UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ELLEN NEWMAN, AMY GROTTE, RACHAEL HERRON, LISA ROBERTS, AMY EDENS, HEIDI LEE, AMBER FERRELL-STEELE, AND TORY BOBADILLA, individually and on behalf of all others similarly situated,	)	
Plaintiffs,	)	No.
v.	)	JURY TRIAL DEMANDED
ALLERGAN INC., F/K/A INAMED CORPORATION; ALLERGAN USA, INC.; and ALLERGAN PLC,	)	
Defendants.	)	

CLASS ACTION COMPLAINT

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Plaintiffs Ellen Newman, Amy Grotte, Rachael Herron, Lisa Roberts, Amy Edens, Heidi Lee, Amber Ferrell-Steele, and Tory Bobadilla ("Plaintiffs"), on behalf of themselves and all others similarly situated, by and through counsel and pursuant to the Federal Rules of Civil Procedure, brings this Class Action Complaint against Defendants Allergan Inc., f/k/a Inamed Corporation, Allergan USA, Inc., and Allergan plc ("Defendants" or "Allergan") and allege as follows:

INTRODUCTION

1. Allergan manufactures and sells BIOCELL saline-filled and silicone-filled breast implants and tissue expanders. BIOCELL products 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.

2. On July 24, 2019, the FDA issued a Class I Recall notice for Allergan's BIOCELL products0F[1] ("Recalled BIOCELL Implants") after concluding that the vast majority of BIA-

[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

ALCL cases occurred in patients who had implanted 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."

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."

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

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, 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);

6. As is clear from its post-recall conduct and representations, Allergan has failed to—and has no plans to—provide medical monitoring for Plaintiffs and the class members due to 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 Allergan smooth implants from Allergan at no cost. Allergan will not, however, pay any other associated fees, including surgical costs.

8. According to the letter, patients who choose to keep their Recalled BIOCELL Implants (and therefore are at a significantly increased risk of developing BIA-ALCL) may be eligible for reimbursement for certain diagnostic and surgical fees, but that dollar figure is capped.

9. BIA-ALCL is a serious cancer that can metastasize and prove fatal. The diagnostic process can be invasive. Treatment includes removal of the implants and may also require chemotherapy and radiation.

10. Now that these products have been recalled, Allergan refuses to appropriately care for, monitor, and compensate Plaintiffs and the class members. Plaintiffs and the class members will 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 Defendants have knowingly exposed Plaintiffs and the class members.

11. For decades, Allergan knew that its Recalled BIOCELL Implants cause BIA-ALCL. Nonetheless, it sold and benefitted from the sale of these products, at Plaintiffs' and the class members' expense.

12. Defendant sold the products with complete disregard and reckless indifference to the safety of Plaintiffs and members of the Nationwide Class defined as: "All persons in the United States who, for personal use, implanted Allergan's BIOCELL products that have been recalled by the FDA and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma."

13. Accordingly, Plaintiffs seek equitable relief for themselves and the Medical Monitoring Class in the form of medical monitoring as a result of their implantation of, and exposure to, the Recalled BIOCELL Implants, which are causing them to be at increased risk for developing breast implant-associated anaplastic large cell lymphoma. Plaintiffs also seek all costs associated with explantation of the Recalled BIOCELL Implants.

THE PARTIES

A. Plaintiffs

14. Plaintiff Ellen Newman is and was a resident and citizen of the Commonwealth of Pennsylvania and the United States at all times relevant to this action. On or about July 2013, Plaintiff received Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants (P040046), Style 410FF, which are on the list of Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have received and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

15. Plaintiff Amy Grotte is and was a resident and citizen of the State of Minnesota and the United States at all times relevant to this action. On or about September 2016, Plaintiff received

the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants (P040046), Style 410MX, which are on the list of Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have received and/or selected these breast implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

16. Plaintiff Rachael Herron is and was a resident and citizen of the State of Oklahoma and/or the State of Texas, as well as the United States, at all times relevant to this action. On or about 1999, Plaintiff received Allergan Natrelle Saline-Filled Breast Implants (P990074), Style 168, which are on the list of Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have received and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

17. Plaintiff Lisa Roberts is and was a resident and citizen of the State of New York and the United States at all times relevant to this action. On or about October 2014, Plaintiff received Allergan Natrelle Silicone-Filled Textured Breast Implants (P020056), Style 110, which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have received and/or selected these implants had she

known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

18. Plaintiff Amy Edens is and was a resident and citizen of the State of Michigan and the United States at all times relevant to this action. On or about May 2003, Plaintiff received Allergan Natrelle Saline-Filled Breast Implants (P990074), Style 468, which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have received and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

19. Plaintiff Heidi Lee is and was a resident and citizen of the State of Arizona and the United States at all times relevant to this action. On or about September 2017, Plaintiff received Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants (P040046), Style 410FX, which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

20. Plaintiff Amber Ferrell-Steele is and was a resident and citizen of the State of Texas and the United States at all times relevant to this action. On or about June 2015, Plaintiff received

Allergan Natrelle Silicone-Filled Textured Breast Implants (P020056), Style TSLP, which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

21. Plaintiff Tory Bobadilla is and was a resident and citizen of the State of Florida and the United States at all times relevant to this action. On or about 1993, Plaintiff received Allergan Natrelle Saline-Filled Breast Implants (P990074), Style 168, which is one of the Recalled BIOCELL Implants. As a direct and proximate result of having the breast implants implanted, Plaintiff is at an increased risk for developing BIA-ALCL and is in need of regular monitoring. Plaintiff would not have received and/or selected these implants had she known prior to the procedure that they would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and other costs and procedures to detect BIA-ALCL.

B. Defendants

22. Defendant Allergan plc is a publicly traded corporation headquartered in Dublin, Ireland. Its administrative headquarters for the United States are in Bridgewater Township, New Jersey.

23. Allergan, Inc., a wholly-owned subsidiary of Allergan plc, is incorporated under the laws of Delaware with a principal place of business in Bridgewater Township, New Jersey.

24. Defendant Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

25. Defendants Allergan plc; Allergan, Inc.; and Allergan USA, Inc. are collectively referred to as "Defendants" or "Allergan."

26. 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.

27. 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.

28. In March 2006, Allergan acquired Inamed and its wholly-owned subsidiary, McGhan, as well as the BIOCELL trademark. In doing so, it assumed the liability for its 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.

29. In 2015, Actavis, a pharmaceutical company headquartered in Dublin, Ireland with a principal place of business in New Jersey, purchased Allergan and adopted the Allergan plc name.

30. Allergan's Medical Aesthetics division, which is responsible for its BIOCELL breast implants and tissue expanders, is overseeing the recall, and is administering Allergan's inadequate Replacement "Warranty."

31. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, Defendants carried out a joint scheme, business plan, or policy in all respects pertinent hereto, and the acts of each Defendant are legally attributable to the other Defendant(s).

JURISDICTION AND VENUE

32. 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; (c) at least one Plaintiffs and is a citizen of a different state than at least one Defendant; and (c) members of the class, including Plaintiff, are citizens of a state and at least one of the Defendants is a citizen or subject of a foreign state.

33. The Court has personal jurisdiction over the Defendants because they have sufficient minimum contacts in this District to render the exercise of jurisdiction by this Court proper and fair.

34. 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 Defendants are subject to personal jurisdiction within this District.

FACTUAL ALLEGATIONS

A. A Relevant History of Breast Implants and Tissue Expanders

35. Breast implants are medical devices that are implanted under the breast tissues to increase breast size, replace breast tissue that has been removed due to cancer, surgery, or other trauma, or to correct developmental defects. Tissue expanders are a type of inflatable breast implant, typically used in breast reconstruction surgeries, to stretch skin and muscle to create space for a more permanent implant.

36. 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.

37. Manufacturers use a variety of techniques to create their textured implants. Allergan's process, which it uses for its Recalled BIOCELL Implants, creates the textured surface

by dipping a silicone capsule into salt crystals before it is dry. The surface is washed and cured, leaving behind a pitted surface with randomly-sized indentations.

38. Every year approximately 400,000 women in the United States receive breast implants for augmentation or reconstruction, and breast augmentation is the most common cosmetic surgery in the country.

39. 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 the authority to review and approve new medical devices, including breast implants.

40. The FDA classifies medical devices depending on the risks associated with the device and the degree of regulation it deems appropriate. Its three-tiered 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. 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).

41. In 1988, in response to growing safety concerns, including reports of gel bleed and capsular contracture and studies warning of the link between silicone implants and cancer, the FDA re-classified both saline- and silicone-filled breast implants as Class III devices. In April 1991, following publication of the new regulations, the FDA began requiring breast implant manufacturers to obtain specific premarket approval ("PMA") by the FDA.

42. Tissue expanders, which are most often used for breast reconstruction, are inflatable breast implants that are slowly filled with saline over a period of time until the implant reaches the

desired size. After the expansion is complete, the patient receives a permanent implant. 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 PMA Process and Manufacturer Responsibilities

43. 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 its PMA process, the FDA evaluates the safety and efficacy of Class III medical devices.

44. 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 and/or PMA Supplement application must include:

a. Proposed indications for use;

b. Description of the device, including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study 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.

45. 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 definition of labeling extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, Directions for Use ("DFU"), and fillers.

46. In order to provide continued reasonable assurance of the safety and effectiveness of the device, following PMA approval the manufacturer is subjected to ongoing and continuous reporting obligations. *See, e.g.*, 21 CFR §§ 803.50 et seq.; 21 CFR §§ 814.80 et seq. For example, 21 CFR § 803.50 requires that a manufacturer report, "[n]o later than 30 calendar days after it receives or becomes aware of information, from any source, that reasonably suggests that a device" "[m]ay have caused or contributed to a death or serious injury" or "has malfunctioned and this device or a similar device… would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." The FDA may institute additional reporting requirements as it determines appropriate. 21 CFR § 814.82.

47. Information is "reasonably known" if it can be obtained by contacting "a user facility, importer or other initial reporter;" is information that is in the manufacturer's possession; or is information that "can be obtain[ed] by analysis, testing, or other evaluation of the device." 21 CFR § 803.50(b). A manufacturer is required to investigate each reported event and evaluate the cause.

48. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to any medical device, including BIOCELL breast implants, rests with the manufacturer.

49. At all relevant times, and pursuant to 21 C.F.R. § 740(a), a PMA applicant manufacturer may voluntarily withdraw its product to carry out its responsibility to protect the public health and well-being from products that present a risk of injury or gross deception.

2. The Development of Allergan's BIOCELL Implants

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

51. Beginning in the early 1990s, and pursuant to the FDA's oversight and approval, McGhan conducted numerous clinical trials of its implants, including clinical trials involving its silicone implants in reconstruction patients (the Adjunct study) and in reconstruction and revision patients (the CORE study). Patient follow-up was to occur until five years post-implantation (Adjunct study) and ten years post-implantation (CORE study).

52. On May 10, 2000, the FDA approved McGhan's PMA 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.

53. As a condition of the Defendant's PMA, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Defendants were required to, *inter alia*,

a. conduct and provide reports on a 10-year post approval study;

b. conduct and provide reports on a retrieval study, which would evaluate explanted implants and the mode of failure;

c. 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";

d. 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 malfunction would occur."1F[2]

54. In 2002, McGhan, which had become Inamed, 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.

55. In November 2006 the FDA approved this device, 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.

56. In February 2013, the FDA approved Defendants' PMA for their 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.

57. As conditions of the 2006 and 2013 approvals, the FDA required Defendants to conduct six post-approval studies to evaluate and characterize the long-term performance and safety of the devices.2F[3]

[2] *See* PMA P990074 Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf/P990074A.pdf (last accessed November 7, 2019).
[3] *See* PMA P20056 Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056a.pdf (last accessed November 7, 2019); and PMA 040046 Approval Order, http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046a.pdf (last accessed November 7, 2019).

58. In its 2002, 2006, and 2013 PMA approval letters, the FDA stated that "[f]ailure to comply with any post-approval 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 act."

3. Allergan's BIOCELL Tissue Expanders

59. 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).

60. The 510(k) process requires the manufacturer to demonstrate that the device is as safe and effect 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.

61. On January 5, 2011, Defendants' 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 the McGhan Magna-Site Tissue Expander, which was initially cleared in 1986 and is also subject to the July 24, 2019 recall.

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

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[4] *See* Clearance Letter for K102806, http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102806.pdf (last accessed November 7, 2019).
[5] *See* Clearance Letter for K143354, http://www.accessdata.fda.gov/cdrh_docs/pdf14/K143354.pdf (last accessed November 7, 2019).

63. The FDA's 510(k) clearance for the Defendants' tissue expanders required Defendants to comply with the labeling and medical device reporting requirements of the FDCA. 21 CFR §§ 801, 803.

64. Throughout the remainder of this Complaint, unless stated otherwise, "implant" refers to both breast implants and tissue expanders.

C. Breast Implant-Associated ALCL

65. BIA-ALCL is not breast cancer. It is a type of non-Hodgkin's lymphoma—cancer of the immune system. BIA-ALCL is a serious cancer that typically occurs in the scar tissue and fluid near the breast implant. Left untreated, it spreads throughout the body and can become fatal.

66. 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 a year or more after surgery and may appear up to at least ten years post-implantation.

67. Diagnostic procedures are invasive and can include ultrasound, computed tomography scans ("CT scan"), and/or magnetic resonance imaging ("MRI"), fluid sampling via fine needle aspiration, and biopsy. Treatment includes surgical removal of the implant and surrounding tissue. Some patients may also require radiation, chemotherapy, or both.

68. The first report of BIA-ALCL in the medical literature occurred in 1997, and additional reports followed.

69. 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.

70. 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."

71. 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 BIOCELL products have a textured outer shell.

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

73. In March 2015, an analysis identified 173 cases of ALCL. The French National Cancer Institute claimed that "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant."

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

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

76. 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."

77. In May 2017, a global analysis of approximately forty governmental databases shoed 363 cases of BIA-ALCL, of which 258 were reported to the FDA.

78. 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 9 deaths.

79. On March 21, 2018, the FDA updated its 2011 warning. It recognized the WHO's designation 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."

80. On May 9, 2018, Australia's TGA reported 72 cases of ALCL in Australian patients. A January 2018 study in JAMA Oncology reported that the risk of developing BIA-ALCL in women with breast implants was 421.8x higher than in women without, "implying an attributable risk approaching 100%."

81. Although the risk of BIA-ALCL is generally believed to be 1/300,000, textured implants substantially increase that risk. 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. These conclusions are consistent with studies in Europe. And 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."

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

83. 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.

84. 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.

85. In its July 24, 2019 safety communication recalling 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.

86. 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 Allergan's BIOCELL textured implants "would likely cause serious, adverse health consequences and potentially death from BIA-ALCL."

D. Allergan Concealed the Risks of its Recalled BIOCELL Implants

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

88. Allergan is responsible for timely communicating complete and accurate safety information regarding its devices, including its Recalled BIOCELL Implants, and for monitoring all reasonably available information and clinical experiences. It also has a duty to file adverse event reports with the FDA.

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

90. 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.

91. 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.

92. Instead of accurately reporting adverse events individually each time an injury occurred, Allergan sought to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure." It did this by filing Alternative Summary reports ("ASRs"), which bypass MAUDE.

93. ASRs were originally developed to reduce paperwork. The program allowed Allergan to report hundreds of thousands of adverse event reports together on less-detailed quarterly spreadsheets. In doing so, Allergan also avoided public disclosure, because ASRs were generally unavailable to the public.

94. 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. Nonetheless, Allergan buried serious events in non-public ASR reports, including a possible case of BIA-ALCL. 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.

95. The FDA discontinued use of ASRs in 2017. Lest there was 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.

96. The FDA has now acknowledged that, until recently, there was a "transparency issue" with the injury reports it had been accepting. It also stated that the surge in reports following the discontinuation of its ASR program reflected the change in its requirements, rather than "a new public health issue."

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

98. Beginning in at least 2006, Allergen possessed information and evidence demonstrating that its Recalled BIOCELL Implants posed a significant risk of BIA-ALCL.

99. Allergan failed to comply with the conditions of its PMAs and violated state and federal law by 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 sell the now-Recalled BIOCELL Implants.

100. Had Allergan complied with its obligations under state and federal law and timely, adequately, and appropriately disclosed the connection between BIOCELL breast implants and tissue expanders and BIA-ALCL, patients, including Plaintiffs and the class members, and their treating physicians would have been able to make an informed decision regarding their use of BIOCELL implants.

101. Applicable state law does not impose duties or requirements materially different from those imposed by federal law, as described herein.

CLASS ACTION ALLEGATIONS

102. Plaintiffs bring this action in their individual capacity and on behalf of the following class ("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 who, for personal use, implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

103. Excluded from the Class are Defendants and any of their affiliates, parents, subsidiaries, officers, and directors; any entity in which Defendants have 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.

104. 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.

105. Numerosity: The FDA has estimated that hundreds of thousands of individuals have been implanted with the Recalled BIOCELL Implants. The September 11, 2019 Class I Recall Notice indicates that there are a total 4,026,287 breast implants and tissue expanders "in commerce." The members of the Class are so numerous that joinder is impractical.

106. Typicality: Plaintiffs' claims are typical of the claims of the class in that Plaintiffs, like all class members, were implanted with the Recalled BIOCELL Implants and face an increased risk of BIA-ALCL. Plaintiffs and the class members were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of herself and the Class Members.

107. Adequacy: Plaintiffs will fairly and adequately protect the interest of the class. Plaintiffs' interests and the interests of all other members of the class are identical, and Plaintiffs are cognizant of her duty and responsibility to each respective class. Further, the interests of the Nationwide Class are not conflicting or divergent but, rather, are common. Accordingly, Plaintiffs can fairly and adequately represent the interests of the Class. Moreover, Plaintiffs' counsel are competent and experienced in litigating class actions, including litigation of this kind. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the Class Members' interests.

108. Commonality and Predominance: There are numerous questions of law and fact common to the class, and these common questions predominate over any issues affecting only individual class members. Questions common to the class 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 was negligent in selling the Recalled BIOCELL Implants;

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

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

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

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

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

109. 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 Plaintiffs 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 Defendants, and thus, individual litigation to redress Defendants' 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.

110. 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 Defendants' Recalled BIOCELL Implants.

111. This action is also properly maintainable under Rule 23(c)(4) in that particular issues common to the class, as described in part in paragraph 101, are most appropriately and efficiently resolved via class action, and would advance the disposition of this matter and the parties' interests therein.

COUNT I: STRICT PRODUCTS LIABILITY- FAILURE TO WARN

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

113. Defendants manufactured, distributed, and/or sold the Recalled BIOCELL Implants that were implanted in Plaintiffs and the class members.

114. Defendants had a duty to warn Plaintiff, the class members, and their physicians regarding the known and knowable dangers of and potential risks posed by its Recalled BIOCELL Implants.

115. The Recalled BIOCELL Implants had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific and medical communities at the time of the manufacture, distribution, and/or sale of the products.

116. The potential risks, including the substantial risk of BIA-ALCL, presented a substantial danger to Plaintiffs and the class members when the BIOCELL products were used or misused an in intended or reasonably foreseeable way.

117. Ordinary consumers, including Plaintiffs and the class members, would not have recognized these potential risks, and Allergan knew this.

118. Allergan failed to adequately warn or instruct Plaintiffs, the class members, and their physicians of the potential risks, including the risk of BIA-ALCL. At the time that Plaintiffs received her implants, Allergan knew or should have known of the clear causal connection between its Recalled BIOCELL Implants and BIA-ALCL, but it did not disclose this information to

Plaintiffs or her physician and did not warn of the significantly greater risk of BIA-ALCL posed by its product.

119. Allergan obtained this information from a variety of sources, including but not limited to its own clinical studies; internal data concerning adverse event reports that was subsequently submitted in ASRs, rather than publicly-available MDRs; published reports and case studies; literature concerning the safety and efficacy of its Recalled BIOCELL Implants; FDA and foreign regulatory communications; and complaints from patients and/or healthcare providers.

120. Allergan then attempted to conceal these true facts by, *inter alia,* failing to report all adverse events to the FDA, improperly reporting certain adverse events via ADRs, which are not publicly available; and failing to include the necessary information in its DFUs, patient labeling.

121. It was foreseeable to Allergan that its failure to provide sufficient instructions and/or warnings, and its failure to timely, adequately, and appropriately report required adverse event information to the FDA, would cause Plaintiffs and the class members irreparable harm, including the increased risk of developing BIA-ALCL. Allergan knew that patients and their physicians, including Plaintiffs and the class members, relied upon its labeling and adverse event disclosures.

122. If Plaintiffs and her physician had been provided with the appropriate information and warnings regarding the causal connection between 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 and would not be at an increased risk of developing BIA-ALCL.

123. Allergan's breach of its duty to warn was a substantial factor in and proximately caused Plaintiffs and the class members injury and damages, including surgical costs for removal of the products and/or ongoing medical monitoring, including invasive diagnostic procedures and other expenses.

COUNT II: NEGLIGENCE

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

125. Allergan has a continuing duty to monitor the Recalled BIOCELL Implants and to discover and report to the FDA any complaints or concerns about product performance or safety. Allergan also has a continuing duty to provide warnings and instructions regarding potential safety hazards associated with the use of its Recalled BIOCELL Implants.

126. Allergan breached these duties by, *inter alia*, failing to (a) 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 Plaintiff, the class members, and their physicians, (c) failing to warn Plaintiff, the class members, and their physicians of the serious risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL; and (d) continuing to manufacture, distribute and/or sell the BIOCELL products notwithstanding these facts.

127. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would have warned of the danger of BIA-ALCL posed by the Recalled BIOCELL Implants.

128. If Plaintiffs and their physicians had been provided with the appropriate information and warnings regarding the causal connection between 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 and would not be at an increased risk of developing BIA-ALCL.

129. Allergan's breaches were a substantial factor in and proximately caused Plaintiffs and the class members to be at increased risk for developing BIA-ALCL and in need of ongoing medical monitoring.

COUNT III: NEGLIGENT RECALL

130. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

131. Despite decades of knowledge that its Recalled BIOCELL Implants pose a significantly increased risk of BIA-ALCL, Allergan continued to sell the products and failed to issue a recall. A reasonable manufacturer, distributor, and/or seller would have recalled the product under the same or similar circumstances.

132. Only when the FDA urged Allergan to recall its Recalled BIOCELL Implants on July 24, 2019 did Allergan do so. In issuing a voluntary recall, Allergan assumed duties to Plaintiffs to exercise reasonable care and act as a reasonable person in issuing and implementing the recall.

133. However, Allergan's recall fails to pay for the full costs associated with surgical removal of Plaintiffs' defective Recalled BIOCELL Implants and therefore does not adequately protect Plaintiffs from injury or risk of harm.

134. As a proximate result of Allergan's breach of duty, Plaintiffs and the class members are at increased risk for developing BIA-ALCL and are in need of ongoing medical monitoring.

COUNT IV: FRAUDULENT CONCEALMENT

135. Plaintiffs incorporates by reference all preceding and subsequent paragraphs.

136. Allergan had a duty to disclose to Plaintiffs and her physician the true dangers and risks posed by its Recalled BIOCELL Implants, including the risk of BIA-ALCL.

137. Rather than complying with its reporting, disclosure, warning, and labeling obligations, Allergan intentionally concealed and/or suppressed material information regarding the

safety and efficacy of the BIOCELL products, including the fact that the products cause BIA-ALCL, as well as the availability of alternative feasible safer designs.

138. These facts were known or knowable to Allergan but were not known to or readily discoverable by Plaintiffs or the class members.

139. Allergan engaged in this fraudulent concealment and suppression with the intent to deceive Plaintiffs and the class members into purchasing its Recalled BIOCELL Implants and to induce healthcare providers, including Plaintiffs' and the class members' physicians, to use the BIOCELL products.

140. If Plaintiffs and the class members had known that Allergan's BIOCELL products posed a substantial risk of BIA-ALCL, a serious disease, they would not have elected to have the recalled products implanted.

141. Allergan's malicious and intentional concealment of material information was a substantial factor in and proximately caused Plaintiffs and the class members injury, including surgical costs for removal of the products and/or ongoing medical monitoring, including invasive diagnostic procedures and other expenses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf all others similarly situated, request that this Court:

A. Enter an order certifying this action as a class action under Federal Rule of Civil Procedure 23(a), (b)(1), (b)(2), (b)(3), and/or (c)(4), as appropriate; appointing Plaintiffs as representatives of the class; and appointing the undersigned counsel as class counsel;

B. Award Plaintiffs and the Class members equitable relief in the form of medical monitoring, including but not limited to the costs of explantation and/or ongoing diagnostic testing;

C. Award other appropriate equitable relief;

D. Award reasonable attorneys' fees and costs, as provided for by law; and

E. Grant such other and further relief that the Court may deem just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs request a trial by jury of all issues triable as of right.

Dated: December 16, 2019

Respectfully Submitted,

By: _____

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JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Ellen Newman, Amy Grotte, Rachael Herron, Lisa Roberts, Amy Edens, Heidi Lee, Amber Ferrell-Steele, Tory Bobadilla

(b) County of Residence of First Listed Plaintiff Montgomery County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jonathan Shub, Kohn, Swift & Graf, P.C.,
1600 Market Street, Suite 2500, Philadelphia PA 19103
(215) 235-1700 jshub@kohnswift.com

DEFENDANTS

Allergan Inc., f/k/a Inamed Corp.; Allergan USA, Inc.; Allergan PLC

County of Residence of First Listed Defendant Morris County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	**PERSONAL INJURY** ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Medical Malpractice **PERSONAL INJURY** ☐ 365 Personal Injury - Product Liability ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability **PERSONAL PROPERTY** ☐ 370 Other Fraud ☐ 371 Truth in Lending ☐ 380 Other Personal Property Damage ☐ 385 Property Damage Product Liability		☐ 625 Drug Related Seizure of Property 21 USC 881 ☐ 690 Other **LABOR** ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Management Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Employee Retirement Income Security Act **IMMIGRATION** ☐ 462 Naturalization Application ☐ 465 Other Immigration Actions	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 **PROPERTY RIGHTS** ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 840 Trademark **SOCIAL SECURITY** ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g)) **FEDERAL TAX SUITS** ☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 400 State Reapportionment ☐ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit ☐ 485 Telephone Consumer Protection Act ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities/ Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes
REAL PROPERTY ☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	**CIVIL RIGHTS** ☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/ Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	**PRISONER PETITIONS** **Habeas Corpus:** ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty **Other:** ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. Section 1332(d)(2)

Brief description of cause:
Class action for negligence, fraud, and medical monitoring regarding recalled breast implants

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ 5,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*

JUDGE Jud. Panel Multidistrict Litig. DOCKET NUMBER MDL 2921

DATE 12/16/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

JS 44 (Rev 02/19) Stack MDL **CIVIL COVER SHEET** 19-5468

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I. (a) PLAINTIFFS

Ellen Newman, Amy Grotte, Rachael Herron, Lisa Roberts, Amy Edens, Heidi Lee, Amber Ferrell-Steele, Tory Bobadilla

(b) County of Residence of First Listed Plaintiff Montgomery County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jonathan Shub, Kohn, Swift & Graf, P.C.,
1600 Market Street, Suite 2500, Philadelphia PA 19103
(215) 235-1700 jshub@kohnswift.com

DEFENDANTS

19 5968

Allergan Inc., f/k/a Inamed Corp., Allergan USA, Inc., Allergan PLC

County of Residence of First Listed Defendant Morris County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for Nature of Suit Code Descriptions

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY		☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	LABOR	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 710 Fair Labor Standards Act	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 720 Labor/Management Relations	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 740 Railway Labor Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 751 Family and Medical Leave Act	☐ 862 Black Lung (923)	☐ 485 Telephone Consumer Protection Act
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 790 Other Labor Litigation	☐ 863 DIWC/DIWW (405(g))	☐ 490 Cable/Sat TV
☐ 196 Franchise			☐ 791 Employee Retirement Income Security Act	☐ 864 SSID Title XVI	☐ 850 Securities/Commodities/ Exchange
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		☐ 865 RSI (405(g))	☐ 890 Other Statutory Actions
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	IMMIGRATION	FEDERAL TAX SUITS	☐ 891 Agricultural Acts
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence	☐ 465 Other Immigration Actions	☐ 871 IRS - Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 896 Arbitration
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			☐ 950 Constitutionality of State Statutes
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*
28 U.S.C. Section 1332(d)(2)

Brief description of cause
Class action for negligence, fraud, and medical monitoring regarding recalled breast implants

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23 F.R.Cv.P.

DEMAND $ 5,000,000.00

CHECK YES only if demanded in complaint
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions)

JUDGE Jud. Panel Multidistrict Litig. DOCKET NUMBER MDL 2921

DATE 12/16/2019

SIGNATURE OF ATTORNEY OF RECORD

DEC 17 2019

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

19 5968

RBS

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 1119 Henley Court, Ambler PA 19002

Address of Defendant: 5 Giralda Farms, Madison, NJ 07940

Place of Accident, Incident or Transaction: Montgomery County, PA

RELATED CASE, IF ANY:

Case Number: MDL 2921 Judge: Date Terminated:

Civil cases are deemed related when ***Yes*** is answered to any of the following questions

1	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	Yes ☐	No ☐
2	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	Yes ☐	No ☐
3	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	Yes ☐	No ☐
4	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	Yes ☐	No ☐

I certify that, to my knowledge, the within case ☐ **is** / ☒ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above

DATE 12/17/2019 Must sign here 53965

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A.	*Federal Question Cases:*	*B.*	*Diversity Jurisdiction Cases:*
☐ 1	Indemnity Contract, Marine Contract, and All Other Contracts	☐ 1	Insurance Contract and Other Contracts
☐ 2	FELA	☐ 2	Airplane Personal Injury
☐ 3	Jones Act-Personal Injury	☐ 3	Assault, Defamation
☐ 4	Antitrust	☒ 4	Marine Personal Injury
☐ 5	Patent	☐ 5	Motor Vehicle Personal Injury
☐ 6	Labor-Management Relations	☑ 6	Other Personal Injury *(Please specify)* 367 Health Care
☐ 7	Civil Rights	☐ 7	Products Liability
☐ 8	Habeas Corpus	☒ 8	Products Liability Asbestos
☐ 9	Securities Act(s) Cases	☐ 9	All other Diversity Cases *(Please specify)*
☐ 10	Social Security Review Cases		
☐ 11	All other Federal Question Cases *(Please specify)*		

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Jonathan Shub, counsel of record *or* pro se plaintiff, do hereby certify

☑ Pursuant to Local Civil Rule 53.2, § 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs

☐ Relief other than monetary damages is sought

DATE 12/17/2019 Sign here if applicable 53965 DEC 17 2019

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38

Civ. 609 (5/2018)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Ellen Newman, et al.,

v

Allergan, Inc., et al.,

CIVIL ACTION

19 5968

NO

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1.03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

12/17/2019	/s/ Jonathan Shub	Plaintiffs and Proposed Class
Date	**Attorney-at-law**	**Attorney for**
(215) 238-1700	(215) 238-1968	jshub@kohnswift.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

DEC 17 2019