

5848. The ordinary intended purpose of Defendant's Recalled BIOCELL Implants—and the purpose for which they are marketed, promoted, and sold—is to serve as a safe silicone-filled breast implant and tissue expander, which was intended to reduce complications post-implantation in the human body. Defendant's BIOCELL products are not fit for that use—or any other use—because they (i) contain latent flaws that render them unsuitable and unsafe for use in the human body; (ii) subject patients to a significantly increased risk of BIA-ALCL; and (iii) pose unreasonable risks of substantial bodily injury. Due to these and other features, Defendant's Recalled BIOCELL Implants are not fit for their ordinary, intended use as breast implants and tissue expanders in the human body.

5849. Had Plaintiffs and the Wyoming Subclass Members known of the unmerchantable condition of the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants or had them implanted.

5850. Defendant has refused to provide appropriate warranty relief, notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Wyoming Subclass Members reasonably expected, at the time of purchase, that their Recalled BIOCELL Implants would not present a substantial risk of bodily harm and were not defective.

5851. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Wyoming Subclass Members have sustained damages in an amount to be determined at trial.

5852. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiffs and the Wyoming Subclass Members have sustained damages in an amount to be determined at trial.

J. VIOLATIONS OF STATE CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES ACTS

COUNT 330
ALABAMA DECEPTIVE TRADE PRACTICES ACT
ALABAMA CODE §§ 8-19-1, ET. SEQ.
Alabama

5853. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5854. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Subclass.

5855. Plaintiffs and the Alabama Subclass Members purchased their Recalled BIOCELL Implants primarily for personal, family or household purposes within the meaning of Ala. Code § 8-19-3(2).

5856. All of the acts complained of herein were perpetrated by Defendant in the course of trade or commerce within the meaning of Ala. Code § 8-19-5.

5857. The Alabama Deceptive Trade Practices Act prohibits unfair or deceptive acts or practices, including, "engaging in . . .unconscionable, false, misleading, or deceptive act[s] or practice[s] in the conduct of trade or commerce." Ala. Code. § 8-19-5(27). Defendant engaged in unlawful trade practices, and unfair or deceptive acts or practices that violated the Alabama Deceptive Trade Practices Act.

5858. Defendant participated in unfair or deceptive trade practices that violated the Alabama Deceptive Trade Practices Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

5859. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

5860. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5861. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

5862. Defendant knew or should have known that its conduct violated the Alabama Deceptive Trade Practices Act

5863. Had Plaintiffs and the Alabama Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

5864. Defendant owed Plaintiffs and the Alabama Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Alabama Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Alabama Subclass Members that contradicted these representations.

5865. Plaintiffs and the Alabama Subclass Members suffered monetary damages as a result of Defendant's conduct.

5866. Defendant's violations present a continuing risk to Plaintiffs and the Alabama Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

5867. Defendant does not maintain a place of business or assets in the state of Alabama thus obviating the need to send any pre-suit notice.

5868. Defendant is liable to Plaintiffs and the Alabama Subclass Members for actual damages sustained or $100, whichever is greater, treble damages, and attorneys' fees and costs. Ala. Code § 8-19-10(a)(1)-(3).

COUNT 331
ALASKA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT
ALASKA STAT. §§ 45.50.471, *ET SEQ.*
Alaska

5869. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5870. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alaska Subclass.

5871. The Alaska Unfair Trade Practices and Consumer Protection Act, among other things, makes it unlawful to (1) represent that goods or services "have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" or "are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another," or (2) "us[e] or employ[] deception, fraud, false pretense, false promise, misrepresentation, or knowingly conceal[], suppress[], or omit[] a material fact with intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods or services whether or not a person has in fact been misled, deceived, or damaged." Alaska Stat. § 45.50.471.

5872. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices, deception, fraud, false pretense, false promise, misrepresentation, and the knowing concealment, suppression, or omission of a material fact with intent that others rely upon that concealment, suppression, or omission, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Alaska Subclass Members, in violation of Alaska Stat. §§ 45.50.471, *et seq.*, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

5873. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted in connection with the sale or advertisement of "goods," as defined Alaska Stat. §§ 45.50.561(a)(9).

5874. The above unlawful acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

5875. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Alaska Subclass members.

5876. Defendant's actions were material to Plaintiffs and Alaska Subclass members, who relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

5877. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and Alaska Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

5878. Plaintiffs and Alaska Subclass members seek relief under Alaska Stat. § 45.50.531 and 45.50.537(a), including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, and attorneys' fees and costs.

COUNT 332
ARIZONA CONSUMER FRAUD ACT
A.R.S. §§ 44-1521, *ET. SEQ.*
Arizona

5879. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5880. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arizona Subclass.

5881. The Arizona Consumer Fraud Act prohibits "[t]he act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or

advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged." A.R.S. § 44-1522.

5882. Defendant engaged in unlawful trade practices, and unfair or deceptive acts or practices that violated the Arizona Consumer Fraud Act.

5883. Defendant participated in unfair or deceptive trade practices that violated the Arizona Consumer Fraud Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

5884. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

5885. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5886. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

5887. Defendant knew or should have known that its conduct violated the Arizona Consumer Fraud Act.

5888. Had Plaintiffs and the Arizona Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

5889. Defendant owed Plaintiffs and the Arizona Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Alabama Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Arizona Subclass Members that contradicted these representations.

5890. Plaintiffs and the Arizona Subclass Members suffered monetary damages as a result of Defendant's conduct.

5891. Defendant's violations present a continuing risk to Plaintiffs and the Arizona Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

5892. Defendant is liable to Plaintiffs and the Arizona Subclass Members for their damages, punitive damages, attorneys' fees costs.

COUNT 333
ARKANSAS DECEPTIVE TRADE PRACTICES ACT
ARK. CODE ANN. §§ 4-88-101, *ET SEQ.*
Arkansas

5893. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5894. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Subclass

5895. The Arkansas Deceptive Trade Practices Act prohibits deceptive and unconscionable trade practices, including, among other things, "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services or as to whether goods are original or new or of a particular standard, quality, grade, style, or model" or "[e]ngaging in any other unconscionable, false, or deceptive act or practice in business, commerce, or trade." Ark. Code Ann. § 4-88-107.

5896. The Arkansas Deceptive Trade Practices Act makes it unlawful to engage in "any deception, fraud, or false pretense" or "[t]he concealment, suppression, or omission of any material fact with intent that others rely upon the concealment, suppression, or omission" "[w]hen utilized in connection with the sale or advertisement of any goods." Ark. Code Ann. § 4-88-108.

5897. Defendant engaged in unlawful deceptive and unconscionable trade practices, deception, fraud, or false pretense, and the concealment, suppression, or omission of any material fact with intent that others rely upon that concealment, suppression, or omission, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Arkansas Subclass Members, in violation of Ark. Code Ann. §§ 4-88-101, *et seq.*, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

5898. The above deceptive and unconscionable trade practices or acts by Defendant were conducted in connection with the sale or advertisement of "goods," as defined Ark. Code Ann. § 4-88-102(4).

5899. The above unlawful acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

5900. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Arkansas Subclass members.

5901. Defendant's actions were material to Plaintiffs and Arkansas Subclass members, who relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

5902. As a direct and proximate result of Defendant's unlawful deceptive and unconscionable acts or practices, Plaintiffs and Arkansas Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

5903. Plaintiffs and Arkansas Subclass members seek relief under Ark. Code Ann. § 4-88-113(f)(1)(A), including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, and attorneys' fees and costs.

COUNT 334
CALIFORNIA CONSUMER LEGAL REMEDIES ACT
CAL. CIVIL CODE §§ 1750, *ET. SEQ.*
California

5904. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5905. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass.

5906. Defendant is a "person" as defined by California Civil Code § 1761(c).

5907. Plaintiffs and California Subclass Members are "consumers" within the meaning of California Civil Code § 1761(d) because they purchased their recalled Recalled BIOCELL Implants primarily for personal, family, or household use.

5908. By failing to disclose and concealing the true risks of the Recalled BIOCELL Implants and by failing to comply with federal law, Defendant violated California Civil Code § 1770(a), as they represented that Recalled BIOCELL Implants had characteristics and benefits that they do not have and represented that the Recalled BIOCELL Implants were of a particular standard, quality, or grade when they were of another. See Cal. Civ. Code §§ 1770(a)(5) & (7).

5909. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5910. Defendant knew of the true risks with Recalled BIOCELL Implants and that they were not suitable for their intended use.

5911. Because of their reliance on Defendant's omissions, Plaintiffs and California Subclass Members, suffered an ascertainable loss of money, property, and/or value. Additionally, because of inherent danger the Recalled BIOCELL Implants pose, Plaintiffs and California Subclass Members were harmed and suffered actual damages.

5912. Defendant was under a duty to Plaintiffs and California Subclass Members the true risks with Recalled BIOCELL Implants because:

a. Defendant was in a superior position to know the true state of facts about the Recalled BIOCELL Implants;

b. Plaintiffs and California Subclass Members could not reasonably have been expected to learn or discover the dangers posed by the Recalled BIOCELL Implants; and

c. Defendant knew that Plaintiffs and California Subclass Members could not reasonably have been expected to learn of or discover the dangers posed by the Recalled BIOCELL Implants.

5913. In failing to disclose the truth about the Recalled BIOCELL Implants, Defendant knowingly and intentionally concealed material facts and breached their duty not to do so.

5914. The facts Defendant concealed from or failed to disclose to Plaintiffs and California Subclass Members are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase and implant Recalled BIOCELL Implants. Had Plaintiffs and California Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased the Recalled BIOCELL Implants and had them implanted.

5915. Plaintiffs and California Subclass Members are reasonable consumers who did not expect the risks inherent with the Recalled BIOCELL Implants. This is the reasonable and objective consumer expectation relating to breast implants.

5916. As a direct and proximate result of Defendant's unfair or deceptive acts or practices, Plaintiffs and California Subclass Members were harmed and suffered, and will continue to suffer, actual damages.

5917. Plaintiffs and California Subclass Members are entitled to equitable relief.

5918. With the filing of this complaint, Plaintiffs and California Subclass Members will provide Defendant with notice of their violations pursuant to California Civil Code § 1782(a). If Defendant fails to provide appropriate relief for its violations within 30 days, Plaintiffs will seek monetary, compensatory, and punitive damages.

COUNT 335
CALIFORNIA UNFAIR COMPETITION LAW
CAL. CIVIL CODE §§ 17200, ET. SEQ.
California

5919. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5920. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass.

5921. California Business & Professions Code § 17200 prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

5922. The acts and practices of Defendant as alleged herein constitute "unfair" business acts and practices under the UCL in that Defendant's conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Defendant's conduct outweighs any conceivable benefit of such conduct.

5923. Defendant has, in the course of its business and in the course of trade or commerce, undertaken and engaged in unfair business acts and practices under the UCL by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

5924. These acts also constitute "fraudulent" business acts and practices under the UCL in that Defendant's conduct is false, misleading, and has a tendency to deceive the Class and the general public.

5925. Plaintiffs and California Class Members have suffered injury in fact and have lost money as a result of Defendant's fraudulent business acts or practices.

5926. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiffs and California Class Members in that Defendant has

systematically perpetrated the unfair conduct upon members of the public by engaging in the conduct described herein.

5927. Pursuant to Business and Professions Code§§ 17200 and 17203, Plaintiffs and California Class Members seek an order providing restitution and disgorgement of all profits relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

5928. Because of their reliance on Defendant's omissions concerning the Recalled BIOCELL Implants, Plaintiffs and California Subclass Members suffered an ascertainable loss of money, property, and/or value and were harmed and suffered actual damages.

5929. Plaintiffs and California Subclass Members are reasonable consumers who did not expect the risks inherent with the Recalled BIOCELL Implants.

5930. Defendant's conduct in concealing and failing to disclose the is unfair in violation of the UCL, because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

5931. Allergan acted in an immoral, unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner, including as follows:

a. Selling Recalled BIOCELL Implants that it knew to present a substantially greater risk of developing BIA-ALCL than competing textured breast implants;

b. Concealing the clear connection between its Recalled BIOCELL Implants and BIA-ALCL from the FDA, consumers, and medical professionals;

c. Failing to disclose that the Recalled BIOCELL Implants have a substantially greater risk of developing BIA-ALCL than competing textured breast implants and;

d. Minimizing the scope of the risks associated with using the Recalled BIOCELL Implants in communications with the public.

5932. The gravity of harm resulting from Allergan's unfair conduct outweighs any potential utility. The practice of selling breast implants that present a substantial health risk to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

5933. The harm from Allergan's conduct was not reasonably avoidable by consumers because only Allergan was aware of the true facts concerning its Recalled BIOCELL Implants and BIA-ALCL, and Allergan did not disclose them, despite receiving information establishing a causal connection between the Recalled BIOCELL Implants and BIA-ALCL from clinical testing, medical literature and studies, communications from the FDA and international agencies, and consumer complaints. Plaintiffs and California Subclass members did not know of and had no reasonable means of discovering the true risk of using the Recalled BIOCELL Implants.

5934. There were reasonably available alternatives that would further Allergan's business interest of satisfying and retaining its customers while maintaining profitability, such as: (1) completely and accurately disclosing adverse events to the public; (2) acknowledging the significantly greater risk of BIA-ALCL with its Recalled BIOCELL Implants and paying for surgery to remove the implants for patients with recalled implants; and (3) disclosing the true extent of the risk of BIA-ALCL to prospective purchasers.

5935. Plaintiffs suffered injury in fact, including lost money or property, as a result of Defendant unfair acts. Absent Defendant unfair conduct, Plaintiffs would not have selected Allergan implants.

5936. Through its unfair conduct, Defendant acquired money that Plaintiffs once had an ownership interest in either directly or through Plaintiffs' medical professionals.

5937. Plaintiffs and California Subclass Members accordingly seek appropriate relief under the UCL, including (a) restitution in full and (b) such orders or judgments as may be necessary to enjoin Allergan from continuing its unfair practices. Plaintiffs also seek reasonable attorneys' fees and costs under applicable law, including California Code of Civil Procedure section 1021.5.

COUNT 336
COLORADO CONSUMER PROTECTION ACT
COLO. REV. STAT. §§ 6-1-101, *ET. SEQ.*
Colorado

5938. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5939. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass.

5940. The Colorado Consumer Protection Act prohibits unfair or deceptive acts or practices, including, "fail[ing] to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction." Colo. Rev. Stat. § 6-1-105(u). Defendant engaged in deceptive acts or practices that violated the Colorado Consumer Protection Act.

5941. Defendant participated in unfair or deceptive trade practices that violated the Colorado Consumer Protection Act as described below and alleged throughout the Complaint. By

concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

5942. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

5943. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5944. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

5945. Defendant knew or should have known that its conduct violated the Colorado Consumer Protection Act.

5946. Had Plaintiffs and the Colorado Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

5947. Defendant owed Plaintiffs and the Colorado Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b)

intentionally concealed the foregoing from Plaintiffs and the Colorado Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Colorado Subclass Members that contradicted these representations.

5948. Plaintiffs and the Colorado Subclass Members suffered monetary damages as a result of Defendant's conduct.

5949. Defendant's violations present a continuing risk to Plaintiffs and the Colorado Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

5950. Defendant is liable to Plaintiffs and the Colorado Subclass Members for actual damages sustained.

COUNT 337
CONNECTICUT UNFAIR TRADE PRACTICES ACT
CONN. GEN. STAT. §§ 42-110A, *ET. SEQ.*
Connecticut

5951. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5952. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Connecticut Subclass.

5953. The Connecticut Unfair Trade Practices Act prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110(b)(a).

5954. Defendant participated in unfair or deceptive trade practices that violated the Connecticut Unfair Trade Practices Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically

misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

5955. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

5956. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5957. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

5958. Defendant knew or should have known that its conduct violated the Connecticut Unfair Trade Practices Act.

5959. Had Plaintiffs and the Connecticut Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

5960. Defendant owed Plaintiffs and the Connecticut Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Connecticut Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while

purposefully withholding material facts from Plaintiffs and the Connecticut Subclass Members that contradicted these representations.

5961. Plaintiffs and the Connecticut Subclass Members suffered monetary damages as a result of Defendant's conduct.

5962. Defendant's violations present a continuing risk to Plaintiffs and the Connecticut Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

5963. Defendant is liable to Plaintiffs and the Connecticut Subclass Members for actual damages, punitive damages, equitable relief, attorneys' fees and costs. Conn. Gen. Stat. § 42-110g(a), (d).

5964. A copy of this complaint is being mailed to the Connecticut Attorney General and the Connecticut Commissioner of Consumer Protection. Conn. Gen. Stat. § 42-110g(d).

COUNT 338
DELAWARE CONSUMER FRAUD ACT
DEL. CODE ANN. § 2511, *ET. SEQ.*
Delaware

5965. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5966. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Delaware Subclass.

5967. The Delaware Consumer Fraud Act prohibits "the act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale . . . of any merchandise." Del. Code Ann. § 2513.

5968. Defendant participated in unfair or deceptive trade practices that violated the Delaware Consumer Fraud Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

5969. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

5970. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5971. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

5972. Defendant knew or should have known that its conduct violated the Delaware Consumer Fraud Act.

5973. Had Plaintiffs and the Delaware Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

5974. Defendant owed Plaintiffs and the Delaware Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Delaware Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Delaware Subclass Members that contradicted these representations.

5975. Plaintiffs and the Delaware Subclass Members suffered monetary damages as a result of Defendant's conduct.

5976. Defendant's violations present a continuing risk to Plaintiffs and the Delaware Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

5977. Defendant is liable to Plaintiffs and the Delaware Subclass Members for all damages sustained. Del. Code Ann. § 2525.

COUNT 339
DISTRICT OF COLUMBIA CONSUMER PROTECTION ACT,
D.C. CODE § 28-3901, ET SEQ.
District of Columbia

5978. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5979. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the D.C. Subclass.

5980. The D.C. Consumer Protection Act prohibits "unfair or deceptive trade practice[s]." D.C. Code § 28-3904.

5981. Defendant participated in unfair or deceptive trade practices that violated the D.C. Consumer Protection Act as described below and alleged throughout the Complaint. By

concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

5982. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

5983. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

5984. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

5985. Defendant knew or should have known that its conduct violated the D.C. Consumer Protection Act

5986. Had Plaintiffs and the D.C. Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

5987. Defendant owed Plaintiffs and the D.C. Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally

concealed the foregoing from Plaintiffs and the D.C. Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the D.C. Subclass Members that contradicted these representations.

5988. Plaintiffs and the D.C. Subclass Members suffered monetary damages as a result of Defendant's conduct.

5989. Defendant's violations present a continuing risk to Plaintiffs and the D.C. Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

5990. Defendant is liable to Plaintiffs and the D.C. Subclass Members for all damages sustained, treble damages of $1,500, punitive damages, attorneys' fees and costs, and injunctive relief. D.C. Code § 28-3905(k)(1).

COUNT 340
FLORIDA DECEPTIVE TRADE PRACTICES ACT,
FLA. STAT. ANN. § 501.201, *ET SEQ*.
Florida

5991. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

5992. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass.

5993. Defendant's business acts and practices alleged herein constitute unfair, unconscionable and/or deceptive methods, acts or practices under the Florida Deceptive and Unfair Trade Practices Act, § 501.201, *et seq*. ("FDUTPA").

5994. At all relevant times, Plaintiffs and the Florida Subclass Members were "consumers" within the meaning of the FDUTPA. F.S.A. § 501.203(7).

5995. Defendant's conduct, as set forth herein, occurred in the conduct of "trade or commerce" within the meaning of the FDUTPA. F.S.A. § 501.203(8).

5996. Defendant's omissions and practices described herein were likely to, and did in fact, deceive and mislead members of the public, including Plaintiffs and the Florida Subclass Members, acting reasonably under the circumstances, to their detriment. By failing to he true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant violated FDUTPA.

5997. Defendant failed to reveal facts that were material to Plaintiffs and the Florida Subclass Members' decisions to purchase and implant the Recalled BIOCELL Implants, and Defendant intended that Plaintiffs and the Florida Subclass Members would rely upon the omissions.

5998. Defendant's actions impact the public interest because Plaintiffs and the Florida Subclass Members were injured in exactly the same way as hundreds or thousands of others purchasing and implanting the Recalled BIOCELL Implants as a result of and pursuant to Defendant's generalized course of deception.

5999. Had Plaintiffs and the Florida Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants.

6000. The foregoing acts, omissions and practices proximately caused Plaintiffs and the Florida Subclass Members to suffer actual damages with they are entitled to recover such damages, together with attorneys' fees and costs of suit.

COUNT 341
GEORGIA FAIR BUSINESS PRACTICES ACT,
GA. CODE §§ 10-1-390, *ET SEQ*.
Georgia

6001. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6002. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Subclass.

6003. The Georgia Fair Business Practices Act prohibits "unfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices." Ga. Code § 10-1-393(a).

6004. Defendant participated in unfair or deceptive trade practices that violated the Georgia Fair Business Practices Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

6005. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

6006. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

6007. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

6008. Defendant knew or should have known that its conduct violated the Georgia Fair Business Practices Act.

6009. Had Plaintiffs and the Georgia Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

6010. Defendant owed Plaintiffs and the Georgia Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Georgia Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Georgia Subclass Members that contradicted these representations.

6011. Plaintiffs and the Georgia Subclass Members suffered monetary damages and ascertainable losses as a result of Defendant's conduct.

6012. Defendant's violations present a continuing risk to Plaintiffs and the Georgia Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

6013. Defendant is liable to Plaintiffs and the Georgia Subclass Members for actual damages, exemplary damages, equitable relief, attorneys' fees and costs. Ga. Code. § 10-1-399.

6014. Defendant do not maintain a place of business or keep assets in the state of Georgia thus obviating the need for any pre-suit notice.

COUNT 342
HAWAII UNFAIR AND DECEPTIVE TRADE PRACTICES ACT,
HAW. REV. STAT. § 480-2 *ET SEQ*.
Hawaii

6015. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6016. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Subclass.

6017. The Hawaii Unfair and Deceptive Trade Practices Act prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Haw. Rev. Stat. § 480-2(a).

6018. Defendant participated in unfair or deceptive trade practices that violated the Hawaii Unfair and Deceptive Trade Practices Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

6019. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

6020. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

6021. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

6022. Defendant knew or should have known that its conduct violated the Hawaii Unfair and Deceptive Trade Practices Act

6023. Had Plaintiffs and the Hawaii Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

6024. Defendant owed Plaintiffs and the Hawaii Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Hawaii Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Hawaii Subclass Members that contradicted these representations.

6025. Plaintiffs and the Hawaii Subclass Members suffered monetary damages as a result of Defendant's conduct.

6026. Defendant's violations present a continuing risk to Plaintiffs and the Hawaii Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

6027. Defendant is liable to Plaintiffs and the Hawaii Subclass Members for actual damages, treble damages, equitable relief, attorneys' fees and costs. Haw. Rev. Stat. § 480-13.

COUNT 343
IDAHO CONSUMER PROTECTION ACT,
IDAHO CODE ANN. §§ 48-601, *ET SEQ.*
Idaho

6028. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6029. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Subclass.

6030. The purpose of the Idaho Consumer Protection Act is to "protect both consumers and businesses against unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce." Idaho Code Ann. § 48-601.

6031. The Idaho Consumer Protection Act prohibits methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce, including, among other things, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have" or "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." Idaho Code Ann. § 48-603.

6032. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Idaho Subclass Members, in violation of Idaho Code Ann. §§ 48-601, *et seq.*, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6033. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted as part of "trade" or "commerce" as defined by Idaho Code Ann. § 48-602(2).

6034. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6035. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Idaho Subclass members.

6036. Plaintiffs and Idaho Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6037. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and Idaho Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6038. Plaintiffs and Idaho Subclass members seek relief under Idaho Code Ann. § 48-608, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, treble damages, civil penalties, and attorneys' fees and costs.

COUNT 344
ILLINOIS CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES ACT
815 ILCS § 505/1, *ET. SEQ.*
Illinois

6039. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6040. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Subclass.

6041. Defendant engaged in unlawful, unfair, and deceptive acts and practices, with respect to the sale and advertisement of the products purchased by Plaintiffs and Illinois Subclass Members, in violation of 815 ILCS § 505/2, including by concealing the true risks of the Recalled

BIOCELL Implants and failing to comply with federal law. These injuries outweigh any benefits to consumers or to competition.

6042. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6043. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Illinois Subclass members.

6044. Plaintiffs and Illinois Subclass members would not have purchased, chosen, and/or paid for all or part of BIOCELL had they known that they would be exposed to the risk of developing BIA-ALCL.

6045. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Illinois Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6046. Plaintiffs and Illinois Subclass members seek relief under 815 ILCS § 505/10a, including, but not limited to injunctive relief, damages, restitution, punitive damages and attorneys' fees and costs.

6047. A copy of this complaint is being sent to the Illinois Attorney General. 815 ILCS § 505/10d.

COUNT 345
INDIANA DECEPTIVE TRADE PRACTICES LAWS
IND. CODE ANN. § 24-5-0.5.1, *ET SEQ.*
Indiana

6048. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6049. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass.

6050. Indiana's deceptive trade practices laws generally adhere to the Uniform Deceptive Trade Practices Act. The purpose of these laws is to "protect consumers from suppliers who commit deceptive and unconscionable sales acts." Ind. Code Ann. § 24-5-0.5.1 (b)(2).

6051. Defendant engaged in unfair, false, misleading, or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Indiana Subclass Members, in violation of Ind. Code Ann. § 24-5-0.5.1, et seq., including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6052. Defendant's actions described above demonstrate its knowledge of its deceptive acts and its intent to defraud Plaintiffs and the Indiana Subclass.

6053. The above unfair, false, misleading, or deceptive acts or practices by Defendant were conducted as part of a "consumer transaction" as defined by Ind. Code Ann. § 24-5-0.5.2(a)(1).

6054. The above unfair, false, misleading, or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6055. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Indiana Subclass members.

6056. Plaintiffs and Indiana Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6057. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Indiana Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6058. Plaintiffs and Indiana Subclass members seek relief under Ind. Code Ann. § 24-5-0.5.1, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, treble damages, civil penalties and attorneys' fees and costs.

COUNT 346
IOWA CONSUMER FRAUD ACT
IOWA CODE §§ 714H, 714.16
Iowa

6059. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6060. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass.

6061. The Iowa Consumer Fraud Act prohibits "practice or act the person knows or reasonably should know is an unfair practice, deception, fraud, false pretense, or false promise, or the misrepresentation, concealment, suppression, or omission of a material fact, with the intent that others rely upon the unfair practice, deception, fraud, false pretense, false promise, misrepresentation, concealment, suppression, or omission in connection with the advertisement, sale, or lease of consumer merchandise, or the solicitation of contributions for charitable purposes." Iowa Code § 714H.3.

6062. Defendant participated in unfair or deceptive trade practices that violated the Iowa Consumer Fraud Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant

knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

6063. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

6064. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

6065. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

6066. Defendant knew or should have known that its conduct violated the Iowa Consumer Fraud Act.

6067. Had Plaintiffs and the Iowa Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

6068. Defendant owed Plaintiffs and the Iowa Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Iowa Subclass Members; and/or (c) made

incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the Iowa Subclass Members that contradicted these representations.

6069. Plaintiffs and the Iowa Subclass Members suffered monetary damages and ascertainable losses as a result of Defendant's conduct.

6070. Defendant's violations present a continuing risk to Plaintiffs and the Iowa Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

6071. Defendant is liable to Plaintiffs and the Iowa Subclass Members for actual damages, treble damages, equitable relief, attorneys' fees and costs. Iowa Code § 714H.5.

6072. A copy of this complaint is being sent to the Iowa Attorney General. Iowa Code § 714H.6.

COUNT 347
KANSAS CONSUMER PROTECTION ACT
KAN. STAT. ANN. §§ 50-623, *ET SEQ.*
Kansas

6073. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6074. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Subclass.

6075. A key policy purpose of the Kansas Consumer Protection Act, which is to be "construed liberally," is "to protect consumers from suppliers who commit deceptive and unconscionable practices." Kan. Stat. Ann. § 50-623.

6076. The Kansas Consumer Protection Act prohibits suppliers from engaging in deceptive acts and practices "in connection with a consumer transaction," which include, among other things, (1) representations made knowingly or with reason to know that "[p]roperty or

services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have," (2) representations made knowingly or with reason to know that "property or services are of particular standard, quality, grade, style or model, if they are of another which differs materially from the representation," (3) "the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact," and (4) "the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact." Kan. Stat. Ann. § 50-626(b)(1-3).

6077. The Recalled BIOCELL Implants purchased by Plaintiffs and Kansas Subclass Members are "property" as defined by Kan. Stat. Ann. § 50-624(j).

6078. Defendant is a "supplier" as defined by Kan. Stat. Ann. § 50-624(l).

6079. Defendant engaged in deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Kansas Subclass Members, in violation of Kan. Stat. Ann. §§ 50-623, *et seq.*, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6080. The above deceptive acts or practices by Defendant were conducted in connection with "consumer transactions" as defined by Kan. Stat. Ann. § 50-624(c).

6081. The above unlawful deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6082. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Kansas Subclass members.

6083. Plaintiffs and Kansas Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6084. As a direct and proximate result of Defendant's deceptive acts or practices, Plaintiffs and Kansas Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6085. Plaintiffs and Kansas Subclass members seek relief under by Kan. Stat. Ann. § 50-634, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, civil penalties and attorneys' fees and costs.

COUNT 348
KENTUCKY CONSUMER PROTECTION ACT
KENTUCKY REVISED STATUTES ANNOTATED §§ 367.110, *ET SEQ.*
Kentucky

6086. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6087. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Subclass.

6088. The Kentucky Consumer Protection Act was passed after its legislature found that "the public health, welfare and interest require a strong and effective consumer protection program to protect the public interest and the well-being of both the consumer public and the ethical sellers of goods and services" and declared unlawful "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce."

6089. Defendant engaged in unfair, false, misleading, or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs

and Kentucky Subclass Members, in violation of Ky. Rev. Stat. Ann. § 367.170, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6090. The above unfair, false, misleading, or deceptive acts or practices by Defendant were conducted in "trade" or "commerce," as defined by Ky. Rev. Stat. Ann. § 367.110(2).

6091. The above unfair, false, misleading, or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6092. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Kentucky Subclass members.

6093. Plaintiffs and Kentucky Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6094. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Kentucky Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6095. Plaintiffs and Kentucky Subclass members seek relief under Kentucky Ky. Rev. Stat. Ann. § 367.220, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 349
MAINE UNFAIR TRADE PRACTICES ACT
ME. REV. STAT. ANN. TIT. 5, §§ 205A, *ET SEQ.*
Maine

6096. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6097. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass.

6098. The Maine Unfair Trade Practices Act prohibits unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. Me. Rev. Stat. Ann. Tit. 5, § 207.

6099. The Maine Unfair Trade Practices Act adopts the interpretations given by the Federal Trade Commission and the Federal Courts to Section 45(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)) to determine what conduct constitutes unfair or deceptive acts and practices. Me. Rev. Stat. Ann. Tit. 5, § 207.

6100. To justify a finding of unfairness, Maine courts have held that an act or practice: (1) must cause, or be likely to cause, substantial injury to consumers; (2) that is not reasonably avoidable by consumers; and (3) that is not outweighed by any countervailing benefits to consumers or competition. *State v. Weinschenk*, 868 A.2d 200, 206 (Me. 2005).

6101. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Maine Subclass Members, in violation of Me. Rev. Stat. Ann. Tit. 5, §§ 205A, *et seq.*, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6102. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted as part of "trade and commerce" as defined by Me. Rev. Stat. Ann. Tit. 5, § 206(3).

6103. The above unlawful acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6104. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Maine Subclass members.

6105. Defendant's actions were material to Plaintiffs and Maine Subclass members, who relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6106. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and Maine Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6107. Plaintiffs and Maine Subclass members seek relief under Me. Rev. Stat. Ann. Tit. 5, § 213, including, but not limited to injunctive relief, restitution, compensatory damages, and attorneys' fees and costs.

6108. Plaintiffs and Maine Subclass members have put Defendant on notice at least 30 days prior to filing suit pursuant to Me. Rev. Stat. Ann. Tit. 5, § 213(1-A).

COUNT 350__
MARYLAND CONSUMER PROTECTION ACT
MD. CODE ANN., COM. LAW §§ 13-101, *ET SEQ*.
Maryland

6109. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6110. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Subclass.

6111. Under the Maryland Consumer Protection Act, "[a] person may not engage in any unfair, abusive, or deceptive trade practice" in the sale of any consumer goods. Md. Code Ann., Com. Law § 13-303(1).

6112. Under the Maryland Consumer Protection Act, unfair, abusive, or deceptive trade practices include, among other things, representations that consumer goods "have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have" or "are of a particular standard, quality, grade, style, or model which they are not"; "[f]ailure to state a material fact if the failure deceives or tends to deceive; or "[d]eception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with…[t]he promotion or sale of any consumer goods." Md. Code Ann., Com. Law § 13-301.

6113. Defendant engaged in unfair, abusive, or deceptive trade practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Maryland Subclass Members, in violation of Md. Code Ann., Com. Law §§ 13-101, *et seq*., including by knowingly making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6114. The above unfair, abusive, or deceptive trade practices by Defendant were conducted in connection with the sale of "consumer goods," as defined by Md. Code Ann., Com. Law § 13-101(d)(1).

6115. The above unfair, abusive, or deceptive trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6116. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Maryland Subclass members.

6117. Plaintiffs and Maryland Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6118. As a direct and proximate result of Defendant's unfair, abusive, or deceptive trade practices, Plaintiffs and Maryland Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6119. Plaintiffs seek relief under Md. Code Ann., Com. Law § 13-408, including, but not limited to compensatory damages, and attorneys' fees and costs.

COUNT 351
MASSACHUSETTS CONSUMER PROTECTION ACT
MASS. GEN. LAWS ANN. CH. 93A, §§ 1-11 *ET SEQ.*
Massachusetts

6120. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6121. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass.

6122. Under the Massachusetts Consumer Protection Act, "unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Mass. Gen. Laws Ann. ch. 93A, § 2.

6123. Defendant engaged in unfair, abusive, or deceptive trade practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Massachusetts Subclass Members, including by knowingly making statements or representations

that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6124. The above unfair, abusive, or deceptive trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6125. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Massachusetts Subclass members.

6126. Plaintiffs and Massachusetts Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6127. As a direct and proximate result of Defendant's unfair, abusive, or deceptive trade practices, Plaintiffs and Maryland Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6128. Plaintiff seek relief under Mass. Gen. Laws Ann. ch. 93A, § 2, including, but not limited to injunctive relief, compensatory damages, statutory damages, and attorneys' fees and costs.

COUNT 352
MICHIGAN CONSUMER PROTECTION ACT
MICH. COMP. LAWS §§ 445.901 *ET SEQ.*
Michigan

6129. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6130. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Michigan Subclass.

6131. The Michigan Consumer Protection Act ("Michigan CPA") prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.…" Mich. Comp. Laws § 445.903(1). Defendant engaged in unfair, unconscionable, or deceptive methods, acts or practices prohibited by the Michigan CPA, including: "(c) Representing that goods or services have… characteristics… that they do not have.…;" "(e) Representing that goods or services are of a particular standard… if they are of another;" "(i) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" "(s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer;" "(bb) Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is;" and "(cc) Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner." Mich. Comp. Laws § 445.903(1).

6132. Defendant engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Michigan Subclass Members, in violation of Mich. Comp. Laws § 445.903, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6133. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted in "[t]rade or commerce," as defined by Mich. Comp. Laws § 445.902(1)(g).

6134. The above unfair and deceptive practices and acts by Defendant were material misrepresentations of a presently existing or past fact.

6135. The representations by Defendant regarding the quality of the Recalled BIOCELL Implants was false.

6136. Defendant knew the representations were false or made it recklessly as a positive assertion without knowledge of its truth.

6137. Defendant intended that persons rely on the above misrepresentation regarding the quality of the Recalled BIOCELL Implants.

6138. Plaintiffs and Michigan Subclass members acted in reliance on Defendant's representations.

6139. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6140. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Michigan Subclass members.

6141. Plaintiffs and Michigan Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6142. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Michigan Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6143. Plaintiffs and Michigan Subclass members seek relief under Mich. Comp. Laws § 445.911, including, but not limited to injunctive relief, damages, attorneys' fees and costs.

COUNT 353
MINNESOTA CONSUMER FRAUD ACT, MINNESOTA UNLAWFUL TRADE PRACTICES ACT, AND MINNESOTA UNIFORM DECEPTIVE TRADE PRACTICES ACT MINN. STAT. §§ 325F.69; 325D.13; AND 325D.44, RESPECTIVELY
Minnesota

6144. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6145. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass.

6146. The MPCFA makes unlawful "[t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby." Minn. Stat. § 325F.69(1). The MPCFA further provides that "any person injured by a violation of [the MPCFA] may bring a civil action and recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney's fees, and receive other equitable relief as determined by the court." Minn. Stat. § 8.31(3a).

6147. Defendant engaged in unlawful, unfair, and deceptive acts and practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Minnesota Subclass Members, in violation of Minn. Stat. §§ 325F.69; 325D.13; and 325D.44, including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6148. The above unfair and deceptive practices and acts by Defendant involved the "sale" of "merchandise," as defined by Minn. Stat. § 325F.68.

6149. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6150. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Minnesota Subclass members.

6151. Plaintiffs and Minnesota Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6152. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Minnesota Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6153. Plaintiffs and Minnesota Subclass members seek relief under Minn. Stat. § 8.31, subd. 3a; and § 325D.45, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 354
MISSISSIPPI CONSUMER PROTECTION ACT
MISS. CODE. ANN. §§ 75-24-1, *ET SEQ.*
Mississippi

6154. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6155. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Subclass.

6156. The Mississippi Consumer Protection Act prohibits, among other things, misrepresentations of representations "of the source, sponsorship, approval, or certification of goods or services"; "[r]epresenting that goods or services have sponsorship, approval,

characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have"; and "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." Miss. Code Ann. § 75-24-5

6157. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Missouri Subclass Members, in violation of Mo. Rev. Stat. § 407.010, *et seq*., including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6158. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6159. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Mississippi Subclass members.

6160. Plaintiffs and Mississippi Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6161. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Mississippi Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6162. Plaintiffs and Mississippi Subclass members seek relief under the Miss. Code. Ann. § 75-24-5, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 355
MISSOURI MERCHANDISING PRACTICES ACT
MO. REV. STAT. § 407.010, *ET SEQ.*
Missouri

6163. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6164. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Subclass.

6165. The Missouri Merchandising Practices Act ("MMPA") was created to protect Missouri consumers from deceptive and unfair business practices.

6166. The MMPA makes it unlawful to engage in any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. § 407.020.1.

6167. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Missouri Subclass Members, in violation of Mo. Rev. Stat. § 407.010, *et seq*., including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6168. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce," as defined by of Mo. Rev. Stat. § 407.010(7).

6169. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6170. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Missouri Subclass members.

6171. Plaintiffs and Missouri Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6172. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Missouri Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6173. Plaintiffs and Missouri Subclass members seek relief under the MMPA, Mo. Rev. Stat. § 407.010, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, civil penalties and attorneys' fees and costs.

COUNT 356
MONTANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT OF 1973
MONT. CODE ANN. §§ 30-14-101, *ET SEQ.*
Montana

6174. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6175. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass.

6176. The Montana Unfair Trade Practices and Consumer Protection Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. § 30-14-103.

6177. Defendant engaged in unlawful methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Montana Subclass members, in violation

of Mont. Code Ann. §§ 30-14-103, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6178. The above unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce," as defined by *id.,* § 30-14-102(8).

6179. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6180. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Montana Subclass members.

6181. Plaintiffs and Montana Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6182. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Montana Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6183. Plaintiffs and Montana Subclass members seek relief under Mont. Code Ann. § 30-14-133, including, but not limited to injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 357
NEBRASKA CONSUMER PROTECTION ACT
NEB. REV. STAT. § 59-1601, ET SEQ.
Nebraska

6184. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6185. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass.

6186. The Nebraska Consumer Protection Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Neb. Rev. Stat. § 59-1602.

6187. Defendant engaged in unlawful methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Nebraska Subclass Members, in violation of Neb. Rev. Stat. § 59-1602, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6188. The above unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce."

6189. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6190. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Nebraska Subclass members.

6191. Plaintiffs and Nebraska Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6192. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Nebraska Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of

the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6193. Plaintiffs and Nebraska Subclass members seek relief under Neb. Rev. Stat. § 59-16-0, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 358
NEVADA DECEPTIVE TRADE PRACTICES ACT
NEV. REV. STAT. §§598.0903 *ET SEQ.*
Nevada

6194. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6195. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Subclass.

6196. The Nevada Deceptive Trade Practices Act, among other things, makes it unlawful to make "a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease or a false representation as to the sponsorship, approval, status, affiliation or connection of a person therewith" and represent "that goods or services for sale or lease are of a particular standard, quality or grade, or that such goods are of a particular style or model, if he or she knows or should know that they are of another standard, quality, grade, style or model." Nev. Rev. Stat. § 598.0915.

6197. Defendant engaged in deceptive trade practices in the course of their business, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Nevada Subclass Members, in violation of Nev. Rev. Stat. § 598.0915, including by making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6198. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6199. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Nevada Subclass members.

6200. Plaintiffs and Nevada Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6201. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Nevada Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6202. Plaintiffs and Nevada Subclass members seek relief under Nev. Rev. Stat. § 41.600, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 359
NEW HAMPSHIRE CONSUMER PROTECTION ACT
N.H. REV. STAT. ANN. § 358-A:1, ET SEQ
New Hampshire

6203. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6204. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Subclass.

6205. The New Hampshire Consumer Protection Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." N.H. Rev. Stat. Ann. § 358-A:2.

6206. Defendant engaged in unlawful methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and New Hampshire Subclass Members, in violation of N.H. Rev. Stat. Ann. § 358-A:2, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6207. The above unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce."

6208. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6209. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the New Hampshire Subclass members.

6210. Plaintiffs and New Hampshire Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6211. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and New Hampshire Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6212. Plaintiffs and New Hampshire Subclass members seek relief under N.H. Rev. Stat. Ann. § 358-A:10, including, but not limited to injunctive relief, damages, treble damages, nd attorneys' fees and costs.

6213. A copy of this complaint is being sent to the New Hampshire Attorney General.

COUNT 360
NEW JERSEY CONSUMER FRAUD ACT
N.J. STAT. ANN. §§ 56:8-1, *ET SEQ*.
New Jersey

6214. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6215. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Jersey Subclass.

6216. The New Jersey Consumer Fraud Act ("NJCFA") makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with

6217. Defendant engaged in unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and New Jersey Subclass Members, in violation of N.J. Stat. Ann. §§ 56:8-2, including by making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6218. The above unfair and deceptive practices and acts by Defendant were material misrepresentations of a presently existing or past fact.

6219. Defendant knew or believed that the above unfair and deceptive practices and acts were material misrepresentations.

6220. Defendant intended that other persons rely on the above unfair and deceptive practices and acts by Defendant were material misrepresentations of a presently existing or past fact, and their reliance was reasonable.

6221. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6222. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the New Jersey Subclass members.

6223. Plaintiffs and New Jersey Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6224. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and New Jersey Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6225. Plaintiffs and New Jersey Subclass members seek relief under N.J. Stat. Ann. §§ 56:8-2.11 and 56:8-19, including, but not limited to a refund of all moneys acquired by Defendant for the Recalled BIOCELL Implants, injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 361
NEW MEXICO UNFAIR PRACTICES ACT
N.M. STAT. ANN. §§ 57-12-1, *ET SEQ.*
New Mexico

6226. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6227. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass.

6228. The New Mexico Unfair Trade Practices Act, N.M. STAT. ANN. §§ 57-12-1, et seq. ("New Mexico UTPA") makes unlawful any "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce." N.M. STAT. ANN. § 57:12-3. Trade or commerce includes the "sale or distribution of any services." N.M. STAT. ANN. § 57-12-2(C).

6229. Defendant engaged in unfair or deceptive trade practices and unconscionable trade practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and New Mexico Subclass Members, in violation of N.M. Stat. Ann. § 57-12-3, including by making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6230. The above unfair or deceptive acts or practices by Defendant were conducted in or affecting "commerce," as defined by *id.,* § 57-12-2(C).

6231. The above unfair or deceptive trade practices and unconscionable trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous, and the type that may, tend to, or does deceive or mislead any person.

6232. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the New Mexico Subclass members.

6233. Plaintiffs and New Mexico Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of

Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6234. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and New Mexico Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6235. By engaging in the practices discussed above, including, but not limited to, Defendant's undisclosed defects, Defendant has violated N.M. Stat. Ann. § 57-12-2.

6236. Plaintiffs and New Mexico Subclass members seek relief under N.M. Stat. Ann. § 57-12-10, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 362
N.Y. GEN. BUS. LAW § 349
New York

6237. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6238. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Subclass.

6239. Plaintiffs and the New York Subclass Members are "persons" within the meaning of New York General Business Law ("New York GBL"). N.Y. GEN. BUS. LAW § 349(h).

6240. Defendant is a "person," "firm," "corporation," or "association" within the meaning of N.Y. GEN. BUS. LAW § 349.

6241. New York's General Business Law § 349 makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. GEN. BUS. LAW § 349. Defendant's conduct, as described in this Complaint, constitutes "deceptive acts or practices" within the meaning of the New York GBL. All of Defendant's deceptive acts and practices, which

were intended to mislead consumers in a material way in the process of purchasing Recalled BIOCELL Implants, constitute conduct directed at consumers and "consumer-oriented." Further, Plaintiffs and the New York Subclass Members suffered injury as a result of the deceptive acts or practice.

6242. Defendant's actions, as set forth above, occurred in the conduct of business, trade or commerce.

6243. Defendant participated in unfair or deceptive trade practices that violated the New York GBL as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale of the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

6244. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

6245. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

6246. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

6247. Defendant knew or should have known that its conduct violated the New York GBL.

6248. Had Plaintiffs and the New York Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

6249. Defendant owed Plaintiffs and the New York Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the New York Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from Plaintiffs and the New York Subclass Members that contradicted these representations.

6250. Plaintiffs and the New York Subclass Members suffered injury in fact to a legally protected interest. As a result of Defendant's conduct, Plaintiffs and the New York Subclass Members were harmed and suffered actual damages.

6251. Defendant's violations present a continuing risk to Plaintiffs and the New York Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

6252. Pursuant to N.Y. GEN. BUS. LAW § 349(h), Plaintiffs and the New York Subclass Members seek actual damages or $50, whichever is greater, in addition to discretionary three times actual damages up to $1,000 for Defendant's willful and knowing violation of N.Y. GEN. BUS. LAW § 349. Plaintiffs and the New York Subclass Members also seek attorneys' fees, an order enjoining Defendant's deceptive conduct, and any other just and proper relief available under the New York GBL.

COUNT 363
NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT
N.C. GEN. STAT. §§ 75-1.1 *ET SEQ.*
North Carolina

6253. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6254. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Carolina Subclass.

6255. North Carolina's Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, et seq. ("NCUDTPA"), prohibits a person from engaging in "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce[.]" The NCUDTPA provides a private right of action for any person injured "by reason of any act or thing done by any other person, firm or corporation in violation of" the NCUDTPA. N.C. Gen. Stat. § 75-16.

6256. Defendant engaged in unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and North Carolina Subclass Members, in violation of N.C. Gen. Stat. § 75-1.1(a), including by making false representations or concealing the true risks of the BIOCELL implants and failing to comply with federal law.

6257. The above unfair or deceptive acts or practices by Defendant were conducted in or affecting "commerce," as defined by *id.,* § 75-1.1(b).

6258. The above unfair or deceptive acts or practices by Defendant were reasonably and intentionally calculated to deceive class members and other consumers.

6259. The above unfair or deceptive acts or practices by Defendant did in fact deceive class members and other consumers, causing them damage.

6260. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6261. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the North Carolina Subclass members.

6262. Plaintiffs and North Carolina Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6263. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and North Carolina Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6264. Plaintiffs and North Carolina Subclass members seek relief under N.C. Gen. Stat. §§ 75-16 and 75-16.1, including, but not limited to injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 364
NORTH DAKOTA CONSUMER PROTECTION ACT
N.D. CENT. CODE § 51-15-01, ET. SEQ.
North Dakota

6265. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6266. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Subclass.

6267. Under North Dakota law, the use of deceptive or unconscionable acts or practices in connection with the sale or advertisement of any merchandise is unlawful. N.D. Cent. Code § 51-15-02.

6268. Defendant engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and North Dakota Subclass Members, in violation of N.D. Cent. Code § 51-15-01, et. seq., including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6269. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6270. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the North Dakota Subclass members.

6271. Plaintiffs and North Dakota Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6272. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and North Dakota Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6273. Plaintiffs and North Dakota Subclass members seek relief under N.D. Cent. Code. § 51-15-09, *et seq*., including, but not limited to injunctive relief, compensatory damages, treble damages, and attorneys' fees and costs. N.D. Cent. Code. § 51-15-09.

COUNT 365
OHIO CONSUMER SALES PRACTICES ACT
OHIO REV. CODE ANN. §§ 1345.01, *ET SEQ.*
Ohio

6274. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6275. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Subclass.

6276. Ohio make it unlawful to "commit an unfair or deceptive act or practice in connection with a consumer transaction" Ohio Rev. Code Ann. § 1345.02.

6277. Defendant engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Ohio Subclass Members, in violation of Ohio Rev. Code Ann. §§ 1345.021 *et seq*., including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6278. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6279. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and Ohio Subclass members.

6280. Plaintiffs and Ohio Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6281. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Ohio Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6282. Plaintiffs and Ohio Subclass members seek relief under Ohio Rev. Code § 1345.09, *et seq*., including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 366
OKLAHOMA CONSUMER PROTECTION ACT
OKLA. STAT. TIT. 15, § 751, *ET SEQ.*
Oklahoma

6283. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6284. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oklahoma Subclass.

6285. The Oklahoma Consumer Protection Act makes it unlawful to make a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person," or engage in "any practice which offends established public policy or if the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." Okla. Stat. tit. 15, § 752.

6286. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Oklahoma Subclass Members, in violation of Okla. Stat. tit. 15, § 752, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6287. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted as part of a "consumer transaction," as defined by Okla. Stat. tit. 15, § 752.

6288. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6289. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Oklahoma Subclass members.

6290. Plaintiffs and Oklahoma Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6291. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Oklahoma Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6292. Plaintiffs and Oklahoma Subclass members seek relief under Okla. Stat. tit. 15, § 75, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, civil penalties and attorneys' fees and costs.

COUNT 367
OREGON UNLAWFUL TRADE PRACTICES LAW
OR. REV. STAT. §§ 646.605, *ET SEQ.*
Oregon

6293. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6294. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Subclass.

6295. Oregon make it unlawful to for any person to employ "any unconscionable tactic in connection with selling, renting or disposing of real estate, goods or services, or collecting or enforcing an obligation." Or. Rev. Stat. § 646.607(1).

6296. Defendant engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Oregon Subclass Members, in violation of Or. Rev. Stat. §§ 646.605, *et seq*., including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6297. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted in "[t]rade" and/or "commerce," as defined by Or. Rev. Stat. § 646.605(8).

6298. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6299. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Oregon Subclass members.

6300. Plaintiffs and Oregon Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6301. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Oregon Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the

products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6302. Plaintiffs and Oregon Subclass members seek relief under Or. Rev. Stat. § 646.638, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, civil penalties and attorneys' fees and costs.

COUNT 368
PENNSYLVANIA UNFAIR TRADE PRACTICES
AND CONSUMER PROTECTION LAW
73 P.S. §§ 201-1, ET. SEQ.
Pennsylvania

6303. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6304. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass.

6305. Plaintiffs and the Pennsylvania Subclass Members purchased their Recalled BIOCELL Implants primarily for personal, family or household purposes within the meaning of 73 P.S. § 201-9.2.

6306. All of the acts complained of herein were perpetrated by Defendant in the course of trade or commerce within the meaning of 73 P.S. § 201-2(3).

6307. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania CPL") prohibits unfair or deceptive acts or practices, including, "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding." 73 P.S. § 201-2(4). Defendant engaged in unlawful trade practices, and unfair or deceptive acts or practices that violated Pennsylvania CPL.

6308. Defendant participated in unfair or deceptive trade practices that violated the Pennsylvania CPL as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law, Defendant

knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

6309. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

6310. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

6311. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

6312. Defendant knew or should have known that its conduct violated the Pennsylvania CPL.

6313. Had Plaintiffs and the Pennsylvania Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiff did not receive the benefit of their bargain as a result of Defendant's misconduct.

6314. Defendant owed Plaintiffs and the Pennsylvania Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Pennsylvania Subclass Members;

and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully withholding material facts from and the Pennsylvania Subclass Members that contradicted these representations.

6315. Plaintiffs and the Pennsylvania Subclass Members suffered injury in fact to a legally protected interest. As a result of Defendant's conduct, Plaintiffs and the Pennsylvania Subclass Members were harmed and suffered actual damages.

6316. Defendant's violations present a continuing risk to Plaintiffs and the Pennsylvania Subclass Members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

6317. Defendant is liable to Plaintiffs and the Pennsylvania Subclass Members for treble their actual damages or $100, whichever is greater, and attorneys' fees and costs under 73 P.S. § 201-9.2(a). Plaintiffs and the Pennsylvania Subclass Members are also entitled to an award of punitive damages given that Defendant's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

COUNT 369
RHODE ISLAND UNFAIR TRADE PRACTICE AND CONSUMER PROTECTION ACT
R.I. GEN. LAWS §§ 6-13.1-1, *ET SEQ*.
Rhode Island

6318. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6319. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass.

6320. The Rhode Island Unfair Trade Practice and Consumer Protection Act ("Rhode Island Act") identifies several types of "unfair" and/or "deceptive trade practices, but also incorporates by reference "the Federal Trade Commission's and federal courts' interpretations of

section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1)," rather than set forth specific definitions of those operative terms. R.I. Gen. Laws § 6-13.1-2.

6321. Rhode Island has adopted a three-part test to determine whether an act is "deceptive": (1) a representation, omission, or practice, that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3), the representation, omission, or practice is material," meaning the representation is important to the consumer and likely to affect their decisions with respect to the product.

6322. Defendant engaged in unlawful, unfair, and deceptive acts and practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Rhode Island Subclass Members, in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq*., including by misrepresenting the true quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6323. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted in "[t]rade" and/or "commerce," as defined by R.I. Gen. Laws § 6-13.1-1(5).

6324. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6325. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Rhode Island Subclass members.

6326. Defendant's actions were material to Plaintiffs and Rhode Island Subclass members, who relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6327. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Rhode Island Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6328. Plaintiffs and Rhode Island Subclass members seek relief under R.I. Gen. Laws §§ 6-13.1-5.2, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, and attorneys' fees and costs.

COUNT 370
SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT
S.C. CODE ANN. §§ 39-5-10, *ET SEQ.*
South Carolina

6329. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6330. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass.

6331. The South Carolina Unfair Trade Practices Act adopts the interpretations given by the Federal Trade Commission and the Federal Courts to Section 5(a) (1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)) to determine what conduct constitutes unfair or deceptive acts and practices. S.C. Code Ann. § 39-5-20.

6332. Defendant engaged in unlawful methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and South Carolina Subclass Members, in violation of S.C. Code Ann. § 39-5-20, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6333. The above unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce," as defined by S.C. Code Ann. § 39-5-10(b).

6334. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6335. The above unfair and deceptive practices and acts by Defendant has impacted the South Carolina public at large if Defendant is not forced to cease engaging in such acts and practices, they are likely to continue.

6336. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the South Carolina Subclass members.

6337. Plaintiffs and South Carolina Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6338. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and South Carolina Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6339. Plaintiffs and South Carolina Subclass members seek relief under S.C. Code § 39-5-140, including, but not limited to restitution, statutory damages, compensatory damages, punitive damages, civil penalties and attorneys' fees and costs.

COUNT 371
SOUTH DAKOTA DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION LAW
S.D. CODIFIED LAWS §§ 37-24-1, *ET SEQ.*
South Dakota

6340. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6341. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Dakota Subclass.

6342. The South Dakota Deceptive Trade Practices and Consumer Protection Law, among other things, makes it unlawful to "[k]nowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise, regardless of whether any person has in fact been misled, deceived, or damaged thereby." S.D. Codified Laws § 37-24-6(1).

6343. Defendant engaged in deceptive trade practices in the course of their business, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and South Dakota Subclass Members, in violation of S.D. Codified Laws §§ 37-24-1, *et seq*., including by making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6344. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6345. Defendant's actions were negligent, knowing and willful, and/or intentional, wanton and reckless with respect to the rights of Plaintiffs and the South Dakota Subclass members.

6346. Plaintiffs and South Dakota Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6347. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and South Dakota Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6348. Plaintiffs and South Dakota Subclass members seek relief under S.D. Codified Laws §§ 37-24-1, *et seq*., including, but not limited to injunctive relief, compensatory damages, statutory damages, civil penalties and attorneys' fees and costs.

COUNT 372
TENNESSEE CONSUMER PROTECTION ACT
TENN. CODE ANN. §§ 47-18-101, *ET SEQ*.
Tennessee

6349. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6350. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass.

6351. The Tennessee Consumer Protection Act ("TNCPA") was enacted to "protect consumers…from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce in part or wholly within [Tennessee]." Tenn. Code Ann. § 47-18-102(2).

6352. The TNCPA makes unlawful, among other things, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have" and "[r]epresenting that goods or services are of a particular standard, quality or

grade, or that goods are of a particular style or model, if they are of another." Tenn. Code Ann. § 47-18-104.

6353. Defendant engaged in unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Tennessee Subclass Members, in violation of Tenn. Code Ann. §§ 47-18-101, *et seq*., including by making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6354. Defendant intended that other persons rely on the above unfair and deceptive practices and acts. These actions by Defendant were material misrepresentations of a presently existing or past fact, and their reliance was reasonable.

6355. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6356. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Tennessee Subclass members.

6357. Plaintiffs and Tennessee Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6358. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Tennessee Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal

of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6359. Plaintiffs and Tennessee Subclass members seek relief under Tenn. Code § 47-18-108-109, including, but not limited to injunctive relief, compensatory damages, statutory damages, punitive damages, statutory damages, civil penalties and attorneys' fees and costs.

COUNT 373
DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION ACT
Tex. Bus. & Comm. Code § 17.41, *ET. SEQ.*
Texas

6360. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6361. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass.

6362. Plaintiffs and the Texas Subclass Members are individuals and therefore "consumers" pursuant to Tex. Bus. & Com. Code § 17.45(4).

6363. Defendant is a "person" within the meaning of Tex. Bus. & Com. Code § 17.45(3).

6364. Defendant is engaged in "trade" or "commerce" or "consumer transactions" within the meaning Tex. Bus. & Com. Code § 17.46(a).

6365. The Texas Deceptive Trade Practices – Consumer Protection Act ("Texas DTPA") prohibits "false, misleading, or deceptive acts or practices in the conduct of any trade or commerce," Tex. Bus. & Com. Code § 17.46(a), and an "unconscionable action or course of action," which means "an act or practice which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree." Tex. Bus. & Com. Code §§ 17.45(5) and 17.50(a)(3).

6366. Defendant participated in unfair or deceptive trade practices that violated the Texas DTPA as described below and alleged throughout the Complaint. By concealing the true risks of

the Recalled BIOCELL Implants and failing to comply with federal law, Defendant knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled BIOCELL Implants. Defendant systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled BIOCELL Implants in the course of their business.

6367. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled BIOCELL Implants.

6368. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public and imposed a serious safety risk on the public.

6369. Defendant knew that the risks inherent in the Recalled BIOCELL Implants made them not suitable for their intended use.

6370. Defendant knew or should have known that its conduct violated the Texas DTPA.

6371. Had Plaintiffs and the Texas Subclass Members known the truth about the Recalled BIOCELL Implants, they would not have purchased and implanted the Recalled BIOCELL Implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendant's misconduct.

6372. Defendant owed Plaintiffs and the Texas Subclass Members a duty to disclose the truth about the Recalled BIOCELL Implants because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled BIOCELL Implants; (b) intentionally concealed the foregoing from Plaintiffs and the Texas Subclass Members; and/or (c) made incomplete representations regarding the Recalled BIOCELL Implants, while purposefully

withholding material facts from Plaintiffs and the Texas Subclass Members that contradicted these representations.

6373. Plaintiffs and the Texas Subclass Members suffered injury in fact to a legally protected interest. As a result of Defendant's conduct, Plaintiff and the Texas Subclass Members were harmed and suffered actual damages.

6374. Defendant's violations present a continuing risk to Plaintiffs and the Texas Subclass Members as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

6375. Pursuant to Tex. Bus. & Com. Code § 17.50, Plaintiffs and the Texas Subclass Members seek an order enjoining Defendant's unfair and/or deceptive acts or practices, damages, multiple damages for knowing and intentional violations, pursuant to § 17.50(b)(1), punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Texas DTPA.

COUNT 374
UTAH CONSUMER SALES PRACTICES ACT
UTAH CODE ANN. §§ 13-11-1, *ET SEQ.*
Utah

6376. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6377. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass.

6378. The Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq*. makes it unlawful to, among other things, "knowingly or intentionally" "indicate[] that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits, if it has not" or "that the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not." Utah Code Ann. § 13-11-4.

6379. A "Consumer transaction" means a sale, lease, assignment, award by chance, or other written or oral transfer or disposition of goods, services, or other property, both tangible and intangible (except securities and insurance) to, or apparently to, a person for…primarily personal, family, or household purposes." Utah Code Ann. § 13-11-3.

6380. Defendant engaged in unfair or deceptive trade practices and unconscionable trade practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Utah Subclass Members, in violation of Utah Code Ann. §§ 13-11-1, *et seq*., including by making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6381. The above unfair or deceptive trade practices and unconscionable trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous, and the type that may, tend to, or does deceive or mislead any person.

6382. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Utah Subclass members.

6383. Plaintiffs and Utah Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6384. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Utah Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6385. By engaging in the practices discussed above, including, but not limited to, Defendant's undisclosed defects, Defendant has violated Utah Code Ann. §§ 13-11-1, *et seq*.

6386. Plaintiffs and Utah Subclass members seek relief under Utah Code Ann. § 13-11-17 and -19, including, but not limited to injunctive relief, compensatory damages, statutory damages, civil penalties and attorneys' fees and costs.

COUNT 375
VERMONT CONSUMER FRAUD ACT
VT. STAT. ANN. TIT. 9, §§ 2451, ET. SEQ.
Vermont

6387. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6388. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Subclass.

6389. The Vermont Consumer Fraud Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in commerce." Vt. Stat. Ann. tit. 9, § 2453, et. seq.

6390. Defendant engaged in unlawful methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Vermont Subclass Members, in violation of Vt. Stat. Ann. tit. 9, § 2453 including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

6391. The above unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce."

6392. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6393. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Vermont Subclass members.

6394. Plaintiffs and Vermont Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL© implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6395. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Vermont Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6396. Plaintiffs and Vermont Subclass members seek relief Vt. Stat. Ann. tit. 9, § 2461(b). including, but not limited to injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 376
VIRGINIA CONSUMER PROTECTION ACT
VA. CODE ANN. §§ 59.1-196, *ET SEQ.*
Virginia

6397. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6398. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virginia Subclass.

6399. The Virginia Consumer Protection Act, Va. Code Ann. §§ 59.1-196, *et seq*. ("VCPA") was enacted to "promote fair and ethical standards of dealings between suppliers and the consuming public."

6400. The VCPA makes unlawful, among other things, any "deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction." Va. Code Ann. § 59.1-200.

6401. Defendant engaged in unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Virginia Subclass Members, in violation of Va. Code Ann. §§ 59.1-196, including by making false representations or concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6402. The above unfair or deceptive acts or practices by Defendant were conducted as part of a "consumer transaction" as defined by Va. Code Ann. § 59.1-198.

6403. The above unfair or deceptive acts or practices by Defendant were reasonably calculated to deceive class members and other consumers and made with intent to deceive.

6404. The above unfair or deceptive acts or practices by Defendant did in fact deceive class members and other consumers, causing them damage.

6405. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6406. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Virginia Subclass members.

6407. Plaintiffs and Virginia Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6408. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Virginia Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6409. Plaintiffs and Virginia Subclass members seek relief under Va. Code Ann. §§ 59.1-196, *et seq*., including, but not limited to injunctive relief, compensatory damages, statutory damages, treble damages, civil penalties and attorneys' fees and costs.

COUNT __
WASHINGTON CONSUMER PROTECTION ACT
WASH. REV. CODE § 19.86.020, ET. SEQ.
Washington

6410. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6411. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Washington Subclass.

6412. The Washington Consumer Protection Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code § 19.86.020.

6413. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Washington Subclass Members, in violation of Wash. Rev. Code §§ 19.86.010, *et seq.*, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6414. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted as part of "trade" or "commerce" as defined by Wash. Rev. Code § 19.86.010.

6415. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6416. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Washington Subclass members.

6417. Plaintiffs and Washington Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6418. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and Washington Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6419. Plaintiffs and Washington Subclass members seek relief under Wash. Rev. Code §§ 19.86.090, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, civil penalties and attorneys' fees and costs.

COUNT 377__
WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT
W. VA. CODE §§ 46A-6-101, *ET SEQ.*
West Virginia

6420. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6421. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass.

6422. The West Virginia Consumer Credit and Protection Act shall be construed liberally to "complement the body of federal law governing unfair competition and unfair, deceptive and fraudulent acts or practices in order to protect the public and foster fair and honest competition." W. Va. Code § 46A-6-101.

6423. The West Virginia Consumer Credit and Protection Act prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." W. Va. Code § 46A-6-104.

6424. The West Virginia Consumer Credit and Protection Act directs that, in construing the Act, "courts be guided by the policies of the Federal Trade Commission and interpretations given by the Federal Trade Commission and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act (15 U. S. C. § 45(a)(1))." W. Va. Code § 46A-6-101.

6425. Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and West Virginia Subclass Members, in violation of W. Va. Code §§ 46A-6-101, *et seq*., including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6426. The above unfair methods of competition and unfair or deceptive acts or practices by Defendant were conducted in "trade" or "commerce," as defined by W. Va. Code § 46A-6-102(6).

6427. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6428. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the West Virginia Subclass members.

6429. Plaintiffs and West Virginia Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6430. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and West Virginia Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6431. Plaintiffs and West Virginia Subclass members seek relief under W. Va. Code § 46A-6-106, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, and attorneys' fees and costs.

6432. Plaintiffs and West Virginia Subclass members have informed Defendant of the alleged violation pursuant to W. Va. Code § 46A-6-106(c).

COUNT 378
WISCONSIN FALSE ADVERTISING ACT
WIS. STAT. § 100.18
Wisconsin

6433. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6434. Plaintiff brings this cause of action on her behalf and on behalf of the members of the Wisconsin Subclass.

6435. Wisconsin law prohibits companies from making "untrue, deceptive, or misleading" statements in any "notice, handbill, poster, bill, circular, pamphlet, letter, sign, placard, card, [or] label" in selling merchandise. Wis. Stat. § 100.18(1).

6436. Defendant made "untrue, deceptive or misleading" statement with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Wisconsin Subclass Members, in violation of Wash. Rev. Code §§ 19.86.010, *et seq.*, including by concealing the true risks of the Recalled BIOCELL Implants and failing to comply with federal law.

6437. The above untrue, deceptive, or misleading acts or practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6438. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Wisconsin Subclass members.

6439. Plaintiffs and Wisconsin Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6440. As a direct and proximate result of Defendant's unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and Wisconsin Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6441. Plaintiffs and Wisconsin subclass members have suffered pecuniary loss and seek damages, including double damages, costs, and attorneys' fees. Wis. Stat. § 108.18(11)(b).

COUNT 379__
WYOMING CONSUMER PROTECTION ACT
WYO. STAT. ANN. §§ 40-12-101, *ET SEQ.*
Wyoming

6442. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6443. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Plaintiffs bring this cause of action on behalf

of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass.

6444. The Wyoming Consumer Protection Act makes it unlawful to "engage[] in a deceptive trade practice…in the course of his business and in connection with a consumer transaction," which includes knowingly "[r]epresent[ing] that merchandise is of a particular standard, grade, style or model, if it is not." Wyo. Stat. Ann. § 40-12-105.

6445. Defendant engaged in unlawful deceptive trade practices and acts with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Wyoming Subclass Members, in violation of Wyo. Stat. Ann. §§ 40-12-101, *et seq*., including by knowingly making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6446. The above deceptive acts or practices by Defendant were conducted in connection with a "consumer transaction," as defined by Wyo. Stat. Ann. § 40-12-102(ii).

6447. The above deceptive trade practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous.

6448. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Wyoming Subclass members.

6449. Plaintiffs and Wyoming Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6450. As a direct and proximate result of Defendant's deceptive trade practices and acts, Plaintiffs and Wyoming Subclass members suffered an ascertainable loss of money or property,

real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6451. Plaintiffs and Wyoming Subclass members seek relief under Wyo. Stat. Ann. § 40-12-108, including, but not limited to injunctive relief, compensatory damages, punitive damages, statutory damages, civil penalties and attorneys' fees and costs.

6452. Plaintiffs and Wyoming Subclass members have put Defendant on notice prior to filing suit pursuant to Wyo. Stat. Ann. §§ 40-12-109 and 40-12-102(a)(ix).

COUNT 380
GUAM CONSUMER PROTECTION ACT
5 G.C.A. §§ 32101, *ET SEQ.*
Guam

6453. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6454. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass.

6455. Under the Guam Consumer Protection Act, "false, misleading, or deceptive acts or practices . . . unlawful." 5 G.C.A. § 32201.

6456. Defendant engaged in false, misleading, or deceptive acts or practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Guam Subclass Members, including by knowingly making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6457. The above unfair, abusive, or deceptive trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6458. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Guam Subclass members.

6459. Plaintiffs and Guam Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6460. As a direct and proximate result of Defendant's false, misleading, unfair or deceptive trade practices, Plaintiffs and Guam Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6461. Plaintiffs and Guam Subclass members seek relief under 5 G.C.A. § 32112, including, but not limited to actual damages, treble damages, punitive damages, and attorneys' fees and costs.

COUNT 381
CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT
12A V.I.C. § 301 *ET SEQ.*
U.S. Virgin Islands

6462. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6463. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virgin Islands Subclass.

6464. Under the Consumer Fraud and Deceptive Business Practices Act, "unfair or deceptive trade acts or practices" are unlawful 12A V.I.C.§ 304.

6465. Defendant engaged in false, misleading, unfair or deceptive acts or practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Virgin Islands Subclass Members, including by knowingly making statements or

representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6466. The above unfair, abusive, or deceptive trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6467. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Virgin Island Subclass members.

6468. Plaintiffs and Virgin Island Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6469. As a direct and proximate result of Defendant's false, misleading, unfair or deceptive trade practices, Plaintiffs and Virgin Island Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6470. Plaintiffs and Virgin Island Subclass members seek relief under 12A V.I.C. § 331, including, but not limited to compensatory, consequential, punitive, equitable, treble damages, and attorneys' fees and costs.

COUNT 382
CONSUMER PROTECTION ACT
4 CMC § 5101 *ET SEQ.*
Northern Mariana Islands

6471. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6472. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass.

6473. Under the Consumer Protection Act, it is unlawful, among other things, to engage "in any act of practice which is unfair or deceptive to the consumer." 4 CMC § 5105.

6474. Defendant engaged in false, misleading, or deceptive acts or practices with respect to the sale and advertisement of the Recalled BIOCELL Implants purchased by Plaintiffs and Northern Mariana Islands Subclass Members, including by knowingly making statements or representations that were false or misleading regarding the quality of the Recalled BIOCELL Implants, concealing the true risks of the Recalled BIOCELL Implants, and failing to comply with federal law.

6475. The above unfair, abusive, unfair, or deceptive trade practices by Defendant were immoral, unethical, oppressive, and unscrupulous.

6476. Defendant's actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Northern Mariana Islands Subclass members.

6477. Plaintiffs and Northern Mariana Islands Subclass members relied on Defendant's representations in that they would not have purchased, chosen, and/or paid for all or part of Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6478. As a direct and proximate result of Defendant's false, misleading, unfair or deceptive trade practices, Plaintiffs and Virgin Island Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future

costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

6479. Plaintiffs and Virgin Island Subclass members seek relief under 4 CMC § 5112, including, but not limited to actual and liquidated damages, consequential, and attorneys' fees and costs.

K. UNJUST ENRICHMENT

COUNT 383
UNJUST ENRICHMENT
Alabama

6480. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6481. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Alabama Subclass in the alternative.

6482. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6483. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6484. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6485. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6486. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6487. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6488. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6489. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 384
UNJUST ENRICHMENT
Arizona

6490. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6491. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arizona Subclass in the alternative.

6492. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6493. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6494. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6495. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6496. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6497. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6498. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6499. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 385
UNJUST ENRICHMENT
Arkansas

6500. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6501. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Arkansas Subclass in the alternative.

6502. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6503. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6504. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6505. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6506. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6507. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6508. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6509. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 386
UNJUST ENRICHMENT
California

6510. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6511. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the California Subclass in the alternative.

6512. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6513. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6514. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6515. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6516. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6517. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6518. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6519. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 387
UNJUST ENRICHMENT
Colorado

6520. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6521. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Colorado Subclass in the alternative.

6522. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6523. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6524. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6525. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6526. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6527. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6528. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6529. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 388
UNJUST ENRICHMENT
Connecticut

6530. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6531. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Connecticut Subclass in the alternative.

6532. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6533. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6534. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6535. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6536. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6537. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6538. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6539. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 389
UNJUST ENRICHMENT
Delaware

6540. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6541. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Delaware Subclass in the alternative.

6542. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6543. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6544. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6545. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6546. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6547. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6548. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6549. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 390
UNJUST ENRICHMENT
District of Columbia

6550. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6551. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the D.C. Subclass in the alternative.

6552. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6553. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6554. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6555. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6556. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6557. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6558. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6559. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 391
UNJUST ENRICHMENT
Florida

6560. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6561. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Florida Subclass in the alternative.

6562. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6563. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6564. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6565. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6566. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6567. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6568. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6569. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 392
UNJUST ENRICHMENT
Georgia

6570. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6571. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Georgia Subclass in the alternative.

6572. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6573. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6574. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6575. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6576. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6577. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6578. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6579. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 393
UNJUST ENRICHMENT
Hawaii

6580. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6581. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Hawaii Subclass in the alternative.

6582. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6583. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6584. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6585. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6586. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6587. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6588. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6589. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 394
UNJUST ENRICHMENT
Idaho

6590. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6591. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Idaho Subclass in the alternative.

6592. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6593. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6594. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6595. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6596. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6597. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6598. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6599. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 395
UNJUST ENRICHMENT
Illinois

6600. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6601. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Illinois Subclass in the alternative.

6602. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6603. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6604. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6605. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6606. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6607. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6608. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6609. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 396
UNJUST ENRICHMENT
Indiana

6610. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6611. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Indiana Subclass in the alternative.

6612. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6613. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6614. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6615. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6616. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6617. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6618. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6619. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 397
UNJUST ENRICHMENT
Iowa

6620. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6621. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Iowa Subclass in the alternative.

6622. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6623. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6624. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6625. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6626. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6627. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6628. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6629. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 398
UNJUST ENRICHMENT
Kansas

6630. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6631. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kansas Subclass in the alternative.

6632. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6633. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6634. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6635. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6636. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6637. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6638. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6639. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 399
UNJUST ENRICHMENT
Kentucky

6640. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6641. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Kentucky Subclass in the alternative.

6642. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6643. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6644. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6645. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6646. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6647. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6648. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6649. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 400
UNJUST ENRICHMENT
Louisiana

6650. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6651. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Louisiana Subclass in the alternative.

6652. Louisiana Civil Code art. 2298 provides "[a] person who has been enriched without cause at the expense of another person is bound to compensate that person."

6653. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6654. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6655. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6656. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6657. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6658. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6659. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6660. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 401
UNJUST ENRICHMENT
Maine

6661. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6662. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maine Subclass in the alternative.

6663. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6664. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6665. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6666. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6667. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6668. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6669. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6670. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 402
UNJUST ENRICHMENT
Maryland

6671. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6672. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Maryland Subclass in the alternative.

6673. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6674. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6675. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6676. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6677. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6678. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6679. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6680. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 403
UNJUST ENRICHMENT
Massachusetts

6681. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6682. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Massachusetts Subclass in the alternative.

6683. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6684. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6685. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6686. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6687. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6688. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6689. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6690. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 404
UNJUST ENRICHMENT
Michigan

6691. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6692. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Michigan Subclass in the alternative.

6693. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6694. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6695. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6696. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6697. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6698. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6699. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6700. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 405
UNJUST ENRICHMENT
Minnesota

6701. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6702. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Minnesota Subclass in the alternative.

6703. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6704. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6705. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6706. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6707. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6708. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6709. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6710. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 406
UNJUST ENRICHMENT
Mississippi

6711. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6712. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Mississippi Subclass in the alternative.

6713. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6714. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6715. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6716. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6717. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6718. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6719. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6720. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 407
UNJUST ENRICHMENT
Missouri

6721. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6722. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Missouri Subclass in the alternative.

6723. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6724. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6725. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6726. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6727. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6728. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6729. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6730. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 408
UNJUST ENRICHMENT
Montana

6731. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6732. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Montana Subclass in the alternative.

6733. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6734. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6735. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6736. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6737. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6738. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6739. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6740. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 409
UNJUST ENRICHMENT
Nebraska

6741. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6742. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nebraska Subclass in the alternative.

6743. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6744. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6745. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6746. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6747. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6748. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6749. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6750. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 410
UNJUST ENRICHMENT
Nevada

6751. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6752. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Nevada Subclass in the alternative.

6753. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6754. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6755. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6756. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6757. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6758. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6759. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6760. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 411
UNJUST ENRICHMENT
New Hampshire

6761. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6762. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Hampshire Subclass in the alternative.

6763. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6764. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6765. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6766. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6767. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6768. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6769. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6770. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 412
UNJUST ENRICHMENT
New Jersey

6771. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6772. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Jersey Subclass in the alternative.

6773. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6774. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6775. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6776. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6777. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6778. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6779. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6780. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 413
UNJUST ENRICHMENT
New Mexico

6781. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6782. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New Mexico Subclass in the alternative.

6783. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6784. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6785. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6786. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6787. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6788. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6789. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6790. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 414
UNJUST ENRICHMENT
New York

6791. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6792. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the New York Subclass in the alternative.

6793. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6794. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6795. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6796. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6797. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6798. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6799. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6800. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 415
UNJUST ENRICHMENT
North Carolina

6801. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6802. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Carolina Subclass in the alternative.

6803. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6804. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6805. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6806. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6807. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6808. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6809. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6810. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 416
UNJUST ENRICHMENT
North Dakota

6811. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6812. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the North Dakota Subclass in the alternative.

6813. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6814. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6815. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6816. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6817. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6818. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6819. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6820. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 417
UNJUST ENRICHMENT
Ohio

6821. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6822. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Ohio Subclass in the alternative.

6823. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6824. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6825. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6826. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6827. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6828. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6829. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6830. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 418
UNJUST ENRICHMENT
Oklahoma

6831. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6832. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Subclass in the alternative.

6833. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6834. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6835. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6836. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6837. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6838. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6839. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6840. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 419
UNJUST ENRICHMENT
Oregon

6841. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6842. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Oregon Subclass in the alternative.

6843. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6844. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6845. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6846. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6847. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6848. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6849. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6850. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 420
UNJUST ENRICHMENT
Pennsylvania

6851. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6852. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Pennsylvania Subclass in the alternative.

6853. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6854. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6855. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6856. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6857. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6858. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6859. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6860. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 421
UNJUST ENRICHMENT
Rhode Island

6861. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6862. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass in the alternative.

6863. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6864. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6865. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6866. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6867. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6868. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6869. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6870. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 422
UNJUST ENRICHMENT
South Carolina

6871. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6872. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the South Carolina Subclass in the alternative.

6873. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6874. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6875. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6876. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6877. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6878. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6879. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6880. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 423
UNJUST ENRICHMENT
South Dakota

6881. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6882. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Rhode Island Subclass in the alternative.

6883. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6884. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6885. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6886. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6887. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6888. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6889. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6890. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 424
UNJUST ENRICHMENT
Tennessee

6891. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6892. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Tennessee Subclass in the alternative.

6893. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6894. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6895. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6896. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6897. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6898. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6899. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6900. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 425
UNJUST ENRICHMENT
Texas

6901. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6902. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Texas Subclass in the alternative.

6903. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6904. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6905. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6906. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6907. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6908. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6909. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6910. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 426
UNJUST ENRICHMENT
Utah

6911. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6912. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Utah Subclass in the alternative.

6913. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6914. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6915. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6916. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6917. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6918. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6919. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6920. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 427
UNJUST ENRICHMENT
Vermont

6921. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6922. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Vermont Subclass in the alternative.

6923. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6924. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6925. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6926. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6927. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6928. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6929. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6930. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 428
UNJUST ENRICHMENT
Virginia

6931. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6932. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virginia Subclass in the alternative.

6933. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6934. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6935. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6936. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6937. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6938. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6939. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6940. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 429
UNJUST ENRICHMENT
Washington

6941. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6942. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Washington Subclass in the alternative.

6943. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6944. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6945. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6946. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6947. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6948. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6949. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6950. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 430
UNJUST ENRICHMENT
West Virginia

6951. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6952. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the West Virginia Subclass in the alternative.

6953. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6954. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6955. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6956. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6957. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6958. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6959. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6960. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 431
UNJUST ENRICHMENT
Wisconsin

6961. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6962. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wisconsin Subclass in the alternative.

6963. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6964. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6965. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6966. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6967. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6968. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6969. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6970. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial

COUNT 432
UNJUST ENRICHMENT
Wyoming

6971. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6972. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Wyoming Subclass in the alternative.

6973. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6974. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled

BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6975. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6976. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6977. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6978. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6979. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6980. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 433
UNJUST ENRICHMENT
Guam

6981. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6982. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Guam Subclass in the alternative.

6983. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6984. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6985. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6986. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6987. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6988. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6989. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

6990. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 434
UNJUST ENRICHMENT
Puerto Rico

6991. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

6992. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Puerto Rico Subclass in the alternative.

6993. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

6994. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

6995. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

6996. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

6997. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

6998. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

6999. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

7000. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 435
UNJUST ENRICHMENT
U.S. Virgin Islands

7001. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

7002. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Virgin Islands Subclass in the alternative.

7003. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

7004. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

7005. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

7006. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

7007. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

7008. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

7009. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

7010. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

COUNT 436
UNJUST ENRICHMENT
Northern Mariana Islands

7011. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

7012. Plaintiffs bring this cause of action on behalf of themselves, the Nationwide Class, and/or a grouping of state subclasses, including the Northern Mariana Islands Subclass in the alternative.

7013. Plaintiffs and each of the Subclass Members conferred a tangible and material economic benefit upon Defendant by purchasing the Recalled BIOCELL implants.

7014. But for Defendant's fraudulent and unconscionable conduct, Plaintiffs and each of the Subclass Members would not have purchased, chosen and/or paid for all or part of the Recalled BIOCELL Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

7015. Defendant refused to compensate Plaintiffs and each of the Subclass Members for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical

and diagnostic fees, medical monitoring, and invasive diagnostic procedures associated with retention of the Recalled BIOCELL Implants.

7016. Under these circumstances, it would be unjust and inequitable for Defendant to retain the economic benefits it received at the expense of Plaintiffs and the Subclass Members.

7017. Failing to require Defendant to provide remuneration under these circumstances would result in Defendant being unjustly enriched at the expense of Plaintiffs and the Subclass Members who endure being exposed to the risk of developing a serious and deadly disease.

7018. Defendant's retention of the benefit conferred upon them by Plaintiffs and the Subclass Members would be unjust, inequitable and not in good conscience.

7019. There is no justification for Defendant to retain the money paid for the Recalled BIOCELL Implants.

7020. Plaintiffs and the Subclass Members suffered damages in an amount to be determined at trial.

L. COUNTS ON BEHALF OF RELEASES SUBCLASS

COUNT 437
Federal Declaratory Judgment, 28 U.S.C. § 2201

7021. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

7022. Plaintiffs Melinda Howard and Amber Ferrell-Steele bring this Count under the Federal Declaratory Judgment Act individually and on behalf of the Releases Subclass.

7023. Allergan designed, manufactured, marketed and sold the Recalled BIOCELL Implants.

7024. In connection with the sale of the Recalled BIOCELL Implants to patients, Allergan provided patients with the Natrelle ConfidencePlus® Warranty.

7025. The Recalled BIOCELL Implants have a textured surface, or shell, which was intended to reduce complications post implantation. Instead, these products subject patients to a significantly increased risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system.

7026. On July 24, 2019, the FDA issued a recall for the Recalled BIOCELL Implants after concluding that the vast majority of BIA-ALCL cases occurred in patients who had implanted Recalled BIOCELL Implants.

7027. On August 16, 2019, the first class action lawsuit against Allergan was filed.

7028. Since that time, several dozen class actions and individual personal injury lawsuits have been filed against Allergan, which resulted in the centralization of these actions by the Judicial Panel on Multidistrict Litigation in this Court.

7029. Despite the filing of these actions, Defendant has improperly procured and continues to procure releases of liability from members of the putative Releases Subclass who have explanted (removed) their recalled breast implants, without providing any notice of their potential rights in this litigation.

7030. Defendant has procured these releases in both the *ConfidencePlus* Warranty Program and *ConfidencePlus* Premier Warranty Program.

7031. These highly prejudicial communications violate public policy restricting a defendant's communications with putative class members and undermine the class action process.

7032. "Misleading communications to class members concerning the litigation pose a serious threat to the fairness of the litigation process, the adequacy of representation and the administration of justice generally." *In re School Asbestos Litig*., 842 F.2d 671, 680 (3d Cir. 1988) (*citing Gulf Oil*, 452 U.S. at 101 n. 12).

7033. Public policy forbids abusive practices during the pendency of litigation such as communications that coerce prospective class members into excluding themselves from the litigation; communications that contain false, misleading or confusing statements; and communications that undermine cooperation with or confidence in class counsel.

7034. Pursuant to the ConfidencePlus® warranty brochure available on Allergan's website ("ConfidencePlus® Brochure"), as of September 2019, this warranty provided coverage for specific conditions: rupture/deflation, capsular contracture Baker Grade III/IV, "late seroma," "late seroma diagnostic testing coverage," and "BIA-ALCL coverage."[35]

7035. However, the ConfidencePlus® Brochure does not clearly advise class members or their surgeons of the need to sign a release to receive the benefits of Allergan's warranty coverage, nor does it fully disclose the terms of any release.

7036. The ConfidencePlus® Brochure does not inform class members or their surgeons of the pendency of this litigation, which may provide class members with additional compensation and medical monitoring, or inform class members or their surgeons of patients' rights to pursue additional claims for damages against Allergan.

7037. Allergan does not clearly advise class members that warranty coverage under the ConfidencePlus® Warranty Program will require them to sign a general release until they are faced with fine print on a claim form—perhaps even after they have incurred the costs they believed would be reimbursed.

7038. Allergan requires surgeons, not patients, to initiate warranty requests online or via paper form. The Claim Initiation Form requests disclosure of the surgeon's information, the reason

[35] The ConfidencePlus® Brochure is also available at https://www.natrelle.com/Content/pdf/warranty_brochure.pdf (last accessed December 21, 2019).

for replacement of the implant (*i.e.* the recall), the patient's information, and identification of the Recalled BIOCELL Implants that are the subject of the claim.

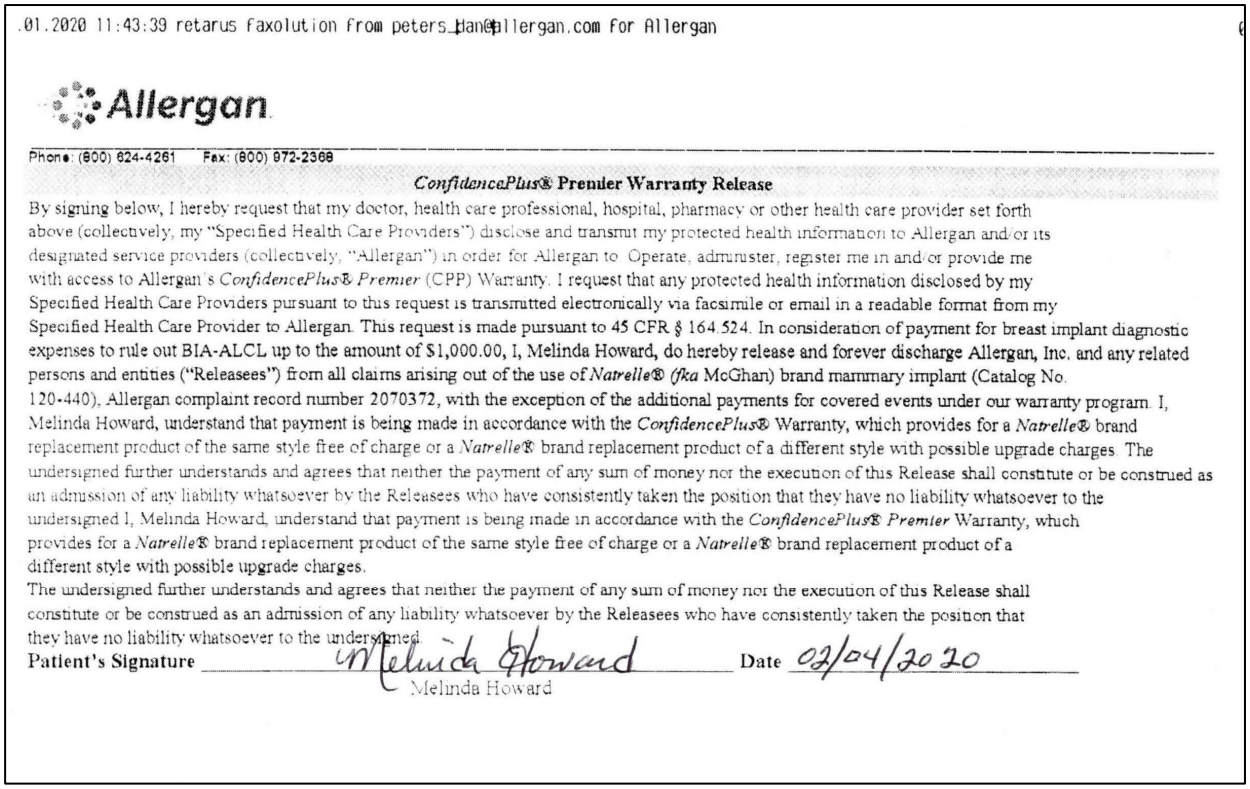
7039. The form does not disclose to the surgeon that the patient will be required to release any claims she may have against Allergan if the claim is completed.

7040. Nowhere on the electronic or hard-copy Claim Initiation Form does Allergan explain the scope of the consent that the patient is purportedly giving when the physician certifies that "the patient is aware of, has consented to, and has directed my disclosure of their information to ALLERGAN to enable services to the patient for such purposes, including to perform product warranty registration and administration purposes…."

7041. Allergan does not provide instructions to the surgeon regarding how to explain the consent to the patient or to advise that a release will be required of the patient to receive compensation.

7042. After the surgeon completes the Claim Initiation Form, Allergan faxes a "Product Claim Form and *ConfidencePlus* Warranty Release" or "Product Claim Form and *ConfidencePlus* Premier Warranty Release" (collectively, "Claim Form") to the surgeon with the specific class member's name on it. This form requires the class member to release all claims against Allergan relating to the Recalled BIOCELL Implants.

7043. An example of the release language at the end of a three-page form is reflected in the release signed by Ms. Howard on February 4, 2020.



.01.2020 11:43:39 retarus faxolution from peters_dan@allergan.com for Allergan

Allergan

Phone: (800) 624-4261 Fax: (800) 872-2368

ConfidencePlus® Premier Warranty Release

By signing below, I hereby request that my doctor, health care professional, hospital, pharmacy or other health care provider set forth above (collectively, my "Specified Health Care Providers") disclose and transmit my protected health information to Allergan and/or its designated service providers (collectively, "Allergan") in order for Allergan to Operate, administer, register me in and/or provide me with access to Allergan's *ConfidencePlus® Premier* (CPP) Warranty. I request that any protected health information disclosed by my Specified Health Care Providers pursuant to this request is transmitted electronically via facsimile or email in a readable format from my Specified Health Care Provider to Allergan. This request is made pursuant to 45 CFR § 164.524. In consideration of payment for breast implant diagnostic expenses to rule out BIA-ALCL up to the amount of $1,000.00, I, Melinda Howard, do hereby release and forever discharge Allergan, Inc. and any related persons and entities ("Releasees") from all claims arising out of the use of *Natrelle® (fka* McGhan) brand mammary implant (Catalog No. 120-440), Allergan complaint record number 2070372, with the exception of the additional payments for covered events under our warranty program. I, Melinda Howard, understand that payment is being made in accordance with the *ConfidencePlus®* Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges. The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned. I, Melinda Howard, understand that payment is being made in accordance with the *ConfidencePlus® Premier* Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges.

The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned.

Patient's Signature Melinda Howard Melinda Howard **Date** 02/04/2020

7044. The release is just one sentence buried among others in fine print.

7045. Presentation of these release provisions on the Claim Form is deceptive given that patients are not told that such a concession is required under the warranty program.

7046. The Claim Form also does not disclose that the class members may be at an increased risk of contracting BIA-ALCL because of the Recalled BIOCELL Implants and that they will release any such claims.

7047. The Claim Form is silent as to the need for class members to consult legal counsel before signing the Claim Form.

7048. In extracting these releases, Allergan does not advise surgeons or class members that there are pending class actions, as well as this Multidistrict litigation which includes individual actions, on behalf of patients who received Allergan's Recalled BIOCELL Implants.

7049. The remedy for a violation of this public policy is to void the extracted releases from class members.

7050. Plaintiffs thus seek a declaration pursuant to the Federal Declaratory Judgement that the releases procured from them and the Releases Subclass are deceptive, misleading and/or void as against public policy.

COUNT 438_
New Jersey Declaratory Judgment Act, N.J. Rev. Stat., § 2A:16-59

7051. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

7052. Plaintiffs Melinda Howard and Amber Ferrell-Steele bring this count under the New Jersey Declaratory Judgment Act individually and on behalf of the Releases Subclass.

7053. Allergan designed, manufactured, marketed and sold the Recalled BIOCELL Implants.

7054. In connection with the sale of the Recalled BIOCELL Implants to patients, Allergan provided patients with the Natrelle ConfidencePlus® Warranty.

7055. The Recalled BIOCELL Implants have a textured surface, or shell, which was intended to reduce complications post implantation. Instead, these products subject patients to a significantly increased risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system.

7056. On July 24, 2019, the FDA issued a recall for the Recalled BIOCELL Implants after concluding that the vast majority of BIA-ALCL cases occurred in patients who had implanted Recalled BIOCELL Implants.

7057. On August 16, 2019, the first class action lawsuit against Allergan was filed.

7058. Since that time, several dozen class actions and individual personal injury lawsuits have been filed against Allergan, which resulted in the centralization of these actions by the Judicial Panel on Multidistrict Litigation in this Court.

7059. Despite the filing of these actions, Defendant has improperly procured and continues to procure releases of liability from members of the putative Releases Subclass who have explanted (removed) their recalled breast implants, without providing any notice of their potential rights in this litigation.

7060. Defendant has procured these releases in both the *ConfidencePlus* Warranty Program and *ConfidencePlus* Premier Warranty Program.

7061. These highly prejudicial communications violate public policy restricting a defendant's communications with putative class members and undermine the class action process.

7062. "Misleading communications to class members concerning the litigation pose a serious threat to the fairness of the litigation process, the adequacy of representation and the administration of justice generally." *In re School Asbestos Litig*., 842 F.2d 671, 680 (3d Cir. 1988) (*citing Gulf Oil*, 452 U.S. at 101 n. 12).

7063. Public policy forbids abusive practices during the pendency of litigation such as communications that coerce prospective class members into excluding themselves from the litigation; communications that contain false, misleading or confusing statements; and communications that undermine cooperation with or confidence in class counsel.

7064. Pursuant to the ConfidencePlus® warranty brochure available on Allergan's website ("ConfidencePlus® Brochure"), as of September 2019, this warranty provided coverage

for specific conditions: rupture/deflation, capsular contracture Baker Grade III/IV, "late seroma," "late seroma diagnostic testing coverage," and "BIA-ALCL coverage."[36]

7065. However, the ConfidencePlus® Brochure does not clearly advise class members or their surgeons of the need to sign a release to receive the benefits of Allergan's warranty coverage, nor does it fully disclose the terms of any release.

7066. The ConfidencePlus® Brochure does not inform class members or their surgeons of the pendency of this litigation, which may provide class members with additional compensation and medical monitoring, or inform class members or their surgeons of patients' rights to pursue additional claims for damages against Allergan.

7067. Allergan does not clearly advise class members that warranty coverage under the ConfidencePlus® Warranty Program will require them to sign a general release until they are faced with fine print on a claim form—perhaps even after they have incurred the costs they believed would be reimbursed.

7068. Allergan requires surgeons, not patients, to initiate warranty requests online or via paper form. The Claim Initiation Form requests disclosure of the surgeon's information, the reason for replacement of the implant (*i.e.* the recall), the patient's information, and identification of the Recalled BIOCELL Implants that are the subject of the claim.

7069. The form does not disclose to the surgeon that the patient will be required to release any claims she may have against Allergan if the claim is completed.

7070. Nowhere on the electronic or hard-copy Claim Initiation Form does Allergan explain the scope of the consent that the patient is purportedly giving when the physician certifies

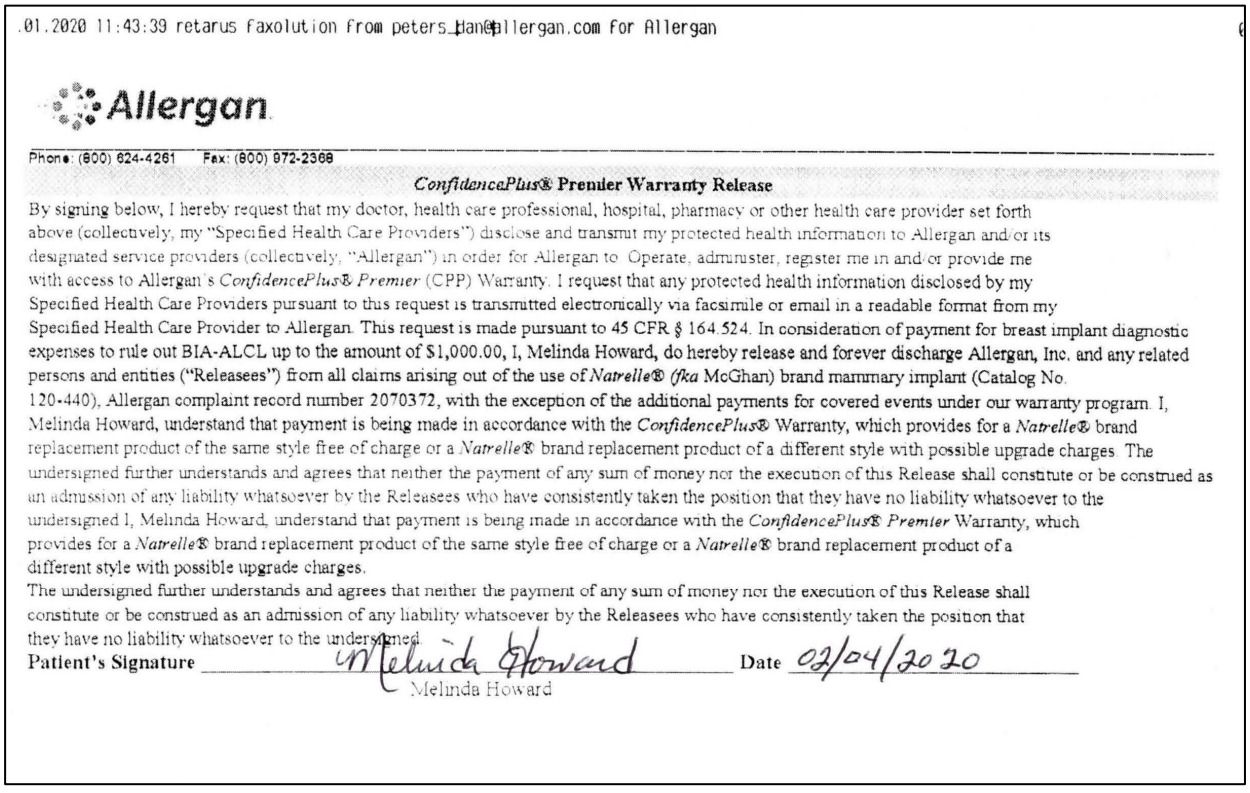
[36] The ConfidencePlus® Brochure is also available at https://www.natrelle.com/Content/pdf/warranty_brochure.pdf (last accessed December 21, 2019).

that "the patient is aware of, has consented to, and has directed my disclosure of their information to ALLERGAN to enable services to the patient for such purposes, including to perform product warranty registration and administration purposes…."

7071. Allergan does not provide instructions to the surgeon regarding how to explain the consent to the patient or to advise that a release will be required of the patient to receive compensation.

7072. After the surgeon completes the Claim Initiation Form, Allergan faxes a "Product Claim Form and *ConfidencePlus* Warranty Release" or "Product Claim Form and *ConfidencePlus* Premier Warranty Release" (collectively, "Claim Form") to the surgeon with the specific class member's name on it. This form requires the class member to release all claims against Allergan relating to the Recalled BIOCELL Implants.

7073. An example of the release language at the end of a three-page form is reflected in the release signed by Ms. Howard on February 4, 2020.



.01.2020 11:43:39 retarus faxolution from peters_dan@allergan.com for Allergan

Allergan

Phone: (800) 624-4261 Fax: (800) 972-2368

***ConfidencePlus*® Premier Warranty Release**

By signing below, I hereby request that my doctor, health care professional, hospital, pharmacy or other health care provider set forth above (collectively, my "Specified Health Care Providers") disclose and transmit my protected health information to Allergan and/or its designated service providers (collectively, "Allergan") in order for Allergan to Operate, administer, register me in and/or provide me with access to Allergan's *ConfidencePlus® Premier* (CPP) Warranty. I request that any protected health information disclosed by my Specified Health Care Providers pursuant to this request is transmitted electronically via facsimile or email in a readable format from my Specified Health Care Provider to Allergan. This request is made pursuant to 45 CFR § 164.524. In consideration of payment for breast implant diagnostic expenses to rule out BIA-ALCL up to the amount of $1,000.00, I, Melinda Howard, do hereby release and forever discharge Allergan, Inc. and any related persons and entities ("Releasees") from all claims arising out of the use of *Natrelle®* (*fka* McGhan) brand mammary implant (Catalog No. 120-440), Allergan complaint record number 2070372, with the exception of the additional payments for covered events under our warranty program. I, Melinda Howard, understand that payment is being made in accordance with the *ConfidencePlus®* Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges. The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned I, Melinda Howard, understand that payment is being made in accordance with the *ConfidencePlus® Premier* Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges.

The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned.

Patient's Signature Melinda Howard **Date** 02/04/2020

Melinda Howard

The release is just one sentence buried among others in fine print.

7074. Presentation of these release provisions on the Claim Form is deceptive given that patients are not told that such a concession is required under the warranty program.

7075. The Claim Form also does not disclose that the class members may be at an increased risk of contracting BIA-ALCL because of the Recalled BIOCELL Implants and that they will release any such claims.

7076. The Claim Form is silent as to the need for class members to consult legal counsel before signing the Claim Form.

7077. In extracting these releases, Allergan does not advise surgeons or class members that there are pending class actions, as well as this Multidistrict litigation which includes individual actions, on behalf of patients who received Allergan's Recalled BIOCELL Implants.

7078. The remedy for a violation of this public policy is to void the extracted releases from class members.

7079. Plaintiffs thus seek a declaration pursuant to the New Jersey Declaratory Judgement Act that the releases procured from them and the Releases Subclass are deceptive, misleading and/or void as against public policy.

COUNT 439
Rescission

7080. Plaintiffs incorporate by reference all preceding and subsequent paragraphs.

7081. Plaintiffs Melinda Howard and Amber Ferrell-Steele bring this count for rescission of executed *ConfidencePlus* Warranty Releases and *ConfidencePlus* Premier Warranty Releases individually and on behalf of the Releases Subclass.

7082. Contracts may be rescinded where there is original invalidity, fraud, failure of consideration or material breach.

7083. The *ConfidencePlus* Warranty Releases and *ConfidencePlus* Premier Warranty Releases should be rescinded because Allergan has acted in a fraudulent and deceptive manner to procure the releases.

7084. Allergan designed, manufactured, marketed and sold the Recalled BIOCELL Implants.

7085. In connection with the sale of the Recalled BIOCELL Implants to patients, Allergan provided patients with the Natrelle ConfidencePlus® Warranty.

7086. The Recalled BIOCELL Implants have a textured surface, or shell, which was intended to reduce complications post implantation. Instead, these products subject patients to a significantly increased risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system.

7087. On July 24, 2019, the FDA issued a recall for the Recalled BIOCELL Implants after concluding that the vast majority of BIA-ALCL cases occurred in patients who had implanted Recalled BIOCELL Implants.

7088. On August 16, 2019, the first class action lawsuit against Allergan was filed.

7089. Since that time, several dozen class actions and individual personal injury lawsuits have been filed against Allergan, which resulted in the centralization of these actions by the Judicial Panel on Multidistrict Litigation in this Court.

7090. Despite the filing of these actions, Defendant has improperly procured and continues to procure releases of liability from members of the putative Releases Subclass who have explanted (removed) their recalled breast implants, without providing any notice of their potential rights in this litigation.

7091. Defendant has procured these releases in both the *ConfidencePlus* Warranty Program and *ConfidencePlus* Premier Warranty Program.

7092. These highly prejudicial communications violate public policy restricting a defendant's communications with putative class members and undermine the class action process.

7093. "Misleading communications to class members concerning the litigation pose a serious threat to the fairness of the litigation process, the adequacy of representation and the administration of justice generally." *In re School Asbestos Litig*., 842 F.2d 671, 680 (3d Cir. 1988) (*citing Gulf Oil*, 452 U.S. at 101 n. 12).

7094. Public policy forbids abusive practices during the pendency of litigation such as communications that coerce prospective class members into excluding themselves from the litigation; communications that contain false, misleading or confusing statements; and communications that undermine cooperation with or confidence in class counsel.

7095. Pursuant to the ConfidencePlus® warranty brochure available on Allergan's website ("ConfidencePlus® Brochure"), as of September 2019, this warranty provided coverage for specific conditions: rupture/deflation, capsular contracture Baker Grade III/IV, "late seroma," "late seroma diagnostic testing coverage," and "BIA-ALCL coverage."[37]

7096. However, the ConfidencePlus® Brochure does not clearly advise class members or their surgeons of the need to sign a release to receive the benefits of Allergan's warranty coverage, nor does it fully disclose the terms of any release.

7097. The ConfidencePlus® Brochure does not inform class members or their surgeons of the pendency of this litigation, which may provide class members with additional compensation

[37] The ConfidencePlus® Brochure is also available at https://www.natrelle.com/Content/pdf/warranty_brochure.pdf (last accessed December 21, 2019).

and medical monitoring, or inform class members or their surgeons of patients' rights to pursue additional claims for damages against Allergan.

7098. Allergan does not clearly advise class members that warranty coverage under the ConfidencePlus® Warranty Program will require them to sign a general release until they are faced with fine print on a claim form—perhaps even after they have incurred the costs they believed would be reimbursed.

7099. Allergan requires surgeons, not patients, to initiate warranty requests online or via paper form. The Claim Initiation Form requests disclosure of the surgeon's information, the reason for replacement of the implant (*i.e.* the recall), the patient's information, and identification of the Recalled BIOCELL Implants that are the subject of the claim.

7100. The form does not disclose to the surgeon that the patient will be required to release any claims she may have against Allergan if the claim is completed.

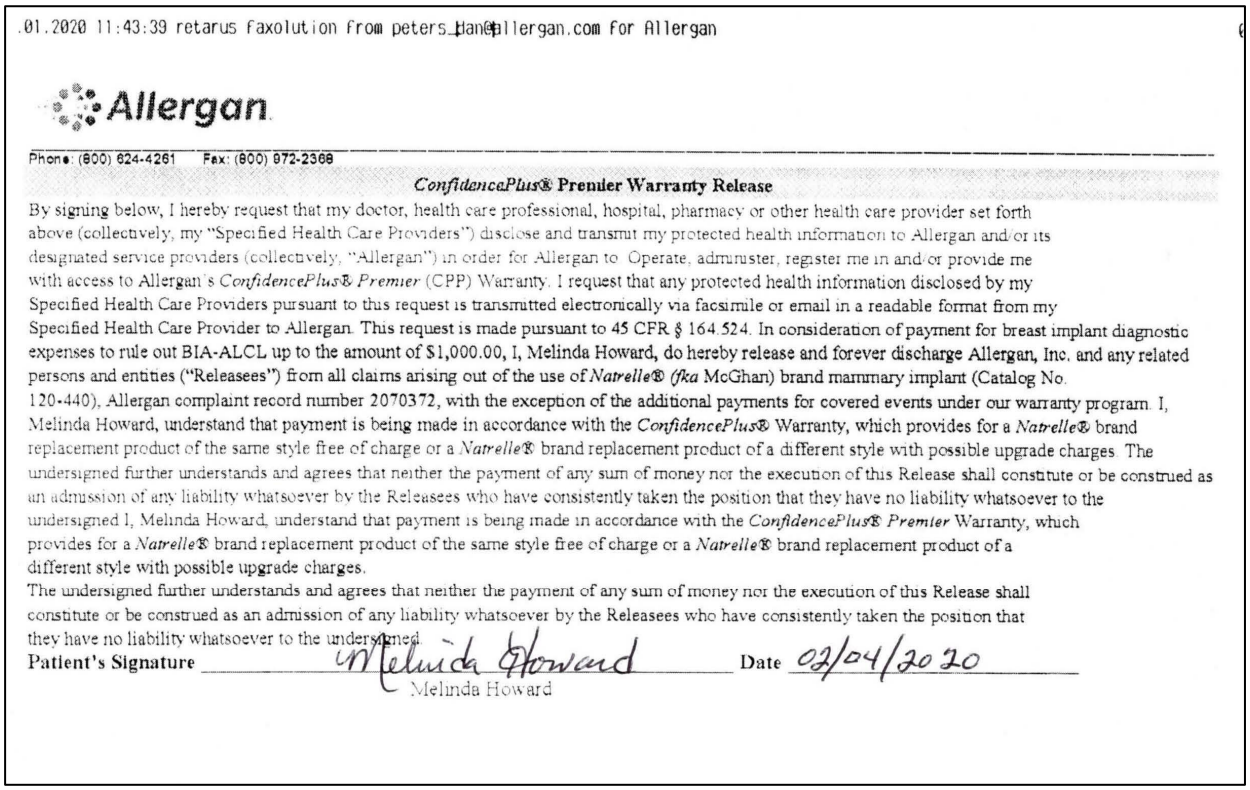
7101. Nowhere on the electronic or hard-copy Claim Initiation Form does Allergan explain the scope of the consent that the patient is purportedly giving when the physician certifies that "the patient is aware of, has consented to, and has directed my disclosure of their information to ALLERGAN to enable services to the patient for such purposes, including to perform product warranty registration and administration purposes…."

7102. Allergan does not provide instructions to the surgeon regarding how to explain the consent to the patient or to advise that a release will be required of the patient to receive compensation.

7103. After the surgeon completes the Claim Initiation Form, Allergan faxes a "Product Claim Form and *ConfidencePlus* Warranty Release" or "Product Claim Form and *ConfidencePlus* Premier Warranty Release" (collectively, "Claim Form") to the surgeon with the specific class

member's name on it. This form requires the class member to release all claims against Allergan relating to the Recalled BIOCELL Implants.

7104. An example of the release language at the end of a three-page form is reflected in the release signed by Ms. Howard on February 4, 2020.



.01.2020 11:43:39 retarus faxolution from peters_dan@allergan.com for Allergan

Allergan

Phone: (800) 624-4261 Fax: (800) 872-2368

ConfidencePlus® Premier Warranty Release

By signing below, I hereby request that my doctor, health care professional, hospital, pharmacy or other health care provider set forth above (collectively, my "Specified Health Care Providers") disclose and transmit my protected health information to Allergan and/or its designated service providers (collectively, "Allergan") in order for Allergan to Operate, administer, register me in and/or provide me with access to Allergan's *ConfidencePlus® Premier* (CPP) Warranty. I request that any protected health information disclosed by my Specified Health Care Providers pursuant to this request is transmitted electronically via facsimile or email in a readable format from my Specified Health Care Provider to Allergan. This request is made pursuant to 45 CFR § 164.524. In consideration of payment for breast implant diagnostic expenses to rule out BIA-ALCL up to the amount of $1,000.00, I, Melinda Howard, do hereby release and forever discharge Allergan, Inc. and any related persons and entities ("Releasees") from all claims arising out of the use of *Natrelle® (fka* McGhan) brand mammary implant (Catalog No. 120-440), Allergan complaint record number 2070372, with the exception of the additional payments for covered events under our warranty program. I, Melinda Howard, understand that payment is being made in accordance with the *ConfidencePlus®* Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges. The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned I, Melinda Howard, understand that payment is being made in accordance with the *ConfidencePlus® Premier* Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges.

The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned.

Patient's Signature Melinda Howard **Date** 02/04/2020

Melinda Howard

7105. The release is just one sentence buried among others in fine print.

7106. Presentation of these release provisions on the Claim Form is deceptive given that patients are not told that such a concession is required under the warranty program.

7107. The Claim Form also does not disclose that the class members may be at an increased risk of contracting BIA-ALCL because of the Recalled BIOCELL Implants and that they will release any such claims.

7108. The Claim Form is silent as to the need for class members to consult legal counsel before signing the Claim Form.

7109. In extracting these releases, Allergan does not advise surgeons or class members that there are pending class actions, as well as this Multidistrict litigation which includes individual actions, on behalf of patients who received Allergan's Recalled BIOCELL Implants.

7110. Allergan's actions are fraudulent, deceptive, and misleading.

7111. Plaintiff, and the *Sloan* Plaintiffs before her, acted within a reasonable time to seek relief from the releases.

7112. Plaintiffs thus seek the equitable remedy of rescission of the executed releases on behalf of themselves and the Releases Subclass.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(1) Certify the Class and Subclasses pursuant to Fed. R. Civ. P. 23(a), (b)(2), (b)(3), or (c)(4), appoint Plaintiffs as representatives of the Class and Subclass, and appoint their counsel as Class Counsel;

(2) Enter judgment for liability in their favor and against Defendant;

(3) Grant equitable relief in the form of a medical-monitoring program to be funded by Defendant;

(4) Award compensatory, punitive and other damages, as may be allowed by law;

(5) Grant Plaintiffs their attorneys' fees and costs.

Dated: May 26, 2020

Respectfully Submitted,

By: /s/ *James E. Cecchi*

James E. Cecchi
Donald A. Ecklund
CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Road
Roseland, New Jersey 07068-1739
United States of America
Ph. 973.994.1700
F. 973.994.1744
JCecchi@carellabyrne.com
Liaison Counsel for Plaintiffs and the putative classes

Shanon J. Carson
John Kerrigan
BERGER MONTAGUE PC
1818 Market St., Suite 3600
Philadelphia, PA 19103
Ph. 215.875.4656
scarson@bm.net
jkerrigan@bm.net

John Albanese
BERGER MONTAGUE PC
43 SE Main Street, Suite 505
Minneapolis, MN 55418
Ph. 612.594.5997
jalbanese@bm.net

Elizabeth A. Fegan
FEGAN SCOTT LLC
150 S. Wacker Dr., 24th Floor
Chicago, IL 60606
Ph. 312-741-1019
Fax 312-264-0100
beth@feganscott.com

Jessica H. Meeder
FEGAN SCOTT LLC
1200 G St., NW, Suite 800
Washington, D.C. 20005-3820

Ph. 202.921.6007
jessica@feganscott.com

Jennifer Lenze
LENZE LAWYERS, PLC
1300 Highland Ave. Suite 207
Manhattan Beach, CA 90266
Ph. (310) 322-8800
F. (310) 322-8811
jlenze@lenzelawyers.com

Virginia Buchanan
LEVIN PAPANTONIO THOMAS MITCHELL RAFFERTY PROCTOR P.A.
316 South Baylen St.
Pensacola, FL 32502
Ph. (850) 435-7023
vbuchanan@levinlaw.com

Co-Lead Counsel