UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

JESSICA KRAFT, INDIVIDUALLY AND AS PARENT OF MINORS L.K., S.K., and O.K.; SHELLI SCHNEIDER, INDIVIDUALLY AND AS PARENT OF MINORS A.S. and W.S.; ANNE BAILEY, INDIVIDUALLY AND AS PARENT OF MINOR D.B.; AMY LAVELLE, INDIVIDUALLY AND AS PARENT OF MINORS Em.L. and El.L.; ELIZABETH BEATON, INDIVIDUALLY AND AS PARENT OF MINOR M.B.; AMANDA AND TYRELL FAUSKE, INDIVIDUALLY AND AS PARENTS OF MINORS C.R.F. and C.J.F.; JENNIFER REIN, INDIVIDUALLY; and JESSICA BERG, INDIVIDUALLY AND AS PARENT OF MINORS A.B. and S.B., individually and on behalf of all others similarly situated, Plaintiffs, v. ESSENTIA HEALTH, INNOVIS HEALTH, LLC d/b/a ESSENTIA HEALTH, DAKOTA CLINIC PHARMACY, LLC, JOHN DOE MANUFACTURERS, and JOHN DOE DISTRIBUTOR, Defendants.	)	No. 3:20-CV-121 JURY TRIAL DEMANDED

SECOND AMENDED CLASS ACTION COMPLAINT

Plaintiffs JESSICA KRAFT, individually and as parent of minors L.K., S.K., and O.K.; SHELLI SCHNEIDER, individually and as parent of minors A.S. and W.S.; ANNE BAILEY, individually and as parent of minor D.B.; AMY LAVELLE, individually and as parent of minors Em.L. and El.L.; ELIZABETH BEATON, individually and as parent of minor M.B.; AMANDA

AND TYRELL FAUSKE, individually and as parents of minors C.R.F. and C.J.F.; JENNIFER REIN, individually; and JESSICA BERG, individually and as parent of minors A.B. and S.B., by and through their attorneys, for their class action complaint on behalf of themselves and all others similarly situated, allege as follows:

I. INTRODUCTION

1. All companies in the supply chain for time- and temperature-sensitive pharmaceutical products ("TTSPPs"), including manufacturers, distributors, and providers, are responsible for ensuring that the products are continuously stored at the proper cold temperature.

2. This responsibility is important because the exposure of vaccines and other TTSPPs to temperatures outside the proper range – called a temperature excursion – results in reduced vaccine potency and the increased risk of vaccine-preventable diseases.

3. Since at least as early as January 2017, Essentia Health and/or Innovis Health, LLC d/b/a Essentia Health (collectively "Essentia Health") sold and administered more than 100 TTSPPs manufactured by the John Doe Manufacturers and stored and distributed by Dakota Clinic Pharmacy, LLC (the "Affected Medications") to Plaintiffs, their children, and putative class members.

4. The Affected Medications were handled and stored outside the proper temperature range and thus subject to one or more temperature excursions.

5. On or about April 6, 2020, Essentia Health notified approximately 50,000 patients, allegedly in Minnesota and North Dakota, that medication or vaccines they received might have been compromised by improper temperature storage by the John Doe Distributor (who Essentia Health did not name publicly at that time) (the "Temperature Excursion").

6. In its answer to the original complaint ("Answer"), Essentia Health identified the John Doe Distributor as Dakota Clinic Pharmacy. ECF No. 17.

7. Plaintiffs and their minor children, as well as class members, have been injured by paying for the Affected Medications and associated medical visits without receiving the benefit of the bargain.

8. The Affected Medications include a broad array of pharmaceuticals, potentially exceeding 100 different medications, including, for example, vaccines, immunotherapy treatments, drugs used to treat seizures and anxiety, medications used to treat multiple sclerosis and Crohn's disease, and chemotherapy drugs.

9. While Essentia Health has offered to revaccinate free of charge, Plaintiffs and class members are entitled to refunds for visits for which they did not receive proper care.

10. Moreover, free vaccines are worthless to the thousands of patients who received vaccines that cannot be re-administered, such as annual flu vaccines for the 2017, 2018, and 2019 flu seasons.

11. In addition, patients may choose to get revaccinated outside of the Essentia Health system and will have to bear additional out-of-pocket costs.

12. Not all of the Affected Medications are vaccines.

13. Some of the Affected Medications cannot or should not be repeated. Chemotherapy drug Doxorubicin (Adriamycin), for example, has a maximum lifetime cumulative dose for each patient to avoid the risk of dangerous side effects.

14. Finally, Plaintiffs and the class members will have to endure additional pain and suffering to get revaccinated, as well as aggravation and time to undergo and attend additional medical examinations.

15. Accordingly, Plaintiffs bring this action for breach of express and implied warranties, for violation of the consumer protection laws of Minnesota and North Dakota, for negligence, and for restitution.

II. JURISDICTION

16. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d)(2), because this is a class action in which the matter in controversy exceeds the sum of $5,000,000 and one or more Defendants is a citizen of a state different from that of at least one class member. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) because all claims alleged herein form part of the same case or controversy.

17. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District and Defendants conduct business in this District and are therefore subject to personal jurisdiction in this District.

III. PARTIES

A. PLAINTIFFS

18. **Plaintiff Jessica Kraft** is a resident of Fargo, North Dakota and a citizen of the United States. Ms. Kraft is the mother of **minor children L.K., S.K., and O.K.**

19. Ms. Kraft received a Hepatitis A vaccine on February 7, 2018 at Essentia's 52nd Ave Clinic and influenza vaccines on October 9, 2018 and December 18, 2019 at Essentia Health-South University Clinic.

20. Ms. Kraft paid in whole or in part for these visits.

21. Ms. Kraft's daughter, L.K., received the following vaccines at Essentia Health-South University Clinic: DTaP <7 years (administered 11/7/17), Hepatitis A, Ped/Adolescent 2

dose (administered 4/4/18), Hib PRP OMP (PedvaxHib) (administered 11/7/17), and Influenza (administered 10/9/18 and 12/18/19).

22. Ms. Kraft's children, L.K., S.K., and O.K., received influenza vaccines at the same clinic.

23. Ms. Kraft also paid in whole or in part for these visits.

24. On information and belief, the vaccines the Kraft children received were distributed by Dakota Clinic Pharmacy or John Doe Distributor to Essentia Health and were subject to the Temperature Excursion.

25. Ms. Kraft received letters from Essentia dated April 7, 2020 and May 5, 2020 advising that "one or more" vaccinations or medications administered to her, L.K., O.K., and S.K. may have been affected by the Temperature Excursion.

26. Ms. Kraft also received an electronic communication from Essentia dated June 10, 2020, advising that L.K.'s affected vaccines were DTaP, Hep A, Hib, and Influenza.

27. Accordingly, as a result of Defendants' actions as alleged herein, Jessica Kraft and her minor children were injured and suffered damages.

28. **Plaintiff Shelli Schneider** is a resident of Fargo, North Dakota and a citizen of the United States. Ms. Schneider is the mother of **minor children A.S. and W.S.**

29. On April 21, 2020, Ms. Schneider received an electronic communication from an Essentia nurse stating, "we were reviewing your child's chart to see which vaccines were affected by the temperature excursion." The nurse advised that the following immunizations were affected for her child, W.S.: DTaP (administered 5/25/18), Hep A (administered 8/24/18 and 2/16/18), Hib (administered 5/25/18), and Influenza (administered 10/12/19, 10/26/18, 11/27/17, and 10/26/17).

30. Ms. Schneider also received a letter dated April 7, 2020 from Essentia Health, advising that "one or more flu vaccinations" administered to A.S. may have been affected by the Temperature Excursion; a letter dated April 7, 2020 from Essentia Health, advising that "one or more flu vaccinations" administered to W.S. may have been affected by the Temperature Excursion; and a letter dated May 5, 2020 from Essentia Health, advising that "one or more flu vaccinations" administered to her may have been affected by the Temperature Excursion.

31. Ms. Schneider paid in whole or in part for these visits and vaccines.

32. Accordingly, as a result of Defendants' actions as alleged herein, Ms. Schneider and her minor children were injured and suffered damages.

33. **Plaintiff Anne Bailey** is a resident of Hillsboro, North Dakota and a citizen of the United States.

34. Ms. Bailey's **minor child, D.B.**, received meningitis and DTaP vaccines in April 2018 at Essentia Health-South University Clinic in the pediatric department. D.B. also received a flu vaccine in the fall of 2018.

35. Anne Bailey received a flu shot at an Essentia walk-in clinic in approximately November 2017.

36. Ms. Bailey understands that the flu vaccines were subject to the Temperature Excursion.

37. After a change in health insurance and physicians, D.B.'s new physician recommended that D.B. get revaccinated because the vaccines were subject to the temperature excursion.

38. On information and belief, the vaccines that D.B. and Anne Bailey received were distributed by Dakota Clinic Pharmacy or John Doe Distributor to Essentia Health and were subject to the Temperature Excursion.

39. Accordingly, as a result of Defendants' actions as alleged herein, Ms. Bailey and her minor child were injured and suffered damages.

40. **Plaintiff Amy Lavelle** is a resident of Moorhead, Minnesota and a citizen of the United States. Ms. Lavelle's **minor children, Em.L. and El.L.**, received flu shots at Essentia on February 7, 2018. Ms. Lavelle paid in whole or in part for these visits.

41. On information and belief, the vaccines the Lavelle children received were distributed by Dakota Clinic Pharmacy or John Doe Distributor to Essentia Health and were subject to the Temperature Excursion.

42. Accordingly, as a result of Defendants' actions as alleged herein, Ms. Lavelle and her minor children were injured and suffered damages.

43. **Plaintiff Elizabeth Beaton** is a resident of Fargo, North Dakota and a citizen of the United States. Ms. Beaton is the mother of **minor child M.B.**

44. On and after December 3, 2018, Ms. Beaton received at least 13 chemotherapy treatments at Essentia Health-South University Clinic and Essentia West Acres Walk-In Clinic to treat her cancer. Ms. Beaton paid in whole or in part for these visits.

45. On or about March 13, 2020, Ms. Beaton received a telephone call from a person who identified themselves as an outside consultant hired by Essentia, who advised her that some of her chemotherapy treatments may have been compromised by the Temperature Excursion.

46. Additionally, Ms. Beaton's daughter, M.B., received a meningococcal vaccine on September 4, 2019 at Essentia Health-South University Pediatrics Clinic. Ms. Beaton also paid in whole or in part for this visit.

47. Ms. Beaton received a letter dated March 31, 2020 from Essentia Health, advising that M.B. "is among the patients who received one or more vaccinations that may have been affected" by the Temperature Excursion. Accordingly, as a result of Defendants' actions as alleged herein, Ms. Beaton and her minor child were injured and suffered damages.

48. **Plaintiff Amanda Fauske** is a resident of Fargo, North Dakota and a citizen of the United States.

49. Amanda Fauske received influenza vaccines on 10/1/2018 and 10/21/2019, and a Tdap vaccine on 12/3/2018 at Essentia Health. Ms. Fauske received a letter from Essentia Health dated July 10, 2020 informing her that the Temperature Excursion "possibly affected" her influenza and Tdap vaccines. Ms. Fauske paid in whole or in part for these visits and vaccines.

50. **Plaintiff Tyrell Fauske** is a resident of Fargo, North Dakota and a citizen of the United States.

51. Amanda and Tyrell Fauske's **minor child, C.R.F.**, received the following vaccines at Essentia Health: DTaP (administered 11/20/17), Hepatitis A, Ped/Adolescent 2 dose (administered 8/15/18 and 11/6/17), Hib PRP OMP (PedvaxHib) (administered 11/20/17), Influenza Fluzone (6-35 Mo) Quad PF (Flu Clinic) (administered 10/13/18 and 12/6/17), Influenza Quad Preservative Free 6-35mo (administered 11/6/17), and MMR (administered 8/8/17).

52. The Fauskes received a letter from Essentia Health dated October 26, 2017, informing them that C.R.F. "received vaccines exposed to out-of-range temperatures," and

recommended that C.R.F. be revaccinated because "the effectiveness . . . may have been decreased."

53. The Fauskes also received a message from Essentia Health dated April 7, 2020, notifying them that "one or more vaccinations [administered to C.R.F.] may have been affected."

54. The Fauskes' other **minor child, C.J.F.**, received the following vaccines at Essentia Health: DTaP-HepB-IPV (Pediarix) (administered 8/21/19, 7/10/19, and 4/24/19), Hepatitis A, Ped/Adolescent 2 (administered 4/1/20), Hib PRP OMP (PedvaxHib) (administered 4/1/20, 7/10/19, and 4/24/19), and Influenza Fluzone (6 months – 64 years) Quad PF (Flu Clinic) (administered 11/20/19 and 10/21/19).

55. The Fauskes received a message from Essentia Health dated April 7, 2020, notifying them that "one or more vaccinations [administered to C.J.F.] may have been affected."

56. The Fauskes paid in whole or in part for these visits.

57. Accordingly, as a result of Defendants' actions as alleged herein, the Fauskes and their two minor children were injured and suffered damages.

58. **Plaintiff Jennifer Rein** is a resident of Moorhead, Minnesota and a citizen of the United States.

59. Ms. Rein received a flu vaccine and a DTaP vaccine at Essentia Health's West Fargo Clinic in November 2017.

60. Ms. Rein paid in whole or in part for this visit.

61. In April 2020, Ms. Rein received an electronic communication from Essentia Health, advising that the vaccines administered to her may have been affected by the Temperature Excursion.

62. Accordingly, as a result of Defendants' actions as alleged herein, Jennifer Rein was injured and suffered damages.

63. **Plaintiff Jessica Berg** is a resident of Fargo, North Dakota and a citizen of the United States. Ms. Berg is the mother of **minors A.B. and S.B**.

64. A.B. received flu vaccines on at least 11/12/18, 12/17/18, 10/12/19, and 11/16/19 at Essentia Health-South University Clinic (Fargo).

65. A.B. also received the following immunizations, among others, at the same clinic: DtaP-HepB-IPV (administered 3/28/18, 5/30/18, and 7/25/18), Hepatitis A, Ped/Adolescent 2 dose (administered 2/18/19), Hepatitis B, Ped/Adolescent 2 dose (administered 1/26/18), Hib PRP OMP (administered 3/28/18 and 5/30/18), Pneumococcal Conjugate (administered 3/28/18, 5/30/18, 7/25/18, and 2/18/19), Rotavirus Pentavalent live Oral 3-dose (administered 3/28/18, 5/30/18, and 7/25/2018), MMR (administered 2/18/19), and Varicella (administered 2/18/19).

66. Ms. Berg paid in whole or in part for these visits.

67. Ms. Berg received an electronic communication from Essentia dated January 20, 2021, informing her that the following "9 individual vaccine administrations" to A.B. were rendered "invalid" by the Temperature Excursion and recommending revaccination: DTaP, DTaP-HepB-IPV, Hepatitis A, Ped/Adolescent 2 dose, and Hib PRP T.

68. The notice also stated that A.B. "had a couple of flu vaccinations that were potentially affected by the temperature excursion."

69. Ms. Berg's other minor daughter, S.B., received a flu shot at Essentia Health-South University Clinic (Fargo) on 10/16/20.

70. Ms. Berg paid in whole or in part for this visit.

71. Ms. Berg received an electronic message from Essentia Health dated January 20, 2021, informing her that S.B.'s flu shots "were potentially affected by the temperature excursion."

72. Ms. Berg has since received follow-up notices from the North Dakota Department of Health, informing her that A.B. and S.B. will not be permitted to enroll in public school if she does not revaccinate them.

73. Jessica Berg received influenza vaccines on or about October 24, 2017 and in 2018; Pneumovax 23 on or about January 28, 2018; and Tdap on or about November 21, 2017, all through Essentia.

74. Accordingly, as a result of Defendants' actions as alleged herein, Ms. Berg and her two minor children were injured and suffered damages.

B. DEFENDANTS

75. **Defendant Essentia Health** is a Minnesota corporation with its principal place of business located in Duluth, Minnesota.

76. Essentia Health is a health system that serves patients in Minnesota, Wisconsin, and North Dakota, in 13 hospitals, 69 clinics, six long-term care facilities, three assisted living facilities, three independent living facilities, five ambulance services, and one research institute.

77. Essentia Health's registered agent is Jessica Fetzer, 3000 32nd Ave., Fargo, ND 58103.

78. **Defendant Innovis Health, LLC** is a Delaware limited liability company with its principal place of business in Fargo, North Dakota.

79. Its principal address, 3000 32nd Ave. S, Fargo, ND 58103, is also listed as the facility for "Essentia Health-Fargo" and "Essentia Health-32nd Avenue Clinic (Fargo)."[1]

80. Innovis joined Essentia in January 2008 and is integrated into Essentia as an Essentia-branded community hospital and clinic.

81. Innovis's registered agent is Jessica Fetzer, 3000 32nd Ave., Fargo, ND 58103.

82. According to Innovis's Sixth Amended and Restated Operating Agreement, dated December 19, 2017, Essentia is the sole member of Innovis.

83. Innovis Health LLC % Essentia Health, 3380 39th Street South, Fargo, ND 58103 is registered with the North Dakota Board of Pharmacy as a wholesaler with a hospital offsite warehouse.

84. Innovis Health Pharmacy LLC % Essentia Health MBR, 3000 32nd Ave SW, Fargo, ND 58103 is registered as a Class B - Hospital Pharmacy with the North Dakota Board of Pharmacy. The pharmacist in charge is listed as Maari Loy.

85. Maari Loy is Essentia's Pharmacy Operations Senior Manager.

86. Class B permits "are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility." N.D. Admin. Code § 61-02-01-01(4)(b).

87. **Defendant Dakota Clinic Pharmacy, LLC** is a North Dakota limited liability company with its principal place of business located at 1702 University Dr. S, Fargo, ND 58103.

[1] https://www.essentiahealth.org/find-facility/profile/essentia-health-fargo/ (last visited August 4, 2021); https://www.essentiahealth.org/find-facility/profile/essentia-health-32nd-avenue-clinic-fargo/ (last visited August 4, 2021).

88. Dakota Clinic's registered agent is Laura Morris, 1702 University Drive South, Fargo, ND 58103-4940.

89. According to Dakota Clinic's Amended and Restated Operating Agreement, effective as of May 1, 2016, Innovis holds a 49% membership interest in Dakota Clinic, and four individuals each hold a 12.75% membership interest in Dakota Clinic.

90. Dakota Clinic's 1702 S. University Dr. and 3000 32nd Ave. S. locations are registered as Class A - Out-Patient Pharmacies with the North Dakota Board of Pharmacy. The pharmacists in charge are listed as Robert R. Haskell and Nicole Rohrbeck, respectively.

91. Robert Haskell is an LLC member and 12.75% owner of Dakota Clinic.

92. According to North Dakota Administrative Code Section 61-02-01-01(4)(a), Class A "permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription."

93. According to Essentia Health, Dakota Clinic Pharmacy is an Essentia-owned pharmacy.[2]

94. According to Essentia Health in its Answer to Plaintiffs' original complaint, Innovis Health contracted with Dakota Clinic for pharmaceutical management services.

95. The **John Doe Manufacturer Defendants** are defendants whose identities and/or involvement with the Temperature Excursion are currently unknown. According to Essentia Health, more than 100 vaccines and medications were affected by the Temperature Excursion and administered to Plaintiffs and the Patient class members. The John Doe Manufacturer

[2] *See* https://www.medica.com/-/media/documents/pharmacy/group/2021-essentia-owned-pharmacies.pdf?la=en&hash=51228A95F64CF6C7816CF989C42F2955 (last visited August 4, 2021)

Defendants manufactured, marketed, distributed, and sold the Affected Medications and are liable as set forth herein.

IV. FACTS

A. Proper pharmaceutical storage and handling is necessary to ensure potency, efficacy, and protection.

1. The CDC sets forth storage and handling guidelines that Defendants failed to follow.

96. According to the Centers for Disease Control (CDC), vaccines must be stored properly from the time they are manufactured until the time they are administered.

97. Vaccines must be continuously stored at the proper temperature. Frozen vaccines, for example, Varicella, MMRV, and Zoster, must be stored in a freezer between -58°F and +5°F (-50°C and -15°C). The CDC provides that all other routinely recommended vaccines should be stored in a refrigerator between 35°F and 46°F (2°C and 8°C).

98. Ensuring that vaccine quality is maintained at proper temperatures "is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers."[3] The CDC explains that: "[a] proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacture to administration of the vaccine."[4]

99. The CDC defines a "temperature excursion" as "[a]ny temperature reading outside ranges recommended in the manufacturers' package inserts . . . ."[5]

[3] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf (last visited August 4, 2021).

[4] *Id*.

[5] https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf (last visited August 4, 2021).

100. Likewise, the World Health Organization has defined a "temperature excursion" as "[a]n excursion event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport."[6]

101. The CDC has explained that "[e]xposure to temperatures outside these ranges may result in reduced vaccine potency and increased risk of vaccine-preventable diseases." The CDC thus recommends: "It is better to not vaccinate than to administer a dose of vaccine that has been mishandled."[7]

102. Other types of pharmaceuticals also have temperature-specific storage requirements. For example, chemotherapy drug Doxorubicin (Adriamycin) and immunosuppressive drug Golimumab (Simponi) are to be stored under refrigeration of 2-8°C, or approximately 36-46°F[8], while MMR vaccines should be stored between -58°F and +46°F [9] before reconstitution.

103. Storing pharmaceuticals outside of their specified temperature range can result in degradation of the products and reduce the effectiveness of the protection or treatment that they provide.

104. Such degradation can leave patients not fully protected against the diseases the pharmaceuticals were being administered to prevent or treat.

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[6] https://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf?ua=1 (last visited August 4, 2021).

[7] https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf (last visited August 4, 2021).

[8] https://www.pfizer.com.au/sites/pfizer.com.au/files/g10005016/f/201311/PI_Adriamycin_212.pdf, pp. 14-15 (last visited August 4, 2021); https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125289s0064lbl.pdf, p. 32 (last visited August 4, 2021).

[9] https://www.fda.gov/media/75191/download, p. 8 (last visited August 4, 2021).

105. Regarding vaccines, for example, degradation can lead to an inadequate immune response, resulting in the potential for disease outbreaks and the public's mistrust of vaccines.

106. Moreover, repeat vaccinations can lead to an increase in adverse reactions.

107. The CDC recommends facilities use purpose-built, or pharmaceutical-grade, refrigerator and freezer units that are specifically designed to store vaccines. These units often have microprocessor-based temperature control with a digital temperature sensor and fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.[10] The CDC also recommends safeguards to ensure the doors of the unit remain closed, including, for example, self-closing door hinges, door alarms, or door locks.[11]

108. According to CDC guidelines, every vaccine storage unit must have a temperature monitoring device (TMD) inside each storage compartment.[12]

109. TMDs must be checked and logged regularly, including "a minimum of 2 times per workday (at the start and end of the workday)" if the TMD does not read minimum/maximum temperatures continuously. Specifically, providers must record:

a. Minimum/maximum temperature;

b. Date;

c. Time;

d. Name of person who checked and recorded the temperature; and

[10] https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf, p. 8 (last visited August 4, 2021).

[11] *Id*.

[12] *Id*. at 9.

e. Any actions taken if a temperature excursion occurred.[13]

110. If a reading is missed, the CDC advises leaving a blank entry in the log.[14]

111. Additional temperature checks are recommended by the CDC "each time vaccines are accessed in the unit," and at least "weekly for changes in temperature trends that might require action."[15]

112. The CDC recommends a "digital data logger" (DDL) as the most accurate type of TMD because it provides detailed information on all temperatures recorded at preset intervals, unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit. The CDC strictly advises against alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial.[16]

113. CDC guidelines further state that "[f]ood and beverage should never be stored in the unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them."[17]

114. Any temperature reading outside the recommended ranges in the pharmaceutical manufacturers' package inserts is considered by the CDC to be a temperature excursion and must be immediately reported to the primary or alternate vaccine coordinator or to a supervisor.

[13] *Id*. at 12.

[14] *Id*.

[15] *Id*. at 11.

[16] *Id*. at 9, 11.

[17] *Id*. at 11.

115. The vaccines subject to the temperature excursion must not be discarded and should be labeled "DO NOT USE" and placed in a separate container apart from other vaccines.[18]

116. The vaccine coordinator, supervisor, or the person reporting the problem should document the temperature excursion with the following information:

a. Date and time of temperature excursion;

b. Storage unit temperature and room temperature (including minimum/maximum temperatures during the time of the event);

c. Name of person completing the report and a description of what happened, the length of time the vaccine(s) may have been affected, inventory of affected vaccines, list of items in the unit other than vaccines, any problems with the storage unit and/or affected vaccines before the event, and any other relevant information.[19]

117. The CDC advises contacting a provider's state immunization program and/or vaccine manufacturer(s) for further guidance on whether to use affected vaccines and whether patients will need to be recalled for revaccination.[20]

2. Pharmaceutical Manufacturers set forth safe temperature ranges for their pharmaceuticals.

118. Pharmaceutical manufacturers also provide requirements for safe storage of TTSPPs, including the Affected Medications.

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[18] *Id*. at 13.

[19] *Id*.

[20] *Id*.

119. For example, the package insert for PEDIARIX, an immunization against diphtheria, tetanus, pertussis, hepatitis B, and poliomyelitis in children – which was among the pharmaceuticals affected by the Temperature Excursion – reads: "Store refrigerated between 2º and 8ºC (36º and 46ºF). Do not freeze. Discard if the vaccine has been frozen."[21]

120. As another example, Fluzone, a medication designed to prevent influenza and which was also among the Affected Medications, includes instructions that read: "Store Fluzone High-Dose Quadrivalent refrigerated at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Discard if vaccine has been frozen."[22]

3. North Dakota and Minnesota Departments of Health set forth storage and handling guidelines that Defendants failed to follow.

121. The North Dakota and Minnesota Departments of Health also set forth best practices and requirements for the safekeeping of TTSPPs.

122. For example, the North Dakota Department of Health's (NDDoH) Immunization Program recommends the use of pharmacy-grade, stand-alone refrigerator and freezer units with built-in thermometers placed at the center, close to the vaccines.[23]

123. The NDDoH 2020 Vaccine Management Policy, published in connection with the Vaccine for Children Program, references the CDC's *Vaccine Storage and Handling Toolkit* and details additional requirements for vaccine storage and monitoring.

124. This policy requires, among other responsibilities, the use of a certified and calibrated continuous recording data logger inside each vaccine storage compartment; that all

[21] https://www.fda.gov/media/79830/download (last visited August 4, 2021).

[22] https://www.fda.gov/media/139731/download (last visited August 4, 2021).

[23] https://www.health.nd.gov/sites/www/files/documents/Files/MSS/Immunizations/Storage_Handling/Refrigerator_freezerguide2019.pdf, p. 1 (last visited August 4, 2021).

thermometers be calibrated and certified in accordance with the National Institute of Standards and Technology or the American Society for Testing and Materials; that providers record the minimum and maximum temperatures, preferably at the beginning of each clinic day (noting that although the minimum/maximum temperature requirement has taken the place of the twice daily temperature checks, it is still recommended for clinic staff to check and document temperature twice daily); and no storage of non-medical food or beverage in any refrigerator that contains vaccines.[24]

125. The policy further states that "[a]ctions must be taken and recorded on every out-of-range temperature," (emphasis omitted) including "record[ing] the temperature on a temperature log and immediately isolat[ing] the affected vaccine."[25]

126. The NDDoH Vaccine Storage Troubleshooting Guide describes the steps that must be taken in the event of a temperature excursion:

a. Contact the primary or backup vaccine coordinator;

b. Document the current, minimum and maximum temperatures, duration of temperature excursion and the time when problem was discovered;

c. Label the vaccine "Do Not Use"; and

d. Store at the appropriate temperature. If your unit is not maintaining the appropriate temperature, transfer the vaccine to other storage units. Do not allow vaccines to remain in a unit while trying to fix it.[26]

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[24] https://www.health.nd.gov/sites/www/files/documents/Files/MSS/Immunizations/Providers/2020%20Vaccine%20Mgmt%20Policy%20Final.pdf, pp. 20, 24, 26 (last visited August 4, 2021).

[25] *Id*. at 26.

[26] https://www.health.nd.gov/sites/www/files/documents/Files/MSS/Immunizations/Storage_Handling/Troubleshootingguide.pdf (last visited August 4, 2021).

127. In its Vaccine Storage Guide, the Minnesota Department of Health (MNDoH) recommends lab- or pharmacy- grade refrigeration and freezer units with a calibrated, continuous temperature monitoring device that has a current and valid Certificate of Calibration.[27]

128. MNDoH further recommends that provider staff check and record current temperatures at the start and end of each clinic day and record the minimum and maximum temperatures once at the start of each clinic day. These records, kept in a temperature log, must also contain the date, time, and name or initials of the individual observing the temperatures.[28]

129. MNDoH guidelines require immediate action be taken on all out-of-range temperatures, including the following:

a. Move vaccine immediately if refrigerated vaccine is less than 2°C (36°F);

b. Determine the cause, if possible;

c. Adjust the thermostat, if necessary;

d. Notify immunization manager or vaccine coordinator; and

e. Monitor the temperature. If the temperature doesn't stabilize in the correct range within 30 minutes:

   i. Stop using the vaccine;

   ii. Mark the vaccine "DO NOT USE";

   iii. Move the vaccine to a storage unit that is maintaining the correct temperature;

   iv. Collect the lot numbers, expiration dates, storage unit temperatures, the room temperature, and the time the unit was out-of-range;

[27] https://www.health.state.mn.us/people/immunize/hcp/vaxhandling.html (last visited August 4, 2021).
[28] *Id.*

v. Evaluate the temperature data;

vi. Determine if any of this vaccine was involved in a previous mishap;

vii. Call the vaccine manufacturer(s);

viii. Report the temperature excursion to the Minnesota Vaccines for Children program (if applicable); and

ix. Document actions taken.[29]

B. The North Dakota Board of Pharmacy's rules, codified through the North Dakota Administrative Code, set forth temperature and storage guidelines that Defendants failed to follow.

130. North Dakota's Administrative Code Title 61 and the North Dakota Board of Pharmacy set forth numerous pharmacy guidelines.

131. N.D. Admin. Code § 61-02-02-01, which sets forth "Building Standards for Pharmacies," requires, *inter alia*, the following:

> **6. Storage of medications. Systems at pharmacy location must ensure medications are stored within the manufacture[r]-recommended temperatures.**
>
> a. Room temperature in the drug storage must be monitored to ensure variations are limited.
>
> b. When medications are stored in a refrigerator or freezer, **the pharmacy shall use a continuous temperature monitoring device that reports excursions** that may occur from accepted temperature levels. Units must exclusively be used for medications.

(Emphasis added).

132. Article 61-07 governs Hospital Pharmacies. Hospital or "medical center" pharmacies are "those portions of a hospital [or medical center] where drugs, medications,

[29] *Id.*

devices, and other materials . . . are manufactured, produced, sold, or distributed." N.D. Admin. Code § 61-07-01-01.

133. N.D. Admin. Code § 61-07-01-06 sets forth "Physical requirements," and requires, *inter alia*:

> 3. **Storage.** All drugs must be stored in designated areas within the hospital pharmacy which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

134. N.D. Admin. Code § 61-07-01-07, regarding "Drug distribution and control," requires, *inter alia*:

> 1. **General.** The director of pharmacy services shall establish written procedures for the safe and efficient distribution of pharmaceutical products. An annual updated copy of such procedures must be on hand for inspections.
>
> 2. **Responsibility.** The director is responsible for the safe and efficient distribution of, control of, and accountability for drugs. The other professional staff of the hospital shall cooperate with the director in meeting this responsibility and in ordering, administering, and accounting for pharmaceutical materials so as to achieve this purpose. Accordingly, the director is responsible for, at a minimum, the following: . . .
>
> > f. Filling and labeling all containers from which drugs are to be administered . . . .
> >
> > * * *
> >
> > h. Records of all transactions of the hospital pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials . . . .
> >
> > * * *
> >
> > m. Meeting all compliance and other requirements of the North Dakota board of pharmacy rules and laws and this chapter.

> 3. **Labeling.**
>
> > a. For use inside the hospital. All drugs dispensed by a hospital pharmacy, not on an individual prescription, intended for use within the hospital, must be dispensed in appropriate containers and adequately labeled so as to identify, at a minimum, brand name or generic name, strength, quantity, source, and expiration date.
>
> * * *
>
> 9. **Records and reports.** The director shall maintain and submit, as appropriate, such records and reports as are required to ensure patient health, safety, and welfare . . . .

135. N.D. Admin. Code § 61-07-01-11 regarding "Quality assurance" requires, *inter alia*, that:

> The director of pharmacy services is responsible for developing procedures for an ongoing quality assurance program of pharmaceutical services that includes a mechanism for reviewing and evaluating drug-related patient care, as well as an appropriate response to findings. This written plan should clearly establish responsibility and the need for documentation of an effective program.

136. N.D. Admin. Code § 61-07-01-13, regarding "Inspection," requires that:

> The director of pharmacy shall inspect, no less than once a month, personally or by qualified designee, all matters within the director's jurisdiction and responsibility and make appropriate written records and notations of such inspections. Such inspections shall verify, at a minimum, that . . . d. Drugs requiring special storage conditions to ensure their stability are properly stored. e. Outdated drugs or otherwise unusable drugs have been identified and their distribution and administration prevented. An area must be designated for authorized storage of such drugs prior to their proper disposition. . . h. All necessary and required security and storage standards are met. . . . j. All policies and procedures of the director and of appropriate committees of the hospital relevant to pharmacy are followed. . . .

137. N.D. Admin. Code § 61-02-09-02, regarding "Continuous quality improvement program," requires, *inter alia*, that "Each pharmacy permittee shall establish continuous quality

improvement program for the purpose of detecting, documenting, assessing, and preventing incidents, near misses, and unsafe conditions."

138. N.D. Admin. Code § 61-04-02-01 notes, regarding physicians, that:

> The exemption contained in subsection 1 of North Dakota Century Code section 43-15-02 for a duly licensed practitioner of medicine [exempting practitioners from the provisions of the chapter regarding pharmacists] . . . shall not exempt such a practitioner who regularly engages in dispensing such remedies to the practitioner's patients for which such patients are charged either separately or together with charges for other professional services, from . . . [the] requirements of the practice of pharmacy as set forth in this chapter or by federal and state laws as they pertain to the regulation of the practice of pharmacy.

4. Essentia's own policies set forth temperature and storage guidelines that Defendants failed to follow.

139. Essentia's own policies recommend "medical grade refrigerator/freezer[s]" outfitted with "Essentia approved thermometers and/or MN/ND State Department of Health . . . data loggers" for storing medications, vaccines, and other pharmaceuticals that require refrigeration.

140. According to Essentia's Temperature Monitoring for Refrigerators/Freezers policy, revised December 21, 2017, individual temperature logs are required for each refrigerator/freezer, and "[s]taff logging temperature will document the current temperature, the Hi and Lo Readings, and initial log as complete."

141. Under Essentia's policy, refrigerators that hold medications (excluding vaccines) shall be checked once daily and recorded on the respective refrigerator/freezer log; refrigerators/freezers that hold vaccines shall be recorded twice daily; and if the vaccines are State DOH sponsored and part of the Vaccine for Children Program, a Data Logger will be used and information must be sent to NDDoH or MNDoH to maintain compliance.

142. Essentia's policy further requires the refrigerator temperature range for medications, vaccines, and specimens to be maintained between 36°F and 46°F, and freezer temperature range to be maintained between -5°F and +5°F.

143. Essentia guidelines require action be taken when temperatures have been out of range or unknown in excess of two hours, including, among other responsibilities,

a. Record the temperature of the involved refrigerator at the time the situation is noted;

b. Relocate the medication/vaccine to a working refrigerator/freezer in the same building and record temperatures to assure correct temperature ranges are maintained;

c. Quarantine the vaccine and label "Do Not Use" until the situation can be further investigated;

d. Contact Pharmacy for proper disposal or care of medications when temperature is in the unacceptable range;

e. Call vaccine manufacturers to determine viability of vaccines; and

f. Complete occurrence report.[30]

C. Dakota Clinic functioned as Essentia's in-house pharmacy through lease and Shared Services Agreements with Innovis d/b/a Essentia.

144. On or about July 1, 2015, Innovis and Dakota Clinic entered into a lease agreement for a term of approximately 10 years, ending on June 30, 2025, whereby Innovis leased pharmaceutical space in its hospital and clinic located at 1702 South University Drive, Fargo, ND, to Dakota Clinic ("South University Lease").

[30] *Id.*

145. Subsequently, on or about March 2, 2016, Innovis and Dakota Clinic entered into a new lease agreement for a term of approximately 9 years, ending on June 30, 2025, whereby Innovis leased space in its hospital and clinic located at 3000 32nd Avenue South, Fargo, ND, to Dakota Clinic ("32nd Avenue Lease").

146. On or about August 1, 2017, Innovis d/b/a Essentia entered into a Shared Services Agreement with Dakota Clinic, pursuant to which Innovis provided staffing, accounting, and administrative services and Dakota Clinic provided clinic pharmaceutical management services.

147. With regard to staffing, "Innovis . . . employ[ed] and furnish[ed] to [Dakota Clinic] all pharmacists, technicians and clerical staff needed to operate [Dakota Clinic's] pharmacy business."

148. Pursuant to the agreement, Dakota Clinic was responsible for reimbursing Innovis for the costs of salaries, benefits, taxes, and employment-related expenses incurred by Innovis in employing such personnel.

149. Innovis's administrative services included maintaining the books and records of Dakota Clinic's pharmacy business and providing other accounting, finance, and human resources services.

150. As compensation for the administrative services, Dakota Clinic paid Innovis [redacted] per month with periodic increases over the life of the agreement.

151. Dakota Clinic also paid rent to Innovis each month pursuant to the parties' lease agreements.

152. As part of the Shared Services Agreement, Dakota Clinic was to provide:

> [T]hrough pharmacists and technicians otherwise staffing [Dakota's] pharmacy business, management of Innovis's clinic pharmaceutical inventory, including but not limited to maintenance of Innovis's formulary, management of ordering and purchasing,

> periodic inspection of storage areas, security of stored pharmaceuticals, controlled substance recordkeeping, conduct of periodic audits and all other actions required for compliance with all local, state and federal laws regulating or otherwise applicable to the pharmaceuticals, [Dakota] or Innovis's clinic.

153. As compensation for these services, Innovis paid Dakota Clinic an annualized fee of [redacted]

154. According to the Shared Services Agreement, Dakota Clinic "operate[d] a pharmacy business and related activities in premises leased from Innovis in its hospital and clinic building at 1702 South University Drive, Fargo, North Dakota."

155. Innovis's address listed on the agreement, for purposes of notice, is 3000 32nd Avenue South, Fargo, ND 58103.

D. The Temperature Excursion was made public after out-of-range temperatures were recorded in connection with a February 2020 refrigerator and pharmaceutical relocation.

156. In or about February 2020, Essentia allegedly took over the management, storage, and distribution process for medications from Dakota Clinic and/or John Doe Distributor.

157. It was at that time that Essentia purportedly learned that Dakota Clinic and/or John Doe Distributor had stored certain vaccines and medications outside of the recommended temperature range, potentially impacting their effectiveness.

158. Essentia allegedly took over Dakota Clinic's services following a termination letter sent in or about December 2019.

159. Kyle Dorow, Essentia Health's Vice President of Finance, wrote to Dakota Clinic Pharmacy, LLC's President (unnamed in the letter), "[p]ursuant to Section 11 of the Shared Services Agreement dated August 1, 2017," to provide "written notice to terminate the DCP Pharmaceutical Services described in Exhibit A" of the Shared Services Agreement "and eliminate the corresponding annualized [redacted] fee effective February 28, 2020."

160. The letter was undated, but the Shared Services agreement provides that the agreement (or some or all of the services described in the agreement) may be terminated by either party with at least 60 days written notice.

161. The letter included "Innovis Health, LLC[,] 3000 32nd Avenue South[,] Fargo, ND 58103" in the top left corner, presumably as the sender's address.

162. The letter was on Essentia Health letterhead and copied "Essentia Health Contract Administration."

163. According to Essentia, in anticipation of the termination of Dakota Clinic's services, a double-door refrigerator and a triple-door refrigerator were moved on February 20 and February 21, 2020, respectively, from Dakota Clinic's location at 1702 South University Drive to Innovis's basement at that same location. Dakota Clinic-stored pharmaceutical product was moved from the triple-door refrigerator to the double-door refrigerator to facilitate the move of the triple-door refrigerator from Dakota Clinic's location.

164. According to Essentia, on February 21, 2020, the temperature in Innovis's basement was reaching 77 degrees Fahrenheit, and Innovis was notified that the double-door refrigerator had gone below the required 36 degrees Fahrenheit temperature range and the empty triple-door refrigerator had a reading of 33 degrees Fahrenheit.

165. According to Essentia, the products in the double-door refrigerator were removed and redistributed to Innovis's clinic departments at the South University location.

166. According to Essentia, Innovis's Pharmacy Operations Senior Manager, Maari Loy, contacted Laura Morris, a pharmacist-owner of Dakota Clinic, regarding the out-of-range temperatures for the two refrigerators that were moved from the Dakota Clinic location.

167. On February 24, 2020, Ms. Loy met with Dakota Clinic's pharmacist-owners at Dakota Clinic and reviewed a temperature log maintained at Dakota Clinic.

E. For nearly three years or more, Defendants knowingly failed to maintain proper pharmaceutical storage temperatures at their facilities.

168. During the relevant time period, Dakota Clinic maintained refrigerator temperature logs using North Dakota Department of Health forms.

169. The instructions on these logs state, among other things, that the staff filling out the log should enter his or her initials, note the time of temperature observation, and write the minimum and maximum temperatures in number on the boxes on the right.

170. The instructions on the logs further state: "Temperatures out of range require immediate action. Write the exact temperature [on] the right and record the detailed information on the back of the form."

171. The logs Dakota Clinic used state "Aim for 40°F" and further caution: "DANGER! Fridge temperatures below 35°F are too cold! Record temperature to the right and take action immediately!"

172. In discovery, Essentia and Dakota Clinic produced monthly refrigerator temperature logs for the months of December 2016; January, September, October, and December 2017; January through September 2018; December 2018 through March 2019; May 2019 through June 2019; and August 2019 through February 2020.

173. According to the CDC and the North Dakota Department of Health, temperature logs must be kept for a minimum of three years.[31]

[31] *See, e.g.*, https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf (last visited August 4, 2021); http://www.ndhealth.gov/immunize/Documents/Providers/Forms/TemplogFrefrigerator.pdf (last visited

174. However, Defendants have not produced logs for February through August 2017, November 2017, October or November 2018, April 2019, or July 2019.

175. Dakota Clinic's logs indicate a failure to follow federal or state guidance, best practices, or laws, or to even follow the instructions on the form.

176. Dakota Clinic's logs reveal that temperatures were not recorded daily, let alone twice per day, and that out-of-range temperatures were regularly recorded.

177. The January 2017 log, for example, shows only three daily recordings.

178. The August 2018 log, for example, shows 19 daily recordings. One reading is at 35°F and 13 are below 35°F – falling as low as 29°F. Only five readings reflect in-range temperatures.

179. The February 2019 log, for example, shows only six recordings, two of which were out-of-range.

180. In February 2020, in the days before the refrigerators' relocation on or about February 20, 2020, only five temperatures were recorded, and two were out-of-range.

181. The logs produced show at least 115 out-of-range recordings, with the lowest recorded temperature of 28°F on July 30, 2018.

182. None of the monthly refrigerator temperature logs maintained by Dakota Clinic show staff initials or the recorded time of temperature observation, and the recorded out-of-range temperatures were not written in the correct column.

183. Dakota Clinic also appears to have used a long-outdated NDDoH temperature log template that references a minimum temperature of 35°F rather than the appropriate minimum of 36°F.

August 4, 2021).

184. The logs Dakota Clinic used appear to have been issued by the NDDoH in 2013 (they bear a small parenthetical next to the form number with what appears to be the month and year: 07-13).

185. The form appears to have been updated by the NDDoH in at least 2016[32] and 2019[33].

186. The newer forms set forth 36°F (rather than 35°F) as the minimum temperature.

187. In addition to the over 115 readings Dakota Clinic logged that fell below 35°F, Dakota's temperature logs reflect more than 30 readings at an also out-of-range 35°F.

F. Defendants administered the Affected Medications subject to temperature excursions for three years to thousands of patients.

188. On or about April 6, 2020, Essentia Health notified nearly 50,000 patients that medication or vaccines they received might have been compromised by improper temperature storage by a wholesale drug distributor, which on information and belief was Dakota Clinic and/or John Doe Distributor.

189. Essentia has written to patients to inform them of the possibility that injectable medications or vaccines they received might have been rendered less effective by improper storage.

190. According to an alert on Essentia's website, more than 100 refrigerated injectable medications could have been compromised.[34]

[32] http://www.ndhealth.gov/immunize/Documents/Providers/Forms/TemplogFrefrigerator.pdf (07-16) (last visited August 4, 2021).

[33] http://www.ndhealth.gov/immunize/Documents/Providers/Forms/TemplogFFridge.pdf (01-19) (last visited August 4, 2021).

[34] https://www.essentiahealth.org/alerts/medication-storage-issue/?utm_source=direct-mail&utm_campaign=medical-storage-issue-fy20 (last visited August 4, 2021).

191. Essentia has also stated on its website that the medications affected may date back to September 2017.

192. However, other Essentia Health employees have advised Plaintiffs that medications they or their children received as early as January 2017 were affected.

193. Essentia explained that the affected medications and vaccines were likely sent to Essentia Health clinics in Minnesota and North Dakota.

194. While Essentia Health has offered to revaccinate free of charge, Plaintiffs and class members are entitled to refunds for visits for which they did not receive proper care. Moreover, free vaccines are worthless to the thousands of patients who received vaccines that cannot be re-administered, such as annual flu vaccines for the 2017, 2018, and 2019 flu seasons, or other medications, like cancer treatment drugs, that have a maximum lifetime dose and cannot be repeated.

195. Additionally, before its Answer to Plaintiffs' original complaint in this lawsuit, Essentia Health had refused to disclose the identity of John Doe Distributor.

196. Essentia Health stated in its Answer to the original complaint that the distributor was Dakota Clinic.

197. Moreover, Essentia Health has not disclosed the steps it has implemented to ensure that proper storage and handling of the vaccines and medications is now in place.

198. Patients may choose to get revaccinated or treated outside the Essentia Health system but will have to bear additional out-of-pocket costs.

199. Finally, Plaintiffs and the class members will have to endure additional pain and suffering to get revaccinated, as well as aggravation and time to undergo and attend additional medical examinations.

G. Defendants had temperature excursions—and improperly administered pharmaceuticals subject to excursions—in the past.

200. This is not the first temperature excursion affecting Essentia Health's patients.

201. In July 2018, Essentia Health announced that Varicella (intended to prevent chickenpox) and Proquad (intended to prevent measles, mumps, and rubella) vaccines administered at Essentia may not have been properly stored at the manufacturer's recommended temperature, resulting in patients receiving potentially less-than-optimal vaccines.

202. Essentia Health recommended that parents bring children in to receive an additional dose of the vaccines to ensure the children are fully protected.

203. Essentia Health further advised, "[w]e have put measures in place so this does not occur again . . . ."[35]

204. According to documents obtained from the North Dakota Department of Health, on October 8, 2018, a high temperature alarm was activated at Essentia Health's West Fargo location when a refrigerator recorded above 46°F for two hours. The highest recorded temperature for the refrigerator on that day was 49.8°F. That same day, a high temperature alarm was activated at Essentia Health's West Fargo location when a freezer recorded above 5°F for 1.5 hours. The highest recorded temperature for the freezer on that day was 18.5°F.

H. Defendants were responsible for implementing Current Good Manufacturing Practices.

205. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices"

[35] https://kbjr6.com/2018/07/23/essentia-health-says-varicella-proquad-vaccines-were-not-properly-stored/ (last visited August 4, 2021).

(CGMPs) to ensure they meet safety, quality, purity, identity, and strength standards. 21 U.S.C. § 351(a)(2)(B).

206. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

207. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse the Affected Medications.

208. Any drug not manufactured in accordance with CGMPs is deemed "adulterated and/or misbranded" and may not be distributed or sold in the United States. 21 U.S.C. §§ 331(a), 351(a)(2)(B). State common law and statutory law mirror these federal standards.

209. Moreover, the U.S. Pharmacopeia Convention (hereinafter "USP") sets forth industry standards applicable—in relevant part—to distributors. Chapter 1079, entitled "Good Storage and Shipping Practices," specifies that: "Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the following: . . . Wholesale distributors; distribution companies involved in automobile, rail, sea, and air services."

210. USP 1079 further provides that the drug product manufacturer bears:

> primary responsibility and accountability including but not limited to the following:…
>
> - Determining proper storage and handling practices
>
> - Communicating proper storage and distribution practices though the supply chain
>
> * * *
>
> - Recalling the drug product if it is found to be adulterated in any part of the supply chain
>
> However, all organizations along the supply chain bear responsibility for ensuring that they handle drug products within adequate storage and distribution parameters that will not affect the drug product identity, strength, quality, purity, or safety.

211. Here, Essentia Health discovered and disclosed that the Affected Medications were subject to temperature excursion, resulting in the destruction of their efficacy or potency.

212. Each Defendant had an obligation to take – and nothing prevented any Defendant from taking – actions to protect the efficacy and potency of the Affected Medications by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

213. Each Defendant breached their duty to provide proper storage, shipping, and temperature specifications as set forth above.

I. The Affected Medications were misbranded and adulterated because they did not maintain the efficacy or potency represented.

214. The manufacture of any misbranded or adulterated drug is prohibited under federal law. 21 U.S.C. § 331(g).

215. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited. 21 U.S.C. § 331(a).

216. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful. 21 U.S.C. § 331(c).

217. Among the ways a drug may be adulterated are:

a. "If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B).

b. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium. . . ." 21 U.S.C. § 351(b).

218. A drug is misbranded:

a. "If its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1).

b. "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 352(c).

c. If the labeling does not contain, among other things, "the proportion of each active ingredient . . . ." 21 U.S.C. § 352(e)(1)(A)(ii).

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of

administration or application, in such manner and form, as are necessary for the protection of users . . . .” 21 U.S.C. § 352(f).

e. “If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein.” 21 U.S.C. § 352(g).

f. If the drug is advertised incorrectly in any manner. 21 U.S.C. § 352(n).

g. If the drug’s “packaging or labeling is in violation of an applicable regulation.” 21 U.S.C. § 352(p).

219. The Affected Medications were adulterated or misbranded as the facilities where they were held did not conform to or were not operated or administered in conformity with current good manufacturing practice.

220. The Affected Medications were adulterated or misbranded as to safety, because they did not have the strength, quality and/or purity characteristics, which they were purported or represented to possess.

221. It is unlawful to introduce a misbranded drug into interstate commerce. Thus, the Affected Medications were unlawfully distributed and sold.

222. By selling the Affected Medications in the stream of commerce, each Defendant warranted to consumers that the Affected Medications were safe and effective.

V. TOLLING/FRAUDULENT CONCEALMENT

223. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

224. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of

facts that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

225. The nature of Plaintiffs' injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims.

226. Plaintiffs bring this Complaint within the applicable statute of limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following Plaintiffs' injuries and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know and had no reason to know of their injuries and/or the wrongful cause of those injuries.

227. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiffs regarding any defects associated with the Affected Medications, including the safety, potency or efficacy of the drugs. Defendants affirmatively withheld and/or misrepresented facts concerning the manner in which the Affected Medications were distributed and sold, and the effects on the Affected Medications. As a result of Defendants' misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Plaintiffs had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

228. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defective manner in which the Affected

Medications were stored —information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known that Defendants' Affected Medications were misbranded, adulterated and defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

VI. CLASS ALLEGATIONS

229. Plaintiffs bring this action in their individual capacity and on behalf of the following class: "All persons and health plans that paid, in whole or in part, for Affected Medications that were administered at Essentia Health or by Innovis Health, and all persons who were administered the Affected Medications at Essentia Health or by Innovis Health." For purposes of this definition, the full list of Affected Medications will be supplemented upon discovery from Essentia Health.

230. 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. Plaintiffs reserve the right to modify or amend the definition of the class, including to add one or more subclasses, after having the opportunity to conduct discovery.

231. The proposed class meets the requirements of Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4).

232. ***Numerosity***. The members of the class are so numerous that joinder is impracticable. Essentia Health has stated that the Affected Medications were administered to nearly 50,000 patients.

233. ***Typicality***. Plaintiffs' claims are typical of the claims of putative class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the

claims of the other class members. Each Plaintiff, like each class member, paid money for the Affected Medications manufactured, distributed, or sold by Defendants, paid money for the medical appointments at which the Affected Medications were administered, and/or were administered the Affected Medications. Plaintiffs, like each class member, were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the class members.

234. ***Adequacy.*** Plaintiffs will fairly and adequately protect the interests of the class members. Plaintiffs' interests and the interests of all other members of the class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

235. ***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, the following:

a. whether the Affected Medications were subject or potentially subject to one or more temperature excursions;

b. whether each Defendant knew or should have known that the Affected Medications were not properly stored, handled, or transported, or otherwise were likely to be subjected to one or more temperature excursions;

c. whether one or more Defendants acted to conceal the fact that the Affected Medications were not properly stored, handled, or transported, or otherwise were likely to be subjected to one or more temperature excursions;

d. whether Defendants' marketing, advertising, or promotion of the Affected Medications misrepresented their efficacy or potency;

e. whether Defendants' failure to disclose that the Affected Medications were not properly stored, handled, or transported, or otherwise were likely to be subjected to one or more temperature excursions affecting their efficacy and potency was unfair, deceptive, fraudulent, or unconscionable;

f. whether Defendants' conduct was knowing or willful;

g. whether Defendants' conduct was negligent;

h. whether Defendants' conduct violated the Minnesota and North Dakota consumer-protection statutes;

i. whether Defendants breached express warranties;

j. whether Defendants breached implied warranties;

k. whether Defendants have been unjustly enriched;

l. whether Plaintiffs and the class members are entitled to recover damages and the appropriate measure of those damages; and

m. the appropriate measure of disgorgement.

236. ***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 Defendants, and thus, individual litigation to redress Defendants' wrongful conduct would be impracticable.

237. 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.

238. Plaintiffs reserve the right to seek certification under Rule 23(c)(4) of common questions related to Defendants' knowledge, conduct, products, and duties.

VII. CAUSES OF ACTION

COUNT I: BREACH OF EXPRESS WARRANTIES (Against All Defendants)

239. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

240. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the defective Affected Medications to consumers, including Plaintiffs, thereby placing the Affected Medications into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

241. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of the Affected Medications, including a duty to ensure that their products met the safety, efficacy and purity requirements of their labels. However, as alleged throughout this pleading, the ability of Defendants to properly disclose the risks associated with the Affected Medications is not limited to representations made on the labeling.

242. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that the Affected Medications were effective, fit, and proper for their intended use.

243. Defendants advertised, labeled, marketed, and promoted the Affected Medications, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that the Affected Medications would conform to the representations.

244. These express representations included incomplete warnings and instructions as to the lack of controls on storage and handling for the Affected Medications that resulted in the temperature excursions. Defendants knew and/or should have known that the warnings and labels did not and do not accurately or adequately set forth the risks of products that were not effective or fit for their intended purpose.

245. The representations about the Affected Medications, as set forth herein, contained or constituted affirmations of fact or promises made by each of the Defendant sellers to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

246. Defendants placed the Affected Medications into the stream of commerce for sale and recommended their use to consumers and the public without adequately warning of the fact that the Affected Medications were not safe, effective or fit for their intended use due to improper storage and handling.

247. Defendants breached these warranties because, among other things, the Affected Medications were defective, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways: (i) Defendants represented that the expiry dates on their products were accurate and that their Affected Medications were safe and effective throughout

the end of the expiry period; and (ii) Defendants represented that their Affected Medications were effective vaccines and immunizations without disclosing that their efficacy or potency was likely to decrease completely or dramatically as a result of temperature excursions from improper storage and handling.

248. Dakota Clinic represented the quality of the Affected Medications to consumers, thereby inducing their purchase and use.

249. Specifically, Dakota Clinic warranted the quality of the Affected Medications to consumers through its management of Innovis's clinic pharmaceutical inventory (including, but not limited to, its responsibilities for compliance with all local, state, and federal laws regulating the Affected Medications) and by distributing the Affected Medications to be administered to consumers.

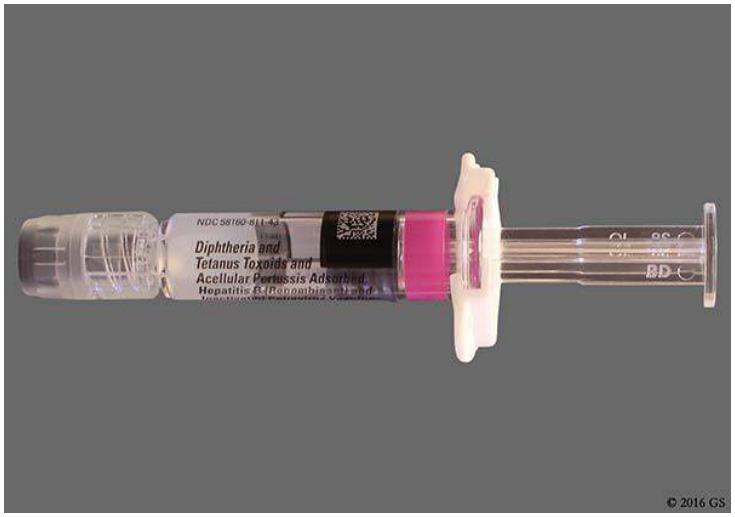
250. Dakota Clinic distributed the Affected Medications to numerous Essentia Health clinics for administration to patients.

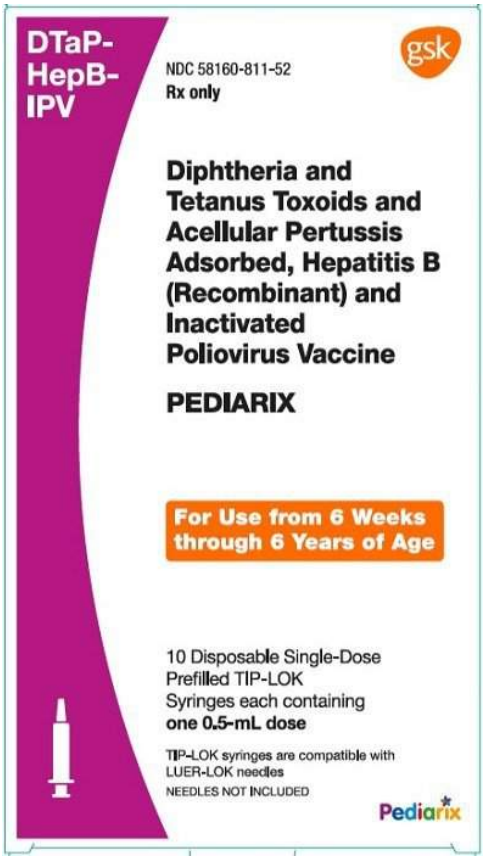
251. Dakota Clinic's distribution of the Affected Medications for administration to consumers was itself an express warranty that the Affected Medications were safe and effective for their intended use and would conform to the representations in their labeling and packaging.

252. For example, Plaintiffs understand through early discovery that over 2,000 patients were administered an improperly stored PEDIARIX vaccine, manufactured by GlaxoSmithKline.

253. PEDIARIX is the brand name of a vaccine intended to prevent illness associated with Diphtheria, Tetanus, Pertussis, Hepatitis B, and Poliovirus.

254. Although labeling and packaging has not yet been produced in discovery, publicly available images show that the diseases the injectable medication was intended to prevent are reflected on the box and on the syringe itself:





255. Innovis, Essentia, and Dakota Clinic each profited, directly and/or indirectly, from sales of the Affected Medications. They are therefore each liable for their breach of the express warranties alleged herein. *See*, *e.g.*, *Durfee v. Rod Baxter Imps., Inc.*, 262 N.W.2d 349, 357-58 (Minn. 1977) ("[t]he distributor . . . who profits indirectly from retail sales, must take responsibility for the solvency of its dealers when its warranty is breached.").

256. In addition, Innovis, Essentia, and Dakota Clinic are so closely linked in the storage and administration of TTSPPs that "they blended into a single unit" at the time the Affected Medications were administered. *See Fode v. Capital RV Ctr.*, 1998 ND 65, ¶ 21, 575 N.W.2d 682, 687.

257. Specifically, Plaintiffs and class members were administered and/or paid for the Affected Medications administered at Essentia Health-branded clinics by Essentia Health providers.

258. Innovis (which is entirely owned by and does business as Essentia) is the largest owner of Dakota Clinic Pharmacy.

259. Dakota Clinic Pharmacy functioned as Essentia's in-house pharmacy, distributing the Affected Medications to numerous Essentia Health clinics to be administered by Essentia Health providers.

260. Dakota Clinic Pharmacy is publicly identified as an Essentia-owned pharmacy.

261. Dakota Clinic Pharmacy also expressly warranted, by its agreement to the Shared Services Agreement, that it would and did manage Innovis's clinic pharmaceutical inventory, "including but not limited to maintenance of Innovis's formulary, management of ordering and purchasing, periodic inspection of storage areas, security of stored pharmaceuticals, controlled substance recordkeeping, conduct of periodic audits and all other actions required for compliance with all local, state and federal laws regulating or otherwise applicable to the pharmaceuticals, [Dakota] or Innovis's clinic."

262. A seller's warranty, whether express or implied, extends to any person who may reasonably be expected to use, consume, or be affected by the goods and who is injured by breach of the warranty. N.D. Cent. Code § 41-02-35 (2-318); Minn. Stat. § 336.2-318.

263. Dakota Clinic Pharmacy knew Plaintiffs and the class would use, pay for, and/or be affected by the Affected Medications.

264. Plaintiffs detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or efficacy profile of Affected Medications in deciding to

purchase, pay for, and/or receive the product. Plaintiffs reasonably relied upon Defendants to disclose known defects. Physicians would not have prescribed—and Plaintiffs would not have purchased or used the Affected Medications—had Defendants properly disclosed the improper storage and handling of the Affected Medications and resulting temperature excursions, either through advertising, labeling, or any other form of disclosure.

265. Defendants had sole access to material facts concerning the nature of the storage and handling associated with their Affected Medications and knew that consumers, payors, and/or users such as Plaintiffs could not have reasonably discovered that the methods of storage and handlings were inadequate and that the resulting representations were inaccurate.

266. Plaintiffs had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Affected Medications.

267. Plaintiffs used, paid for, and/or were exposed to Affected Medications as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, or otherwise released into the stream of commerce by Defendants.

268. Defendants' breach of these express warranties was a substantial factor in causing Plaintiffs' harm.

269. As a direct and proximate result of Defendants' breach of these warranties, as alleged herein, Plaintiffs sustained an economic loss and other injuries.

COUNT II: BREACH OF IMPLIED WARRANTIES
(Against All Defendants)

270. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

271. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the Affected Medications, which

were defective to consumers, including Plaintiffs, thereby placing the Affected Medications into the stream of commerce.

272. Before the time Plaintiffs used and/or paid for the Affected Medications, each Defendant impliedly warranted to their consumers, including Plaintiffs, that the Affected Medications were of merchantable quality and were safe and fit for the use for which they were intended—specifically, as consumer medication.

273. Dakota Clinic Pharmacy represented the quality of the Affected Medications to consumers, thereby inducing their purchase and use.

274. Specifically, Dakota Clinic Pharmacy warranted the quality of the Affected Medications to consumers through its management of Innovis's clinic pharmaceutical inventory (including, but not limited to, its responsibilities for compliance with all local, state, and federal laws regulating the Affected Medications) and by distributing the Affected Medications to be administered to consumers.

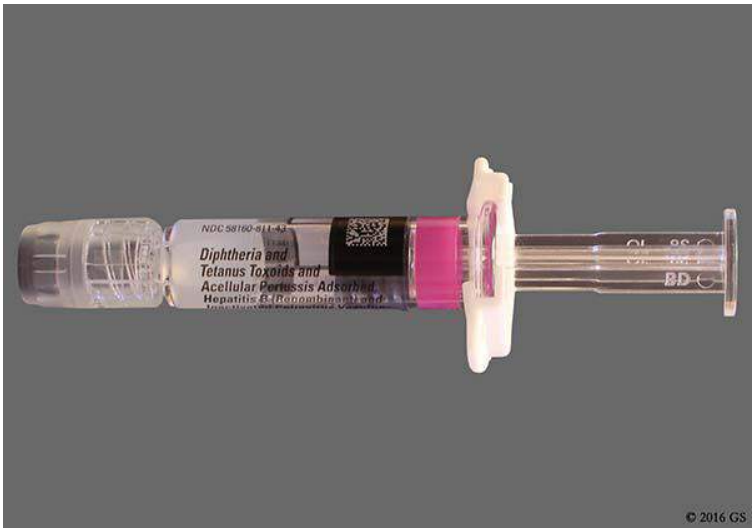
275. Dakota Clinic Pharmacy distributed the Affected Medications to numerous Essentia Health clinics for administration to patients.

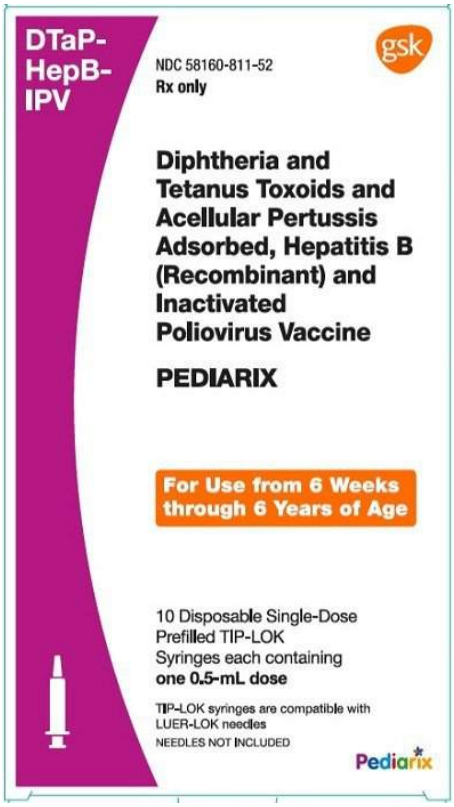
276. Dakota Clinic Pharmacy's distribution of the Affected Medications for administration to consumers was itself a warranty that the Affected Medications were safe and effective for their intended use and would conform to the representations in their labeling and packaging.

277. For example, Plaintiffs understand through early discovery that over 2,000 patients were administered an improperly stored PEDIARIX vaccine, manufactured by GlaxoSmithKline.

278. PEDIARIX is the brand name of a vaccine intended to prevent illness associated with Diphtheria, Tetanus, Pertussis, Hepatitis B, and Poliovirus.

279. Although labeling and packaging has not yet been produced in discovery, publicly available images show that the diseases the injectable medication was intended to prevent appear on the box and on the syringe itself:





280. Innovis, Essentia, and Dakota Clinic Pharmacy each profited, directly and/or indirectly, from sales of the Affected Medications. They are therefore each liable for their breach of the warranties alleged herein. *See*, *e.g.*, *Durfee v. Rod Baxter Imps., Inc.*, 262 N.W.2d 349, 357-58 (Minn. 1977) ("[t]he distributor . . . who profits indirectly from retail sales, must take responsibility for the solvency of its dealers when its warranty is breached.").

281. In addition, Innovis, Essentia, and Dakota Clinic Pharmacy are so closely linked in the storage and administration of TTSPPs that "they blended into a single unit" at the time the

Affected Medications were administered. *See Fode v. Capital RV Ctr.*, 1998 ND 65, ¶ 21, 575 N.W.2d 682, 687.

282. Specifically, Plaintiffs and class members were administered and/or paid for the Affected Medications administered at Essentia Health-branded clinics by Essentia Health providers.

283. Innovis (which is entirely owned by and does business as Essentia) is the largest owner of Dakota Clinic Pharmacy.

284. Dakota Clinic Pharmacy functioned as Essentia's in-house pharmacy, distributing the Affected Medications to numerous Essentia Health clinics to be administered by Essentia Health providers.

285. Dakota Clinic Pharmacy is publicly identified as an Essentia-owned pharmacy.

286. Dakota Clinic Pharmacy also warranted, by its agreement to the Shared Services Agreement, that it would and did manage Innovis's clinic pharmaceutical inventory, "including but not limited to maintenance of Innovis's formulary, management of ordering and purchasing, periodic inspection of storage areas, security of stored pharmaceuticals, controlled substance recordkeeping, conduct of periodic audits and all other actions required for compliance with all local, state and federal laws regulating or otherwise applicable to the pharmaceuticals, [Dakota] or Innovis's clinic."

287. A seller's warranty, whether express or implied, extends to any person who may reasonably be expected to use, consume, or be affected by the goods and who is injured by breach of the warranty. N.D. Cent. Code § 41-02-35 (2-318); Minn. Stat. § 336.2-318.

288. Dakota Clinic Pharmacy knew Plaintiffs and the class would use, pay for, and/or be affected by the Affected Medications.

289. But Defendants failed to disclose that the Affected Medications were not effective when used as intended.

290. Plaintiffs and class members were intended beneficiaries of the implied warranties made by Defendants to purchasers of their Affected Medications.

291. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiffs and class members, would use and/or pay for the Affected Medications as marketed by Defendants, which is to say that Plaintiffs and class members were foreseeable users of and payors for the Affected Medications.

292. Defendants intended that Affected Medications be used in the manner in which Plaintiffs and class members, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though the Affected Medications were not adequately stored and thus were not effective.

293. In reliance upon Defendants' implied warranty, Plaintiffs and class members used the Affected Medications as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

294. Plaintiffs could not have reasonably discovered or known of the risks of serious injury associated with the Affected Medications.

295. Defendants breached their implied warranty to Plaintiffs and class members in that the Affected Medications were not of merchantable quality, safe, or fit for their intended use due to their inadequate storage and cooling.

296. Defendants' breach of these implied warranties was a substantial factor in causing Plaintiffs' and class members' harm.

297. As a direct and proximate result of Defendants' breach of implied warranties, as alleged herein, Plaintiffs and class members sustained economic losses and other injuries.

COUNT III: VIOLATION OF CONSUMER PROTECTION AND DECEPTIVE TRADE PRACTICES LAWS
(Against All Defendants)

298. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

299. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable deceptive or fraudulent acts, or trade practices in violation of the Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.68, et seq., and North Dakota Consumer Protection Law, N.D. Cent. Code §§ 51-15-01, et seq.

300. Plaintiffs used and/or paid for Defendants' Affected Medications and suffered ascertainable losses as a result of Defendants' actions in violation of consumer protection laws.

301. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have paid for the Affected Medications, and would not have incurred related medical costs and injuries.

302. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiffs for Affected Medications that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

303. Unfair methods of competition or deceptive acts or practices that were proscribed by law include:

a. Representing that goods or services have characteristics, ingredients, uses benefits or qualities they do not have;

b. Representing that Affected Medications are of a particular standard, quality, and grade when they are not;

c. Advertising goods or services with the intent not to sell them as advertised;

d. Engaging in fraudulent and deceptive conduct that creates a likelihood of confusion or misunderstanding.

304. Between at least August 2017 and February 2020, Dakota Clinic Pharmacy was responsible for maintaining, storing, and distributing TTSPP inventory, including Innovis's inventory, at its premises at 1702 University Dr. S, Fargo, ND 58103, which it leased from Innovis.

305. During that time, Dakota Clinic Pharmacy had a retail pharmacy license and, pursuant to a Shared Services Agreement, managed the pharmaceutical inventory for Innovis d/b/a Essentia.

306. Dakota Clinic Pharmacy (like Essentia and Innovis) was required to monitor and log the temperatures at which the TTSPPs were kept to ensure they were within the safe temperature range mandated by the pharmaceutical manufacturers, CDC, NDDoH, and others.

307. Dakota Clinic Pharmacy knowingly failed to adequately monitor the storage conditions of the Affected Medications.

308. When it did monitor the storage conditions of the Affected Medications, Dakota Clinic Pharmacy knew that the recorded temperatures were below the minimum safe temperature for TTSPPs.

309. Dakota Clinic Pharmacy did not, as it was required to do, isolate pharmaceuticals kept at out-of-range temperatures and mark them "DO NOT USE" until the department of health and/or manufacturers could advise Dakota Clinic Pharmacy regarding how to proceed.

310. Instead, Dakota Clinic Pharmacy knowingly distributed these Affected Medications for administration to Plaintiffs and class members.

311. In its public disclosures, Essentia Health refers to Dakota Clinic Pharmacy as its former "distribution partner."

312. According to Essentia Health's public disclosures, "affected medications and vaccines were likely sent to Essentia Health clinics in Fargo, Casselton, Detroit Lakes-Hwy 10, Hankinson, Jamestown, Lisbon, Moorhead and Moorhead Downtown, Valley City and Wahpeton. Some Essentia Health clinics may have only received affected flu vaccinations, including our clinics in Ada, Bagley, Fosston, Graceville, and Oklee."

313. Dakota Clinic Pharmacy's distribution of the Affected Medications for administration to and/or payment by Plaintiffs and class members was deceptive, fraudulent, conducted on false pretenses, misleading, unconscionable, and misrepresentative because it knew the Affected Medications had not been properly stored, may not be effective, and should not be administered to patients.

314. Dakota Clinic Pharmacy intended for others, including Plaintiffs and class members, to rely on its misleading and deceptive distribution of the Affected Medications in connection with the sale of those medications to Plaintiffs and class members.

315. As a result of Dakota Clinic Pharmacy's conduct, Plaintiffs and class members understood that the Affected Medications they received and/or paid for were properly stored, safe, and effective when they were not. Plaintiffs and class members were thus injured.

316. Plaintiffs and class members were injured by the cumulative and indivisible nature of Defendants' conduct, which created demand for the Affected Medications.

317. Defendants had a statutory duty to refrain from unfair or deceptive acts and/or trade practices in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, sale, and/or administration of the Affected Medications.

318. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Affected Medications and would not have incurred related medical costs.

319. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to Plaintiffs constituted unfair and deceptive acts and trade practices in violation of state consumer protection statutes.

320. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers and sellers who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

321. Plaintiffs are the type of consumers, as defined in these statutes, that these statutes were designed to protect.

322. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising by knowingly and falsely representing that the Affected Medications were fit to be used for the purposes for which they were intended, when in fact they were not effective or potent due to the temperature excursion, and by other acts alleged herein.

323. The actions and omissions of Defendants as alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against

unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

324. Defendants had actual knowledge of the defective condition of the Affected Medications and failed to take any action to cure such defective and dangerous conditions.

325. Plaintiffs and their individual physicians relied upon Defendants' misrepresentations and omissions. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and did, in fact, deceive reasonable consumers, including Plaintiffs, about the inherently defective nature of the Affected Medications.

326. Defendants had an ongoing duty to Plaintiffs to refrain from unfair and deceptive practices under these statutes in the course of their business. Specifically, Defendants owed Plaintiffs a duty to disclose all the material facts concerning the efficacy and potency (or lack thereof) of the Affected Medications because they possessed exclusive knowledge. Instead, they intentionally concealed the dangers of the temperature excursions and their effects on the Affected Medications from Plaintiffs, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

327. The facts regarding the storage and handling of the Affected Medications that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiffs, who considered such facts to be important with regards to their purchase decisions and medical visits with respect to the Affected Medications.

328. Plaintiffs purchased the Affected Medications in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding the Affected Medications. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiffs would not have purchased the drug(s) (or paid for the medical visit(s)) and would not have been injured.

329. Defendants' deceptive, fraudulent, and unconscionable representations to patients, physicians, consumers, and third-party payors, including Plaintiffs, constituted unfair and deceptive acts and practices.

330. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

331. Defendants' unlawful acts and practices complained of herein affect the public interest, as the violations regarding widely sold drugs, including vaccinations and immunizations designed to prevent communicable diseases, were harmful to the general public.

332. Defendants' actions and omissions as identified in this Complaint show that Defendants acted willfully, maliciously, and/or intentionally disregarded Plaintiffs' rights so as to warrant the imposition of punitive damages, or other applicable statutory damages including treble damages where available.

COUNT IV: UNJUST ENRICHMENT
(Against All Defendants)

333. Plaintiffs incorporate by reference every allegation set forth in preceding paragraphs as if fully stated herein.

334. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released the Affected

Medications into the stream of commerce, and therefore owed a duty of reasonable care to provide safe and effective medications.

335. Defendants knew or should have known that the Affected Medications were not safe, effective, or of the quality required to provide the protections promised by the vaccines and immunizations.

336. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the Affected Medications were not safe, effective, or of the quality required to provide the protections promised by the vaccines and immunizations.

337. Defendants requested and received a measurable benefit at the expense of Plaintiffs and class members in the form of payment for their Affected Medications and/or payment for the associated medical visits.

338. Dakota Clinic Pharmacy was unjustly enriched as a party to the Shared Services Agreement and as a party in the chain of distribution with Innovis and Essentia.

339. Plaintiffs and class members conferred a benefit on Dakota Clinic Pharmacy by paying for the Affected Medications that were maintained and distributed by Dakota Clinic Pharmacy.

340. As part of the Shared Services Agreement, Dakota Clinic Pharmacy provided "management of Innovis's clinic pharmaceutical inventory, including but not limited to maintenance of Innovis's formulary, management of ordering and purchasing, periodic inspection of storage areas, security of stored pharmaceuticals, controlled substance recordkeeping, conduct of periodic audits and all other actions required for compliance with all

local, state and federal laws regulating or otherwise applicable to the pharmaceuticals, [Dakota] or Innovis's clinic."

341. As compensation for these services, Innovis paid Dakota Clinic Pharmacy an annualized fee of [redacted]

342. Plaintiffs and class members were intended beneficiaries of the Shared Services Agreement, which was intended in part to ensure that the pharmaceutical inventory administered to Plaintiffs and class members was kept safely and in compliance with all applicable laws.

343. Discovery will provide additional evidence regarding the financial transactions and flow of payment between Plaintiffs, Essentia, Innovis d/b/a/ Essentia (owned by Essentia), and Dakota Clinic Pharmacy (partially owned by Innovis d/b/a Essentia), which evidence is currently known only to Defendants.

344. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiffs conferred onto Defendants at Plaintiffs' detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiffs.

345. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

346. Plaintiffs are entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiffs to the position they occupied prior to dealing with Defendants.

COUNT V: NEGLIGENCE
(Against All Defendants)

347. Plaintiffs incorporate by reference every allegation set forth in the preceding paragraphs as if fully stated herein.

348. At all relevant times, each Defendant owed duties to Plaintiffs and class members and was obligated to properly store, handle, and maintain the Affected Medications, including, but not limited to, (1) continuously storing the Affected Medications at the proper temperature until they were administered; (2) not administering pharmaceuticals that were improperly stored; and (3) not charging Plaintiffs or class members for ineffective products or services.

349. These duties specifically included, but were not limited to, keeping vaccines and medications within manufacturers' and CDC-recommended temperature ranges; using appropriate temperature monitoring devices to track such temperatures; routinely monitoring and logging the temperatures in which TTSPPs were stored; taking immediate corrective action to address temperature excursions, including documenting the date, time, and length of time of the temperature excursion, and minimum/maximum temperatures during the time of the excursion; and quarantining and labeling affected medications "DO NOT USE" until further instruction from manufacturers and/or the state's department of health.

350. Dakota Clinic Pharmacy, as the party responsible for "management of Innovis's clinic pharmaceutical inventory, . . . periodic audits and all other actions required for compliance with all local, state and federal laws regulating or otherwise applicable to the pharmaceuticals" according to the Shared Services Agreement, breached its duties when, among other shortcomings, it failed to maintain adequate records documenting out-of-range temperatures, failed to record refrigerator and freezer temperatures each day in Dakota Clinic Pharmacy's temperature logs, failed to document the name or initials of the individual observing the temperatures, failed to document out-of-range temperatures in the proper location on the temperature logs, failed to keep its refrigerator and freezer temperatures within acceptable range, failed to quarantine pharmaceuticals affected by out-of-range temperatures, allowed

pharmaceuticals affected by out-of-range temperatures to be dispensed and administered to patients, and failed to inform patients they received pharmaceuticals affected by out-of-range temperatures.

351. Innovis d/b/a Essentia, as the party responsible for maintaining records of Dakota Clinic Pharmacy's pharmacy business and providing the staff needed to operate Dakota Clinic Pharmacy's pharmacy business (according to the Shared Services Agreement), and as 49% owner (the largest membership stake of Dakota Clinic Pharmacy), and Essentia, as the sole member of Innovis, breached their duties when, among other shortcomings, they failed to maintain adequate records documenting pharmaceutical refrigerator and freezer temperatures, failed to maintain adequate records documenting out-of-range temperatures, failed to keep refrigerator and freezer temperatures within acceptable range, failed to record refrigerator and freezer temperatures each day in Dakota Clinic Pharmacy's temperature logs, failed to document the name or initials of the individual observing the temperatures, failed to document out-of-range temperatures in the proper location on the temperature logs, failed to quarantine pharmaceuticals affected by out-of-range temperatures, failed to oversee Dakota's services under the Shared Services Agreement, and allowed pharmaceuticals affected by out-of-range temperatures to be dispensed and administered to patients.

352. Essentia and Innovis d/b/a Essentia further breached their duties in administering improperly stored pharmaceuticals to Plaintiffs and class members.

353. All Defendants breached these duties when, among other shortcomings, they failed to continuously store the Affected Medications at the proper temperature.

354. As a direct and proximate result of Defendants' breaches, as alleged herein, Plaintiffs sustained economic losses and other injuries.

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Grant certification of the Class, appoint Plaintiffs as Class Representatives, and appoint their counsel as Class Counsel;

B. Enter judgment against Defendants and in favor of Plaintiffs;

C. Award Plaintiffs compensatory damages and any other damages allowed by law;

D. Award Plaintiffs their attorneys' fees and costs in bringing this action; and

E. Grant such other and further relief as this Court deems appropriate.

Dated: August 13, 2021

JESSICA KRAFT, INDIVIDUALLY AND AS PARENT OF MINORS L.K., S.K., and O.K.; SHELLI SCHNEIDER, INDIVIDUALLY AND AS PARENT OF MINORS A.S. and W.S.; ANNE BAILEY, INDIVIDUALLY AND AS PARENT OF MINOR D.B.; AMY LAVELLE, INDIVIDUALLY AND AS PARENT OF MINORS Em.L. and El.L.; ELIZABETH BEATON, INDIVIDUALLY AND AS PARENT OF MINOR M.B.; AMANDA AND TYRELL FAUSKE, INDIVIDUALLY AND AS PARENTS OF MINORS C.R.F. and C.J.F.; JENNIFER REIN, INDIVIDUALLY; and JESSICA BERG, INDIVIDUALLY AND AS PARENT OF MINORS A.B. and S.B., individually and on behalf of all others similarly situated,

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JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: August 13, 2021

JESSICA KRAFT, INDIVIDUALLY AND AS PARENT OF MINORS L.K., S.K., and O.K.; SHELLI SCHNEIDER, INDIVIDUALLY AND AS PARENT OF MINORS A.S. and W.S.; ANNE BAILEY, AS PARENT OF MINOR D.B.; AMY LAVELLE, AS PARENT OF MINORS Em.L. and El.L.; ELIZABETH BEATON, INDIVIDUALLY AND AS PARENT OF MINOR M.B.; AMANDA AND TYRELL FAUSKE, INDIVIDUALLY AND AS PARENTS OF MINORS C.R.F. and C.J.F.; JENNIFER REIN, INDIVIDUALLY; and JESSICA BERG, AS PARENT OF MINORS A.B. and S.B., individually and on behalf of all others similarly situated,

By: */s/ Elizabeth A. Fegan*

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