UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

CIVIL ACTION NO.

M.P. and S.S., on behalf of themselves and all others similarly situated,

Plaintiffs,

vs. **JURY TRIAL DEMANDED**

ALLERGAN, Inc., f/k/a INAMED CORPORATION, ALLERGAN USA, Inc., and ALLERGAN PLC,

Defendants.
_____/

CLASS ACTION COMPLAINT

Plaintiffs M.P. and S.S.[1] bring this class action lawsuit against Defendants Allergan, Inc. f/k/a Inamed Corporation, Allergan USA, Inc., and Allergan plc (collectively, "Defendants" or "Allergan"), individually and on behalf of all others similarly situated (the "Class"), and allege as follows:

NATURE OF ACTION

1. Allergan manufactured, marketed, distributed, and sold Allergan BIOCELL© ("Biocell") saline-filled breast implants and tissue expanders since 2000 and silicone-filled breast implants and tissue expanders since 2006. These defective textured breast implants and tissue

[1] Due to privacy concerns, initials are being used instead of Plaintiffs' true names. Plaintiffs have chosen to proceed using a pseudonym at this stage because they each have a substantial privacy right in the personal medical information revealed herein, which "outweighs the customary and constitutionally-embedded presumption of openness in judicial proceedings." *Plaintiff B. v. Francis*, 631 F.3d 1310, 1315-16 (11th Cir. 2011) (citation and internal quotation marks omitted).

expanders are linked to a deadly cancer of the immune system, Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL").

2. The United States Food and Drug Administration ("FDA") recently requested that Allergan remove these defective implants, after determining that "use of these devices may cause serious injuries or death."[2]

3. In response to the FDA's request, on July 24, 2019, Allergan announced a worldwide recall of these defective implants and tissue expanders.[3]

4. Due to Allergan's manufacturing, marketing, distribution, and sale of these defective implant products and Allergan's failure to warn Plaintiffs of the risks related thereto, Plaintiffs purchased and underwent surgery to have the Allergan defective breast implants placed within their bodies and thus are now exposed to the severe and heightened risk of developing lymphoma.

5. Despite its knowledge and admission of the defect, Allergan is refusing to pay for the majority of its affected patients' surgical costs relating to the defective implant products.[4]

---

[2] *Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer*, U.S. FOOD & DRUG ADMIN. (Sept. 12, 2019), https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer.

[3] *FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market*, U.S. FOOD & DRUG ADMIN. (Jul. 24, 2019), https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan [hereinafter *FDA takes action to protect patients from risk of certain textured breast implants*].

[4] *See BIOCELL® Replacement Warranty*, ALLERGAN at 1-2, https://www.allergan.com/-/media/allergan/documents/us/Products/Biocell/BIOCELL-Replacement-Warranty.pdf (last visited Nov. 15, 2019) [hereinafter *BIOCELL® Replacement Warranty*]; *Natrelle ConfidencePlus Warranty Program*, NATRELLE at 2-4 (Sept. 2019), https://www.natrelle.com/Content/pdf/warranty_brochure.pdf [hereinafter *Natrelle ConfidencePlus Warranty Program*].

Allergan is also refusing to pay, in most cases, for the medical monitoring related to the significantly increased risk of BIA-ALCL.[5]

6. Allergan's unwarranted position leaves hundreds of thousands of patients in fear for their lives and with the heavy burden of covering fees for surgeries, diagnosis, treatment, and medical monitoring, most of which will not be covered by Allergan or their own insurance companies.

7. Accordingly, Plaintiffs bring this action individually and on behalf of others in the United States to seek relief for damages caused by Allergan's conduct.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). The proposed Class consists of thousands or more members. The amount in controversy exceeds $5 million, exclusive of interests and costs. Plaintiffs have a different citizenship from Defendants, and most putative class members also have different citizenship from Defendants.

9. This Court has jurisdiction over Defendants. Through their business activities, including their marketing, solicitation, advertising, distribution, and sale, Defendants have intentionally availed themselves of the customers and markets in Florida and in this District. Defendants have carried out business activities within this District that form the basis of this action, and Defendants have engaged in tortious conduct and caused damages to Plaintiffs and the Class, rendering the exercise of jurisdiction by this Court just and proper.

[5] *See Natrelle ConfidencePlus Warranty Program*, *supra* note 4, at 2-4. The warranty excludes coverage for patients that have removed their Biocell Natrelle textured breast implant products. *See id.* at 4. And although the warranty provides a limited monetary amount for diagnostic testing of BIA-ALCL, the patient must have also been already diagnosed with late seroma. *See id.* 2-4.

10. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) and (c)(2) because a substantial part of the events or omissions and/or misrepresentations giving rise to Plaintiffs' action occurred in this District. Among other things, Plaintiffs underwent surgeries involving the Allergan breast implants and tissue expanders that are the subject of this action in this District.

PARTIES

11. Plaintiff M.P is a citizen of the State of Florida, residing in Hillsborough County. Plaintiff M.P. was implanted with an Allergan Biocell product, NATRELLE® ("Natrelle") 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, Style FM, in part based on her consultation with her doctor and representations about the safety and efficacy of the Allergan breast implants. These Defective Implants[6] were part of Allergan's recall on July 24, 2019 (the "Recall"). Plaintiff M.P. incurred expenses related to that breast implant procedure.

12. When Plaintiff M.P. found out about the Recall, she was concerned about the danger associated with the Defective Implants and consulted with her doctors. In consultation with her doctors, Plaintiff M.P. decided to have the Defective Implants removed and is scheduled for surgery later this year.

13. Although Plaintiff M.P. may seek reimbursement from her insurance company, she will incur out-of-pocket costs associated with the surgical procedure as well as with the time she will take off work in order to recover from the procedure. Her insurance company will likely only cover part of the related costs and fees, if any.

14. According to the terms of Allergan's breast implant warranty, Allergan will not reimburse Plaintiff M.P. for any of the surgical fees relating to the removal of the defective implant

[6] The term "Defective Implants" refers to all recalled Allergan Biocell saline-filled or silicone-filled breast implants or tissue expanders. A list identifying the specific devices covered by Allergan's July 2019 recall are identified *infra* ¶ 126.

because she has not been diagnosed with BIA-ALCL.[7] And according to the terms of Allergan's breast implant warranty, Allergan will likely not cover any of the fees related to diagnostic testing before the implants are removed.[8] Thus, Plaintiff M.P. will be forced to cover most, if not all, of the surgical costs, diagnostic testing fees, medical monitoring, and other related costs and fees herself.

15. Plaintiff M.P. would not have had the Defective Implants implanted had she known prior to the procedure that these Defective Implants would subject her to the greater risk of contracting BIA-ALCL in addition to costs associated with removal, replacement, diagnosis, medical monitoring, treatment, and other related fees and procedures.

16. Plaintiff S.S. is a citizen of the State of Florida, residing in Hillsborough County. Following a bilateral mastectomy, on May 25, 2016, Plaintiff S.S. was implanted with an Allergan Biocell product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, Style FX, in part based on her consultation with her doctor and representations about the safety and efficacy of the Allergan breast implants. These Defective Implants were part of Allergan's Recall. Plaintiff S.S. incurred expenses related to that breast implant procedure.

17. When Plaintiff S.S. found out about the Recall, she was concerned about the danger associated with the Defective Implants and consulted with her doctors. Although Plaintiff S.S. desires to have the Defective Implants removed, her doctors have advised she is currently unable to have them removed due to the health complications she faces.

---

[7] *See BIOCELL® Replacement Warranty*, *supra* note 4, at 1-2; *Natrelle ConfidencePlus Warranty Program*, *supra* note 4, at 2-3.

[8] *See Natrelle ConfidencePlus Warranty Program*, *supra* note 4, at 2-3.

18. Although Plaintiff S.S. may seek reimbursement from her insurance company, she will incur out-of-pocket costs associated with the surgical procedure as well as with diagnostic testing and medical monitoring. Her insurance company will likely only cover part of the costs and fees related thereto, if any.

19. According to the terms of Allergan's breast implant warranty, Allergan will not reimburse Plaintiff S.S. for any surgical fees relating to the removal of the defective implant because she has not been diagnosed with BIA-ALCL.[9] And according to the terms of Allergan's breast implant warranty, Allergan will only cover a limited amount of the fees related to diagnostic testing, if any.[10] Thus, Plaintiff S.S. will be forced to cover most, if not all, of the surgical costs, diagnostic testing fees, and other related costs and fees herself.

20. Plaintiff S.S. would not have had the Defective Implants implanted had she known prior to the procedure that these Defective Implants would subject her to the greater risk of contracting BIA-ALCL in addition to costs associated with removal, replacement, diagnosis, medical monitoring, treatment, and other related fees and procedures.

21. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan plc also maintains administrative headquarters in New Jersey and California.

22. Allergan plc manufactured, marketed, distributed, and sold Biocell saline-filled and silicone-filled breast implants and tissue expanders, which are the subject of this action and have been recalled by Allergan plc.

---

[9] *Id.*

[10] *Id.*

23. Shares of Allergan plc are traded on the New York Stock Exchange (NYSE: AGN). In its most recent Form 10-K filed with the SEC, Allergan plc stated that it does business in the United States, through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which generated nearly 80% of the company's $15.8 billion in net revenue during the year ending on December 31, 2018.

24. Defendant Allergan Inc., f/k/a Inamed Corporation ("Inamed"), f/k/a McGhan Medical Corporation ("McGhan"), is a wholly owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business located at 5 Giralda Farms, Madison, New Jersey 07940.

25. Defendant Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business located at 5 Giralda Farms, Madison, New Jersey 07940.

26. Defendants Allergan plc, Allergan Inc., and Allergan USA, Inc. comprise a global pharmaceutical leader with a vast portfolio of medical and therapeutic products, including breast implants and tissue expanders. Defendants Allergan plc, Allergan Inc., and Allergan USA, Inc. acted jointly to manufacture, market, distribute, and sell Biocell products, including the Defective Implants, sharing knowledge regarding those products. At all relevant times, Defendants Allergan plc, Allergan Inc., and Allergan USA, Inc. acted as the agents and as the alter egos of each other. Accordingly, Defendants Allergan plc, Allergan Inc., and Allergan USA, Inc. are referred to collectively herein as "Allergan" or "Defendants."

FACTUAL ALLEGATIONS

A. The Nature of Breast Implants

27. Breast implants are medical prosthetic products implanted during a surgical procedure under an individual's breast tissue or under the chest muscle. Breast implants are used to augment or change the breast's size and/or shape in both cosmetic surgeries and in reconstruction surgeries following a mastectomy, a congenital abnormality, or other damage to the breast.

28. Breast implants are available in a variety of sizes and contain a silicone outer shell. "Silicone" refers to a group of polymers based on the element silicon. Silicone polymers may be produced in a variety of forms, including oil, gels, or elastomers (rubber). Breast implants are defined by their filler materials, which typically consist of one of three materials: either silicone gel, sterile saltwater ("saline"), or a composite filler.

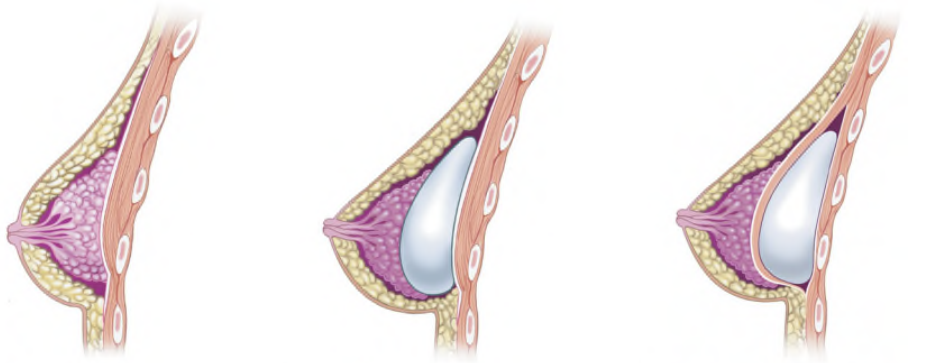
29. The breast implant's outer shell can be smooth or textured. A textured implant has a slightly roughened surface, which provides increased friction between the implant and its surroundings, such as the tissue.

30. Allergan uses the Natrelle brand for its textured breast implants. Biocell is the name of the outer shell of Allergan's textured breast implants.

31. Breast implant and tissue expander manufacturers utilize various and, at times proprietary, techniques to texture the surface of their breast implant products. Allergan utilizes the "lost-salt" technique to create its Biocell implants and tissue expanders, *i.e.*, the Defective Implants. Allergan creates the Biocell shell by dipping the implant into uncured silicone. Before the surface of the implant dries, it is pressed into a bed of fine, granular salt and then cured in a laminar flow oven to create an irregular pattern of surface pores.

32. Allergan designed and marketed its Biocell textured shell with a rough surface to which tissue can adhere, keeping the breast implants and tissue expanders in position once inserted into the body. Allergan designed its Biocell textured shell to produce overhangs at the opening of the surface pores to promote greater tissue adherence. This is in contrast to smooth shells on breast implants and tissue expanders, which may move around and thus may increase the risk of rotation, displacement, or unwanted shifting.

33. In a cosmetic breast surgery, the breast implant is placed either on top of the muscle and under the breast gland (referred to as "subglandular" augmentation) or is placed partially under the pectoralis major muscle (referred to as "submuscular" augmentation). The different placements are depicted in the images below.

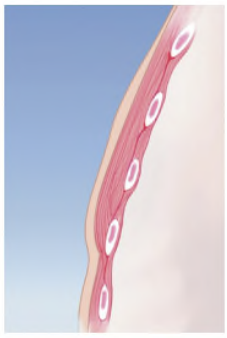


11

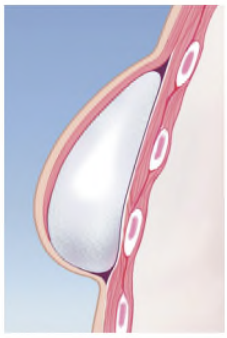
34. Breast reconstruction surgeries using breast implants are typically performed in one of two ways. Immediate breast reconstruction can be performed at the time of the mastectomy with the general surgeon removing the breast tissue and inserting a breast implant.

[11] *See Making an Informed Decision: Breast Surgery with NATRELLE® Saline-Filled Breast Implants*, ALLERGAN at 33, https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/labeling/natrelleus/salineimplants/m711rev10_web.pdf (last visited Nov. 15, 2019).

35. Typically, breast reconstructions are performed as a staged procedure following a mastectomy. The first stage begins with the placement of a breast tissue expander. The tissue expander is a balloon-like device composed of elastic silicone rubber, inserted unfilled, and gradually filled with sterile saline fluid. The tissue expander helps to create a breast shaped space for the breast implant. The tissue expander may be placed at the time of the mastectomy or the placement of the tissue expander may be delayed until months or years later. The image below depicts the tissue expander placement.



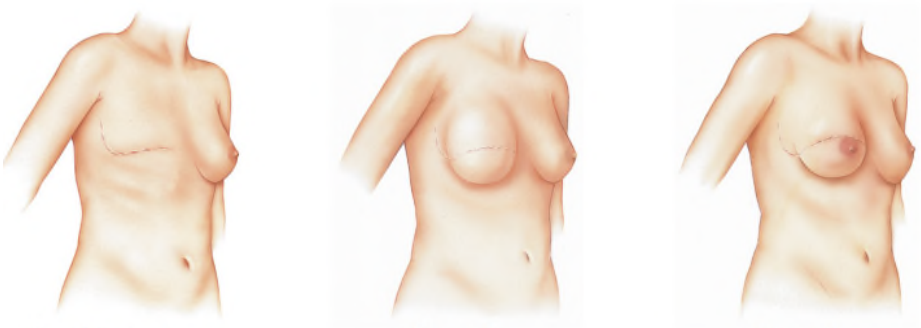
Side View, Breast Tissue Removed



Side View, Expander Inserted and Filled [12]

36. The second breast reconstruction stage involves removing the tissue expander, which should not be used longer than a period of six months. During this stage, the tissue expander is exchanged with a breast implant. The image below depicts the different stages using the tissue expander and the breast implant.

[12] *Id*. at 41.



[13]

37. Breast implant procedures are commonplace with millions of American having breast implants. Indeed, there are over 300,000 cosmetic breast surgeries and over 100,000 breast reconstruction surgeries per year in the United States alone.

38. From 2000 through 2016, breast augmentations in the United States increased by 37% and breast reconstructions after mastectomy increased by 39%.

B. <u>BIA-ALCL</u>

39. BIA-ALCL is a type of non-Hodgkin's lymphoma, cancer of the immune system.

40. Specifically, when the Defective Implants are surgically placed in a patient's body, the textured surface disrupts the body's normal healing process by what was thought and marketed as resulting in scar tissue that was less firm than that produced by the smooth-walled implants. This was thought to be due to a textured implant's slightly roughened surface, which provides increased friction between the implant and its surrounding, such as the breast tissue. Thus, Allergan claimed the textured surface aided to hold the breast implant in position.

41. Instead, it is now believed that the Defective Implants' textured surface creates an implant-induced chronic inflammation, which results in injury to the structure of cells in and

[13] *Id*. at 42.

around the Defective Implants.[14] It is believed that chronic infection and/or implant toxins related to the breast implants are related to BIA-ALCL.[15]

42. Due to the use of the Defective Implants, Plaintiffs and Class members have sustained this serious cellular damage to their bodies. Consequently, a currently unknown number of such Class members will develop BIA-ALCL in the future due to this physical damage and neoplastic transformation.

43. BIA-ALCL's main symptoms include persistent swelling in the breasts, presence of a mass or lumps around the breast implant products, asymmetry around the breast implant products, and pain in the area of the breast implant products. Following a healthcare provider's evaluation, evidence of fluid collection around the breast implant product ("seroma") is often observed. Some BIA-ALCL patients have reported the presence of lumps under the skin and/or thick and noticeable scar capsules around the breast implant products ("capsular contracture").

44. According to the FDA:

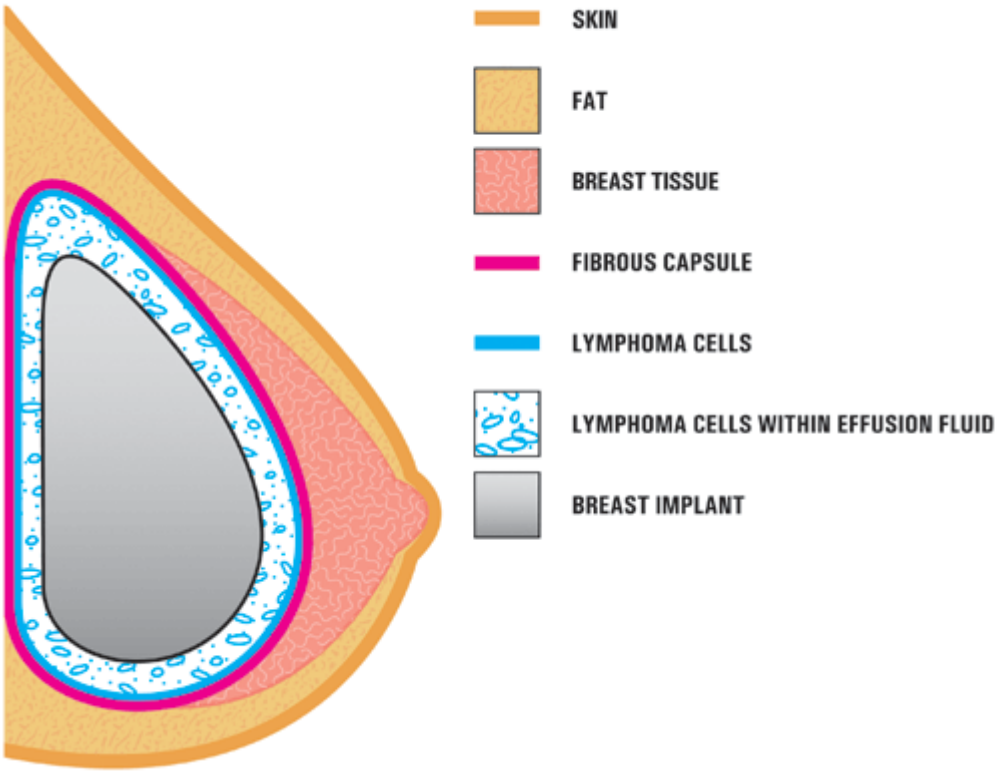
> In the case studies reported in the literature, BIA-ALCL is usually found near the breast implant, contained within the fibrous scar capsule, and not in the breast tissue itself. The illustration below shows the location of the ALCL in these reports. In most cases, the ALCL cells were found in the fluid surrounding the implant (seroma) or contained within the fibrous scar capsule.[16]

---

[14] George EV, Pharm J, Houston C, *et al.*, *Breast Implant-Associated ALK-Negative Anaplastic Large Cell Lymphoma: A Case Report and Discussion of Possible Pathogenesis,* 6 INT. J. CLIN. EXP. PATHOL. 1631–42 (2013) [hereinafter *Breast Implant-Associated ALK-Negative Anaplastic Large Cell Lymphoma*]; Bizjak M, Selmi C, Praprotnik S, *et al.*, *Silicone Implants and Lymphoma: The Role of Inflammation*, 65 J. AUTOIMMUN. 64–73 (2015) [hereinafter *Silicone Implants and Lymphoma: The Role of Inflammation*].

[15] Florian Fitzal, Suzanna D. Turner, & Lukas Kenner, *Is Breast Implant-Associated Anaplastic Large Cell Lymphoma a Hazard of Breast Implant Surgery?*, PUBMED CENT. (Apr. 3, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6501645/.

[16] *Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2019), https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl (citing Thompson *et al.*, *Effusion-Associated Anaplastic Large Cell*



17

45. Even if an individual's risk of developing BIA-ALCL is considered low, this cancer is serious and can lead to death, particularly if not treated promptly.

46. Although in the majority of cases, BIA-ALCL is found in the scar tissue and fluid near the breast implants, in some cases, BIA-ALCL can spread throughout the body.

47. BIA-ALCL may be treated with capsulectomy, or surgery to remove the breast implant and surrounding scar tissue and/or capsule that has thickened and hardened around the breast implant. But in some patients, treatment of BIA-ALCL may also require chemotherapy and radiation treatment.

Lymphoma of the Breast: Time for it to be Defined as a Distinct Clinico-Pathological Entity, HEMATOLOGICA (Nov. 2010), http://www.haematologica.org/content/95/11/1977.full).

[17] *Id.*

48. The recommended diagnostic testing for BIA-ALCL is invasive and rigorous. On February 6, 2019, the FDA provided several recommendations to healthcare providers, including:

> Collect fresh seroma fluid and representative portions of the capsule and send for pathology tests to rule out BIA-ALCL. Diagnostic evaluation should include cytological evaluation of seroma fluid or mass with Wright Giemsa stained smears and cell block immunohistochemistry/flow cytometry testing for cluster of differentiation (CD30) and Anaplastic Lymphoma Kinase (ALK) markets.[18]

49. The symptoms of BIA-ALCL may occur well after the surgical incision has healed, often years after the breast implant placement.

C. Allergan's Defective Breast Implants and Tissue Expanders

50. In 2011, a summary of published reports, evidence, and studies was published that identified 27 cases of ALCL. Notably, the summary concluded that there was a connection between ALCL and breast implants.

51. In January 2011, the FDA released a report on BIA-ALCL, listing as its main conclusion that: "[b]ased on the published case studies and epidemiological research, the FDA believes that there is a possible association between breast implants and ALCL."[19] In addition, the FDA noted that although it was not prepared to associate BIA-ALCL with a certain type of breast implant, "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."[20]

---

[18] *Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL) – Letter to Healthcare Providers*, U.S. FOOD & DRUG ADMIN. (Jul. 24, 2019), https://www.fda.gov/medical-devices/letters-health-care-providers/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl-letter-health-care-providers [hereinafter *Breast Implant Associated-Anaplastic Large Cell Lymphoma*].

[19] *ALCL & Breast Implants: Preliminary FDA Findings*, IMPLANTINFO (Jan. 2011), http://www.implantinfo.com/media/news/alcl-and-breast-implants-preliminary-fda-findings.aspx.

[20] *Id.*

52. In March 2015, an analysis identified 173 cases of ALCL.

53. Also, in March 2015, the French National Cancer Institute announced, "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant."

54. On May 19, 2016, the World Health Organization ("WHO") provided the disease with the official designation of "BIA-ALCL." The WHO classified BIA-ALCL as a distinct clinical entity, separate from other categories of ALCL.

55. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to discuss the connection between ALCL and breast implants as well as to provide ongoing advice.

56. On March 21, 2017, the FDA released an Updated Safety Alert, a safety communication pertaining to the nature of BIA-ALCL. In that safety communication, the FDA recognized the WHO's designation that BIA-ALCL can occur after a patient receives breast implants. The FDA also stated: "At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."[21]

57. In May 2017, a global analysis of approximately 40 governmental databases identified 363 cases of BIA-ALCL. Of those 363 cases, 258 were reported to the FDA.

58. In September 2017, the FDA reported that it had received a total of 414 Medical Device Reports ("MDRs")[22] associated with ALCL and breast implants, including nine deaths.

---

[21] *FDA update on rare breast implant-associated type of lymphoma,* APHA PHARMACISTS PROVIDER CARE (Mar. 22, 2017), https://pharmacistsprovidecare.com/article/fda-update-rare-breast-implant-associated-type-lymphoma.

[22] The term MDR is used herein to refer both to Medical Device Reports as well as Medical Device Reporting.

59. On May 9, 2018, Australia's TGA reported 72 cases of ALCL in Australia.

60. On March 21, 2018, the FDA released another warning stating that it was aware of 414 total cases of BIA-ALCL. Still, Allergan continued to manufacture and sell the defective breast implants and tissue expanders.

61. In December 2018, Allergan textured breast implants lost their European certification and subsequently were suspended from the European and Brazilian markets.

62. In February 2019, the FDA sent a letter to healthcare providers across the United States warning them about the link between textured breast implants and BIA-ALCL. The FDA noted that there has been "[a] significant body of medical literature [that] has been published since the FDA's 2011 report on BIA-ALCL" and "the majority of patients who develop BIA-ALCL have had textured implants."[23]

63. The natural occurrence of ALCL is 1/300,000. Nonetheless, the FDA recently cited to studies placing the estimated current risk of BIA-ALCL in women with textured implants to be between 1/3,817 and 1/30,000. These risks are consistent with the ones reported in Europe. In December 2016, the Australia TGA reported a risk of BIA-ALCL in women with textured implants to be between approximately 1/1,000 to 1/10,000.

D. Allergan Failed to Disclose to its Patients The Known Risks of its Defective Breast Implants and Tissue Expanders

64. In 1976, the Federal Food, Drug, and Cosmetic Act ("FDCA") was amended by Congress with the passage of the Medical Device Amendments ("MDA"). Upon enacting the MDA, the FDA designated saline-filled breast implants as Class II devices. During a premarket notification process, the implants could be publicly sold so long as manufacturers subsequently

[23] *Breast Implant Associated-Anaplastic Large Cell Lymphoma*, *supra* note 18.

provided "reasonable assurance" of the implants' safety and effectiveness. *See* 21 U.S.C. § 360e(d)(2).

65. In 1988, in response to increased safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices requiring premarket approval ("PMA").

66. In April 1991, upon final publication of new regulations, the FDA began requiring manufacturers of breast implants to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants.

67. Through its PMA process, the FDA engages in scientific evaluations of the safety and effectiveness of Class III medical devices. The FDA considers Class III devices to create the greatest risk to human safety. These Class III devices require the implementation of special controls, such as the requirement to obtain PMA pursuant to 21 U.S.C. § 360 prior to marketing the product to the public.

68. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement Application must provide specific types of information, specifically:

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

d. Summary of studies, including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk;

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

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

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

69. In January 1992, because of safety and efficacy concerns, the FDA announced a voluntary moratorium on silicone gel-filled breast implants. The FDA requested manufacturers stop supplying those implants and requested surgeons stop implanting them while the FDA engaged in a further review of those breast implant devices.

70. In April 1992, the FDA entered into an agreement with McGhan setting forth the requirements for McGhan to conduct and submit data for their clinical trials of the silicone breast implant devices for use in breast reconstruction patients.

71. In March 1998, the FDA approved McGhan's study protocol. This allowed McGhan to begin enrolling patients in the study, which was referred to as the "Adjunct Study" and involved breast reconstruction patients. McGhan was to take all reasonable steps to ensure that it received informed consent from all patients before implantation of any device on a form consistent with that which had previously been approved by the FDA, and McGhan was to make sure all product labeling was consistent with the agreement and the terms of the approved protocols.

72. Also, in 1998, the FDA approved McGhan's investigational device exemption ("IDE") for use of the same devices for breast augmentation. This study was referred to as the "CORE" study, which involved breast reconstruction, revision-augmentation, and revision-reconstruction patients. McGhan was to take all reasonable steps to ensure that it received informed consent from all patients before implantation of any device on a form consistent with that which had previously been approved by the FDA, and McGhan was to ensure that all product

labeling was consistent with the agreement and the terms of the approved protocols. Patient follow-up was to be at 0-4 weeks, 6 months, 12 months, 24 months, and annually through 10 years.

73. As the Adjunct and CORE studies progressed, the FDA continued its oversight and considered material submitted about these studies by McGhan each year.

74. In late 1999 through early 2000, the Advisory Panel on General and Plastic Surgery reviewed implants PMAs. This panel met in open session on March 1-3, 2000, where the general consensus was that patient labelling should include as much information as possible to address all possible risks and complications with information on expected outcomes and that the information should be focused on product-specific data.

75. On May 10, 2000, the FDA announced that it had approved McGhan's PMA for Biocell textured shell surfaced saline-filled breast implants for augmentation in women aged 18 and older and for reconstruction in women of any age application, including Styles 163, 168, 363 and 468.

76. As a condition of McGhan's PMA, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, McGhan was required to submit written report information concerning any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that was attributable to the device and (a) had not been addressed by the devices' labelling or (b) had been addressed by the device's labeling, but occurred with unexpected severity or frequency.[24]

77. According to the approval order, McGhan was required to report to the FDA information from any source that reasonably suggests that a device marketed by the Defendant may have caused or contributed to a death or serious injury; or has malfunctioned and such device

[24] 21 C.F.R. § 814.82(a)(9) (2019).

or similar device marketed by the manufacturer or importer would likely cause or contribute to the death or serious injury if the malfunction were to reoccur.[25]

78. In January 2002, McGhan, who at that time was now known as Inamed, submitted to the FDA the first PMA for their silicone gel-filled breast implants.

79. On March 23, 2006, Allergan, Inc. completed its acquisition of Inamed, which expanded Allergan's global position as a premier specialty medical device company in high-growth markets such as the breast implant market.

80. On November 17, 2006, the FDA granted premarket approval of Allergan's Natrelle Silicone Gel-Filled Breast Implants, classifying the breast implants as Class III medical devices.[26] FDA granted the premarket approval based on Allergan's clinical studies. These studies claimed to have followed hundreds of women with silicone gel-filled breast implants throughout four years.

81. In February 2013, the FDA granted premarket approval of Allergan's Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.[27]

82. As conditions of the FDA's 2006 and 2013 approvals, the FDA required Allergan to perform six post-approval studies to characterize the long-term safety and performance of its implants.[28] Those required post-approval studies included:

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

[25] *See* PMA P990074 Approval Order.

[26] *See* PMA P020056 Approval Order.

[27] *See* PMA P040046 Approval Order.

[28] *See* PMA P020056 Approval Order; PMA P040046 Approval Order; *see also FDA Update on the Safety of Silicone Gel-Filled Breast Implants*, U.S. FOOD & DRUG ADMIN. at 7 (Jun. 2011), https://www.fda.gov/media/80685/download.

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

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

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

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

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

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

83. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to any medical device, including Allergan's Biocell breast implants, rests with the PMA applicant manufacturer, *i.e.*, Allergan.

84. The PMAs provided: "Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

E. <u>The FDA's 510(k) Clearance Protocols for Allergan's Biocell's Tissue Expanders</u>

85. Biocell tissue expanders do not pass through the premarket approval (PMA) process. Instead, they are "cleared" through the 510(k) process. A 510(k) application is a premarket notification made to the FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device.[29]

[29] 21 C.F.R. § 807.92(a)(3) (2019).

86. The 510(k)- clearance process does not independently assess the device for safety or effectiveness. Rather, the manufacturer is required only to demonstrate that the device is as safe and effective as (*i.e.*, "substantially equivalent" to) a predicate 510(k) device, which itself need only have shown that it was as safe and effective as another predicate device, etc. Accordingly, a device that is both unsafe and ineffective can obtain 510(k) so long as it is "as safe and effective" as a predicate device that was "as safe and effective" as another predicate device, and so on. Often the original or "root" predicate device that these copies of copies of copies are predicated upon is itself a device that pre-dated the 1976 Medical Device Amendments to the FFDCA and thus would not have been required to demonstrate safety or effectiveness, meaning that no device in the chain of predicates was ever determined to be safe and effective.

87. On January 5, 2011, Allergan's Natrelle 133 Tissue Expander with Suture Tabs—constructed from silicone elastomer and consisting of an expansion envelope with a Biocell texture surface—received 510(k) clearance by the FDA and was classified as a Class II device subject to special controls found at 21 C.F.R. § 878.3600.[30] The device was deemed substantially equivalent to the existing Natrelle Style 133 Series Tissue Expander Matrix, itself a 510(k) device that was recalled in July 2019.[31]

88. On August 20, 2015, Allergan's Natrelle 133 Plus Tissue Expander received 510(k) clearance by the FDA as an unclassified device.[32] The device was deemed substantially equivalent to the Mentor CPX 4 Breast Tissue Expander and CPX 4 Breast Tissue Expander with Suture

[30] *See* 73 Fed. Reg. 78242 (Dec. 22, 2008); K102806 Clearance Letter.

[31] *See* K862203 Clearance Letter.

[32] *See* K143354 Clearance Letter.

Tabs, which are themselves 510(k) devices,[33] predicated on a previous Mentor 510(k) device that was cleared in 2001.[34]

89. 510(k) clearance for the Defendants' devices[35] requires Allergan to comply with the labeling and medical device reporting requirements of the United States Federal Food, Drug, and Cosmetic Act ("FFDCA").[36]

90. Upon receipt of premarket approval, Class III device manufacturers are subject to a continuous obligation to comply with MDR pursuant to 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a), most notably being required to report adverse events to the FDA.

91. The MDR regulation (21 C.F.R. § 803) includes strict mandatory requirements for manufacturers to monitor and report to the FDA particular adverse events and issues that are related to their devices.[37] Specifically:

> Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.[38]

[33] *See* K130813 Clearance Letter.

[34] *See* K011500 Clearance Letter.

[35] *See* K102806 Clearance Letter; K143354 Clearance Letter.

[36] 21 C.F.R. §§ 801, 803 (2019).

[37] *Medical Device Reporting (MDR): How to Report Medical Device Problems*, U.S. FOOD & DRUG ADMIN. (Jul. 8, 2019), https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems [hereinafter *How to Report Medical Device Problems*].

[38] *Id*.

This is required of any information that is "reasonably known" to the manufacturer, which includes: "[a]ny information that [the manufacturer] can obtain by contacting a user facility, importer, or other initial report;" "[a]ny information in [the manufacturer's] possession;" and "[a]ny information that [the manufacturer] can obtain by analysis, testing, or other evaluations of the device."[39]

92. According to the FDA, "Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products."[40]

93. "The Manufacturer and User Facility Device Experience (MAUDE) database contains mandatory reports filed by manufacturers and importers from August 1996 to present, all mandatory user facility reports from 1991 to present, and voluntary reports filed after June 1993."[41] The MAUDE database "houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers."[42]

94. From the date of the FDA's approval on November 17, 2006 through December 31, 2010, the FDA received 133 individual MDRs related to silicone gel-filled breast implants manufactured by Allergan or Mentor, another breast implant manufacturer. The manufacturers submitted only 24 of those reports, with user facilities submitting 25 of the reports and the remaining 84 reports consisting of voluntary reports.

---

[39] 21 C.F.R. § 803.50 (2019).

[40] *How to Report Medical Device Problems*, *supra* note 37.

[41] *Id.*

[42] *Id.*

95. To conceal the true number of adverse event reports, instead of using its own name, Allergan used incorrect manufacturer names, such as "Costa Rica" and "Santa Barbara," to report the required adverse event reports.[43]

96. Due to Allergan's fraudulent and intentional conduct, Allergan's consumers, healthcare professionals, and the FDA were unable to detect trends in Allergan's breast implant products. This deprived the market of crucial, material information to make an informed decision as to the safety and efficacy of Allergan's breast implant products.

97. Up through 2017, Allergan's practice was to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure."[44] Allergan achieved this through Alternative Summary Reports ("ASRs").

98. Prior to 2017, instead of filing an adverse event report for each individual adverse report, Allergan filed ASRs for various adverse event reports at one time. The ASRs required less detail than the individual adverse reports. Notably, the ASRs were previously not available to the public through the MAUDE database.

---

[43] *See, e.g.*, *Maude Adverse Event Report: Allergan (Costa Rica) Style 168 Saline Filled Breast Implant Prosthesis, Breast, Inflatable, Internal, Saline*, U.S. FOOD & DRUG ADMIN. (Oct. 31, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 [hereinafter *Maude Adverse Event Report*].

[44] Sasha Chavkin, *Breast Implant Injuries Kept Hidden as New Health Threats Surface*, INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (Nov. 26, 2018), https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/.

99. "In 2017, the FDA began to sunset the ASR Program and requiring manufacturers with ASR exemptions to submit, in addition to the spreadsheet, a companion report that includes the total number of events being summarized."[45]

100. Before 2017, there were approximately less than 200 breast implant adverse events reported each year. In 2017, with the revised FDA requirements, there were 4,567 breast implant adverse events reported that year. That number continued to rise at a staggering rate, with 8,242 breast implant adverse events reported in the first half of 2018 alone.

101. On June 21, 2019, the FDA announced that "[i]n the spirit of promoting public transparency, the FDA is making Alternative Summary Reporting (ASR) data available to the public on the MDR Data Files Page. These data files include ASRs submitted to the FDA between 1999 and April 2019."[46] "The companion reports [required after 2017 to accompany ASRs] are available in the public MAUDE database and represent a subset of the events in the ASR spreadsheets posted on the MDR Data Files Page."[47]

102. As of the date of this Complaint, a search performed on the MAUDE database identified approximately 397 BIA-ALCL cases and approximately 1,700 injury reports.

103. Due to Allergan's improper reporting practices, consumers and healthcare professionals relying on public information, such as these reports, were unable to properly assess the safety of Allergan's breast implants.

---

[45] *How to Report Medical Device Problems, supra* note 37.

[46] *Id.*

[47] *Id.*

104. Indeed, Allergan reported a case of possible BIA-ALCL through a non-public ASR.[48]

105. Pursuant to state laws, including Florida law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

106. Monitoring and reporting adverse events is extremely time sensitive. This is particularly true for those events for which both federal regulations and Florida law require reports, such as those events suggesting a connection between a medical device and breast cancer, ALCL, and/or BIA-ALCL.

107. Contrary to its requirements under federal and state law, Allergan failed to report adverse events from the post-market approval studies required as part of Allergan's breast implants' PMA approval. These unreported events would have led to reports indicating the breast implants' connection to serious injury and/or death. It is a logical conclusion that information in adverse reports and other communications to the FDA pertaining to adverse events linked to serious injury or death would reach the users of those medical devices and the healthcare professionals involved with implanting them.

108. Had Allergan not intentionally and recklessly disregarded its duty to adequately warn about all adverse events of which Allergan became aware or should have become aware as well as its duty to identify, monitor, and report all adverse events and all risks associated with the Defective Implants, Plaintiffs and the Class would have decided against implantation of the Defective Implants.

[48] *Maude Adverse Event Report, supra* note 43 ("[A] possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl), a type of nonhodgkin[']s lymphoma.").

109. Under applicable state law,[49] Allergan had a duty to exercise reasonable care in adequately warning Plaintiffs, Class members, and/or health care professionals—including the medical professionals performing cosmetic surgeries and reconstruction surgeries using breast implants and/or tissue expanders—about the dangers and risks of the Defective Implants. Furthermore, Allergan had a duty to exercise reasonable care in adequately warning those same individuals about all adverse events of which Allergan became aware or should have become aware as well as a post-market duty to identify, monitor, and report all adverse events and all risks associated with the Defective Implants.

110. Despite having knowledge and possession of evidence evidencing the use of the Defective Implants was dangerous and likely to place consumers' health at serious risk, Allergan refused or recklessly failed to monitor, identify, disclose, and warn of the health hazards and risks associated with its Defective Implants. Likewise, Allergan refused or recklessly failed to monitor, identify, disclose, and warn of all adverse events that were known or should have been known to Allergan.

111. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was permitted to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" to "reflect newly acquired information."[50]

112. From the dates of the design and manufacturing of the Defective Implants and through the present, Allergan continually acquired new information regarding the strong

[49] State law does not impose duties or requirements materially different from those duties or requirements imposed by federal law.

[50] 21 C.F.R. § 814.39(d)(1)-(2) (2019).

connection between the development of BIA-ALCL and its Defective Implants, which was significantly higher than that with any other textured breast implants and with other breast implants in general.

113. Based on the newly acquired information, Allergan had the right to unilaterally make changes to the Directions For Use ("DFU") for its Defective Implants to add or strengthen the warnings about the connection between those implants and the development of BIA-ALCL.

114. Instead of exercising its right to unilaterally strengthen the information about the link between its implants and BIA-ALCL, Allergan instead actively concealed its acquired knowledge of the causal link by manipulating adverse event reports and other public disclosures, as discussed at length above.

115. Allergan had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its Defective Implants. Instead, Allergan refused, intentionally and recklessly failing to revise its product labeling.

116. Allergan was required at all material times to promptly report any information suggesting that any one of its products may have contributed to a serious injury, or had malfunctioned, and the malfunction would be likely to contribute to a serious injury if it were to recur.

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

118. Each of the above-cited deficiencies in Allergan's post-market compliance constituted a "failure to comply with any post-approval requirement" and each constituted a

ground for withdrawal of the PMA. Defendants' conduct violated Defendants' duties under the law.

119. Regardless of Allergan's intentional and reckless failures to comply with post-approval requirement, including those failures discussed above, Allergan continued to commercially distribute its Defective Implants. As expressly stated in the PMA, Allergan's distribution thereof was a violation of federal law.

120. Had Allergan substantially complied with the PMA, rather than flagrantly, recklessly, and intentionally underperforming and/or disregarding the post-approval requirements, as discussed above, Allergan's disclosures would have led to increased knowledge, including public knowledge, of the dangers and risks connected to Allergan's Defective Implants. Furthermore, Allergan's physician and patient labeling would have significantly changed over time, and patients, including Plaintiffs and the Class, and healthcare professionals, including Plaintiffs' breast implant surgery physicians, would not have purchased or implanted Allergan's Defective Implants.

F. <u>The Allergan Recall and the Allergan Warranties</u>

121. At all times relevant, and pursuant to 21 C.F.R. § 7.40(a), a PMA applicant manufacturer may voluntarily recall its product to carry out its responsibility to protect the public health and well-being from products that present a risk of injury or gross deception.

122. On July 24, 2019, the FDA requested the recall of a specific type of textured breast implant products manufactured by Allergan due to the risk of BIA-ALCL.[51] According to the FDA, using Allergan's textured breast implants causes a risk of BIA-ALCL six times higher than

[51] *FDA takes action to protect patients from risk of certain textured breast implants*, *supra* note 3.

using other manufacturers' textured breast implants.[52] The principal FDA deputy commissioner, Dr. Amy Abernethy, announced:

> The FDA has been diligently monitoring this issue since we first identified the possible association between breast implants and ALCL in 2011 and, at that time, communicated to patients and providers that there is a risk for women with breast implants, more frequently occurring in women with textured implants, for developing this disease. Since that time, we have worked to increase awareness and encourage reporting of all cases to the FDA so that we could continue to monitor this potential safety signal. As this issue and the science have continued to develop, we have been monitoring the reports in databases, including external patient registries, and in scientific literature.[53]

123. Dr. Abernethy further stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health."[54] Dr. Abernethy added: "Once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."[55]

124. In that July 2019 press release, the FDA announced that Biocell breast implants and tissue expanders were attributed with an increase in reported cases of BIA-ALCL—573 cases of BIA-ALCL throughout the world, including 33 deaths. Of those 573 known cases of BIA-ALCL, approximately 84% (or 481 cases) were associated with Allergan products. Of those 33 known cases of deaths caused by BIA-ALCL, 12 of the 13 patients for whom the breast implant manufacturer was known were confirmed to have an Allergan breast implant at the time of the BIA-ALCL diagnosis. These incidents were a "significant increase" from the FDA's prior update earlier in 2019, evidencing a rise of 116 new BIA-ALCL cases, including 24 deaths.

---

[52] *Id*.

[53] *Id*.

[54] *Id.*

[55] *Id*.

125. In response, also on July 24, 2019, Allergan issued its global Recall covering its Biocell textured breast implants and tissue expanders. In its July 24, 2019, press release, Allergan explained that its Defective Implants would "no longer be distributed or sold in any market where they are currently available" and requested that "[e]ffective immediately, healthcare providers should no longer implant [the Defective Implants] and unused products should be returned to Allergan."[56]

126. The below chart identifies the breast implant and tissue expanders included in that Recall:

> **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:
>
> - Style 163 – Biocell Textured Shaped Full Height, Full Projection Saline Breast Implants
> - Style 168 – Biocell Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
> - Style 363 – Biocell Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
> - Style 468 – Biocell Textured Shaped Full Height Moderate Projection Saline Breast Implants
>
> **Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:
>
> - Style 110 – Biocell Textured Round Moderate Projection Gel Filled Breast Implants
> - Style 115 – Biocell Textured Round Midrange Projection Gel Filled Breast Implants
> - Style 120 – Biocell Textured Round High Projection Gel Filled Breast Implants

[56] *Company Announcement: Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders*, U.S. FOOD & DRUG ADMIN. (Jul. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergan-voluntarily-recalls-biocellr-textured-breast-implants-and-tissue-expanders [hereinafter *Allergan Company Announcement*].

- Style TRL – Natrelle Inspira Biocell Textured Responsive Silicone-Filled Breast Implants
- Style TRLP – Natrelle Inspira Biocell Textured Responsive Silicone-Filled Breast Implants
- Style TRM – Natrelle Inspira Biocell Textured Responsive Silicone-Filled Breast Implants
- Style TRF – Natrelle Inspira Biocell Textured Responsive Silicone-Filled Breast Implants
- Style TRX – Natrelle Inspira Biocell Textured Responsive Silicone-Filled Breast Implants
- Style TCL – Natrelle Inspira Biocell Textured Cohesive Silicone-Filled Breast Implants
- Style TCLP – Natrelle Inspira Biocell Textured Cohesive Silicone-Filled Breast Implants
- Style TCM – Natrelle Inspira Biocell Textured Cohesive Silicone-Filled Breast Implants
- Style TCF – Natrelle Inspira Biocell Textured Cohesive Silicone-Filled Breast Implants
- Style TCX – Natrelle Inspira Biocell Textured Cohesive Silicone-Filled Breast Implants
- Style TSL – Natrelle Biocell Textured Soft Touch Silicone-Filled Breast Implants
- Style TSLP – Natrelle Biocell Textured Soft Touch Silicone-Filled Breast Implants
- Style TSM – Natrelle Biocell Textured Soft Touch Silicone-Filled Breast Implants
- Style TSF – Natrelle Biocell Textured Soft Touch Silicone-Filled Breast Implants
- Style TSX – Natrelle Biocell Textured Soft Touch Silicone-Filled Breast Implants

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046. The following are the textured styles:

- Style 410 FM
- Style 410 FF
- Style 410 MM
- Style 410 MF
- Style 410 FL
- Style 410 ML
- Style 410 LL
- Style 410 LM
- Style 410 LF
- Style 410 FX
- Style 410 MX

- Style 410 LX

Allergan Natrelle Dual-Gel styles LX, MX, and FX.

Allergan Natrelle Komuro breast implants styles KML, KMM, KLL, and KLM.

Allergan Natrelle Ritz Princess breast implants styles RML, RMM, RFL, and RFM.

Allergan Natrelle 150 Full Height and Short Height double lumen implants.

Allergan tissue expanders for the breast that have Biocell texturing originally cleared as:

- Natrelle 133 Plus Tissue Expander (K143354)
- Natrelle 133 Tissue Expander with Suture Tabs (K102806)

[57]

127. On July 30, 2019, the Senior Vice President of Allergan plc's U.S. Medical Aesthetics sent the below letter to Allergan's plastic surgery customers:

[57] *See The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication*, U.S. FOOD & DRUG ADMIN. (Aug. 7, 2019), https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue#list; *The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication*, U.S. FOOD & DRUG ADMIN. (Jul. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/allergan-voluntarily-recalls-biocellr-textured-breast-implants-and-tissue-expanders.

July 30, 2019

Dear Allergan Plastic Surgery Customer,

In follow-up to Allergan's voluntary recall of unused BIOCELL® products, we created the **BIOCELL® Replacement Warranty** for all patients currently implanted with BIOCELL® textured implants.

For patients in the U.S. who, as a result of the recall announcement on July 24, 2019, choose to replace their BIOCELL® textured devices with smooth devices in consultation with their plastic surgeon, Allergan will provide Allergan smooth device replacements for free. The program will run for 24 months, until July 24, 2021, and will apply to revision surgeries on or after the date of the recall announcement, July 24, 2019.

The decision to get a breast implant revision is a personal decision between patients and their plastic surgeons, and must be decided based on the appropriate discussion of benefits and risks. **As part of this program, Allergan will not provide surgical fee assistance to revision patients.** This decision is in-line with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL") due to the low risk of developing BIA-ALCL. Patients who decide to keep their BIOCELL® textured devices will continue to be covered under the NATRELLE® ConfidencePlus® warranty, which includes reimbursement for up to $1,000 in diagnostic fees and up to $7,500 in surgical fees related to diagnosing and treating BIA-ALCL.

Some frequently asked questions about this policy are attached. You may initiate a replacement request under the BIOCELL® Replacement Warranty by talking with your Allergan Plastic Surgery Sales representative or by contacting the Allergan Product Surveillance team prior to surgery at 1-800-624-4261.

Sincerely,

Carrie Strom

Carrie Strom

Senior Vice President, U.S. Medical Aesthetics

Allergan plc

58

[58] *Letter to Allergan Plastic Surgery Customers*, ALLERGAN (Jul. 30, 2019), https://www.drteitelbaum.com/breast/breast-augmentation-revision/breast-implant-

128. Allergan has admitted to the defective and dangerous nature of its Defective Implants, recognizing, in relevant part, that there was "global safety information" about the increased risk of cancer associated with its Defective Implants.[59]

129. But despite its knowledge and admission of the defect, Allergan has left its affected patients with a pitiful choice. Allergan will provide its affected patients a free Allergan smooth implant product to be used as a replacement for the current Defective Implants where Allergan would cover the cost of the new implant product itself but will not cover any related surgical fees.[60] To those patients who qualified under certain events, such as a BIA-ALCL diagnosis, Allergan may provide a minimal monetary amount for out-of-pocket diagnostic and surgical fees associated with the diagnosis and treatment of BIA-ALCL related to its Defective Implants.[61]

130. Allergan's unwarranted position with respect to its affected patients is even more callous in light of its knowledge of the dangers of BIA-ALCL.

131. Despite knowing for years about the growing safety data that these defective breast implants and tissue expanders were dangerous and greatly increased the risk of BIA-ALCL, Allergan delayed issuing the Recall, failed to identify, monitor and report adverse events relating to the Defective Implants, and failed to warn and/or properly disclose all adverse events and all risks associated with the Defective Implants.

---

problems/alcl/pdf/Customer_Letter_-_BIOCELL_Replacement_Warranty_with_FAQ_update_7_30_19.pdf (emphasis in original).

[59] *Allergan Company Announcement*, *supra* note 56, at 1-2.

[60] *See BIOCELL® Replacement Warranty*, *supra* note 4, at 3.

[61] *See Natrelle ConfidencePlus Warranty Program*, *supra* note 4, at 2-4.

CLASS ALLEGATIONS

132. Plaintiffs bring this action individually on behalf of themselves and as a class action, pursuant to Federal Rule of Civil Procedure 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Class consists of the following:

> **Nationwide Class**: All persons in the United States who have been implanted with Biocell saline-filled or silicone-filled breast implants or tissue expanders that have been recalled.

Or, in the alternative,

> **Florida Subclass**: All persons in Florida who have been implanted with Biocell saline-filled or silicone-filled breast implants or tissue expanders that have been recalled.

133. Together, the Nationwide Class and the Florida Subclass shall be collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) assigned to this case.

134. Plaintiffs reserve the right to redefine the Class prior to class certification.

135. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

136. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. Plaintiffs are informed and believe that the proposed Class contains at least thousands of individuals in whom the Defective Implants were implanted from 2000 through at least July 24, 2019. The Class is therefore sufficiently numerous to make joinder

impracticable, if not impossible. The precise number of Class members is unknown to Plaintiffs at this time, but the Class members are readily ascertainable and can be identified by Defendants' records.

b. Existence and Predominance of Common Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitations:

i. Whether Defendants were unjustly enriched by the sale of the Defective Implants;

ii. Whether Defendants were negligent and/or reckless in selling the Defective Implants;

iii. Whether Defendants failed to exercise reasonable care in issuing and implementing recalls of the Defective Implants;

iv. Whether Defendants failed to identify, monitor, and/or report adverse events relating to the Defective Implants to the FDA, healthcare professionals, and/or consumers, including Plaintiffs and the Class;

v. Whether Defendants failed to warn and/or properly disclose to Plaintiffs and the Class all adverse events and all risks associated with the Defective Implants;

vi. Whether Defendants' practices constitute unfair or deceptive acts or practices;

vii. The appropriate nature of class-wide equitable relief; and

viii. The appropriate measurement of restitution and/or measure of damages to Plaintiffs and members of the Class.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiffs' claims are typical of the claims of all members of the Class who were implanted with the Defective Implants.

d. Adequacy: Plaintiffs are adequately representative of the Class because Plaintiffs' interests do not conflict with the interests of the Class that Plaintiffs seek to represent; Plaintiffs have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their undersigned counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

CAUSES OF ACTION

COUNT I - STRICT LIABILITY – MANUFACTURING DEFECT
On Behalf of the Class

137. Plaintiffs and the Class incorporate the preceding paragraphs 1 through 136 as though fully set forth herein.

138. On or before July 24, 2019, Defendants manufactured and placed into commerce the Defective Implants that were implanted into Plaintiffs and members of the Class.

139. The Defective Implants reached Plaintiffs in substantially the same manner in which they were placed into commerce by Defendants and were not modified or changed before, during or after the time they were implanted into Plaintiffs.

140. The Defective Implants were defective and unreasonably dangerous as a result of manufacturing defects, which proximately caused Plaintiffs' injuries. Specifically, when the Defective Implants are surgically placed in the body, the textured surface disrupts the body's normal healing process and was thought to result in scar tissue that was less firm than that produced by smooth-walled implants. However, it is believed that the Defective Implants' textured surface creates an implant-induced chronic inflammation that results in injury to the structure of cells in and around the implant. Plaintiffs and Class members have sustained such cellular damage as a result of the Defective Implants, and a currently unknown number of such Class members will go on to develop BIA-ALCL as a result of this damage and neoplastic transformation.

141. This manufacturing defect was the direct result of Defendants' failure to comply with the applicable federal regulations, as discussed in the Factual Allegations, for manufacturing of the Defective Implants and before placing them into the stream of commerce.

142. Plaintiffs and Class members have also been injured by undergoing surgery and implantation of a medical device and invasive diagnostic procedures, and in some cases an explant procedure, that they would not have had done if they were made aware of the true risks posed by the Defective Implants.

143. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT II - STRICT LIABILITY – DESIGN DEFECT
On Behalf of the Class

144. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

145. Defendants designed, developed, manufactured, marketed, assembled, tested, distributed, and sold the Defective Implants that were implanted into Plaintiffs and members of the Class.

146. The Defective Implants reached Plaintiffs in substantially the same manner in which they were designed by Defendants and were not modified or changed before, during, or after the time they were implanted into Plaintiffs.

147. The Defective Implants were defective and unreasonably dangerous as a result of design defects, which proximately caused Plaintiffs' injuries. Specifically, when the Defective Implants are surgically placed in the body, the textured surface, as designed by Defendants, disrupts the body's normal healing process and was thought to result in scar tissue that was less firm than that produced by smooth-walled implants. However, it is believed that the Defective Implants' textured surface creates an implant-induced chronic inflammation that results in injury to the structure of cells in and around the implant. Plaintiffs and Class members have sustained such cellular damage as a result of the Defective Implants, and a currently unknown number of such Class members will go on to develop BIA-ALCL as a result of this damage and neoplastic transformation.

148. Plaintiffs and Class members have also been injured by undergoing surgery and implantation of a medical device and invasive diagnostic procedures, and in some cases, an explant procedure, that they would not have had done if they were made aware of the true risks posed by the Defective Implants.

149. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT III - STRICT LIABILITY – FAILURE TO WARN
On Behalf of the Class

150. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

151. Defendants had a duty to warn Plaintiffs and the Class members regarding the true risks associated with the Defective Implants through submitting accurate adverse event reports as well as amending its warnings contained within the Defective Implants' Directions for Use ("DFU").

152. In and around the date of Plaintiffs' implant surgeries, Allergan's DFU for the Natrelle 410 implants failed to relay Allergan's actual knowledge of the clear causal connection between the Defective Implants and BIA-ALCL, an association that was significantly greater than the risk posed by other manufacturers' breast implants and tissue expanders.

153. From the dates of the design and manufacture of the Defective Implants, Defendants continually acquired new information regarding the true risks of the Defective Implants and their clear causal connection to BIA-ALCL but failed to warn Plaintiffs, Class members, their physicians, the FDA, and other healthcare professionals by not submitting accurate adverse event reports and failing to unilaterally strengthen their warnings. Defendants' failure to identify, monitor, and report accurate adverse events rendered their warnings and/or disclosures inadequate.

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

155. Despite Allergan's ability to unilaterally strengthen its warnings regarding the newly acquired knowledge of the link between the Defective Implants and BIA-ALCL, it instead chose to actively conceal this knowledge and causal association through its manipulation of adverse event reports and other reporting data.

156. Had Allergan properly reported those adverse events, the FDA would have required it to add warnings to the label or otherwise disseminate the additional adverse event information to the implanting doctors at a minimum, and would have required the Defective Implants be recalled and removed from the market once Allergan disclosed the true causal association between the Defective Implants and BIA-ALCL.

157. Moreover, if implanting physicians had been provided with the appropriate warnings regarding the causal connection between the Defective Implants and BIA-ALCL, they would have chosen to use an alternative product that did not present such a high risk of BIA-ALCL.

158. Defendants' breaches of their duty to warn have caused Plaintiffs and Class members damages in the form of surgical costs of removal of the Defective Implants and/or diagnostic testing fees, medical monitoring fees, and other costs and fees associated with having used the products.

159. Plaintiffs and Class members would not have purchased, chosen, and/or paid for all or part of the Defective Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

160. The Defective Implants proximately caused Plaintiffs' injuries. When the Defective Implants are surgically placed in the body, the textured surface disrupts the body's normal healing process and was thought to result in scar tissue that was less firm than that produced

by smooth-walled implants. However, it is believed that the Defective Implants' textured surface creates an implant-induced chronic inflammation that results in injury to the structure of cells in and around the implant.[62] Plaintiffs and Class members have sustained such cellular damage as a result of the Defective Implants, and a currently unknown number of such Class members will go on to develop BIA-ALCL as a result of this damage and neoplastic transformation.

161. Plaintiffs and Class members have also been injured by undergoing a surgery and implantation of a medical device and invasive diagnostic procedures, and in some cases an explant procedure, that they would not have had done if they were made aware of the true risks posed by the Defective Implants.

162. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT IV - NEGLIGENCE
On Behalf of the Class

163. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

164. Defendants, as the manufacturers and designers of a Class III medical device, had a duty and were required to comply with and not to deviate from federal statutory and regulatory requirements that applied to the Defective Implants, and similarly had a duty to comply with Florida's common law. Namely,

a. Pursuant to 21 C.F.R § 814.80, Defendants had a duty to manufacture, package, store, label, distribute, and advertise the Defective Implants subject to the PMA order. Any deviation from the PMA in a manner inconsistent with the conditions

[62] *Breast Implant-Associated ALK-Negative Anaplastic Large Cell Lymphoma, supra* note 14; *Silicone Implants and Lymphoma: The Role of Inflammation, supra* note 14.

for approval specified by the approval order, without authorization from the FDA, was a violation of federal law;

b. Pursuant to 21 C.F.R §§ 814.82 and 814.84, Defendants had a duty and were required to provide all of the post-approval reports and information identified by the FDA in the devices' PMA approval orders. Any deviation from the PMA approval orders, or failure to provide the information or materials known or knowable to Defendants, was a violation of federal law and was also a violation of Florida's common law duties owed as manufacturers and sellers to the Plaintiffs;

c. Pursuant to 21 C.F.R §§ 820.100, 820.20, and 820.198, Defendants had a duty and were required to establish and maintain procedures for ongoing quality reviews of its devices and for implementing corrective and preventative action if processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned products, and other sources of quality data identify potential causes of nonconforming product or other quality problem; and

d. Defendants were required to be pro-active and investigate the cause of nonconformities and implement effective corrective action. Defendants failed to do so in violation of federal law and also in violation of Florida's common law duties owed as manufacturers and sellers to the Plaintiffs.

165. In parallel with federal law, Florida law imposes post-sale duties upon Defendants. They owed a common law duty to monitor the sale, development, and use of the Defective Implants, to discover defects and hazards associated with the use of the Defective Implants, warn the government, doctors, and users of these defects and hazards, and to take other actions or protect those exposed to these defects and hazards.

166. Further, in parallel with federal law, Florida law treats violations of federal statutes and regulations as evidence of common law negligence and Defendants, as manufacturers, designers, sellers, and distributors of products in Florida, owed a common law duty to comply with all applicable federal laws and regulations.

167. Defendants owed a duty of care to Plaintiffs and Class members, who were foreseeable end users, to design and manufacture the Defective Implants so that they would not be defective or unreasonably dangerous to foreseeable end users, including Plaintiffs and Class members.

168. Despite their duties, Defendants, by and through their agents, were negligent and careless in that they failed to comply with and not deviate from 21 C.F.R §§ 814.80, 814.82, and 814.84, and 21 C.F.R. §§ 820.30, 820.80, and the conditions set in the PMA approval orders, in violation of both the orders, 21 C.F.R. § 820.100, and Florida's common law duties owed as designers, manufacturers, and sellers.

169. Defendants breached their duty of care by, among other things:

a. Negligently and recklessly designing and manufacturing the defective and unreasonably dangerous Defective Implants and failing to take all necessary steps to ensure that: the Defective Implants functioned as designed, specified, promised, and intended; and that the Defective Implants did not suffer from a common, uniform defect;

b. Negligently and recklessly failing to establish and maintain adequate and thorough quality assurance and evaluation systems that, if properly established and maintained, would have caused Defendants and others to discover the increased risk of BIA-ALCL associated with the Defective Implants; and as a result of this

negligence and recklessness, Defendants' processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned products, and other sources of quality data failed to identify the increased risk of BIA-ALCL associated with the Defective Implants;

c. Negligently and recklessly failing to exercise reasonable care in issuing and implementing recalls of the Defective Implants;

d. Negligently and recklessly failing to identify, monitor, and/or report adverse events relating to the Defective Implants to the FDA, healthcare professionals, and/or consumers, including Plaintiffs and the Class;

e. Negligently and recklessly failing to warn and/or properly disclose to Plaintiffs and the Class all adverse events and all risks associated with the Defective Implants; and

f. Refusing to pay for the surgical removal, diagnostic testing, and medical monitoring of Plaintiffs' and Class members' Defective Implants as well as other related costs and fees, notwithstanding the clear connection between the Defective Implants and BIA-ALCL and the continuing risk the Defective Implants pose to Plaintiffs' and Class members' health.

170. The Defective Implants designed and manufactured by Defendants proximately caused Plaintiffs' injuries. Specifically, when the Defective Implants are surgically placed in the body, the textured surface disrupts the body's normal healing process and was thought to result in scat tissue that was less firm than that produced by smooth-walled implants. However, it is believed that the Defective Implants' textured surface creates an implant-induced chronic

inflammation that results in injury to the structure of cells in and around the implant.[63] Plaintiffs and Class members have sustained such cellular damage as a result of the Defective Implants, and a currently unknown number of such Class members will go on to develop BIA-ALCL as a result of this damage and neoplastic transformation.

171. Plaintiffs and Class members have been injured by undergoing a surgery and implantation of the Defective Implants and invasive diagnostic procedures, and in some cases an explant procedure, that they would not have had done if they were made aware of the true risks posed by the Defective Implants.

172. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT V - FRAUDULENT MISREPRESENTATION AND CONCEALMENT
On Behalf of the Class

173. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

174. Defendants fraudulently made affirmative misrepresentations concerning material facts regarding the Defective Implants and omitted other material facts. Namely, Defendants failed to disclose to Plaintiffs and the Class members the true risks associated with the Defective Implants through submitting inaccurate adverse event reports as well as incomplete warnings contained within the product DFUs.

175. First, during the time before Plaintiffs underwent implant surgeries, Defendants did not include any warning within their DFU for the Natrelle 120 implants.[64]

[63] *Id*.

[64] *See Directions for Use: NATRELLE Silicone-Filled Breast* Implants, ALLERGAN (2015), https://web.archive.org/web/20170606132137/https://www.allergan.com/miscellaneous-pages/allergan-pdf-files/l034-03_silicone_dfu.

176. Further, only beginning in 2014 did Allergan first include the following warning within its DFU for the Natrelle 410 implants:

> Anaplastic Large Cell Lymphoma
>
> - Based on information reported to FDA and found in medical literature, a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing ALCL in the fluid or scar capsule adjacent to the implant.
>
> - ALCL has been reported globally in patients with an implant history that includes Allergen's and other manufacturers' breast implants.[65]

177. These representations failed to relay Defendants' actual knowledge of the clear causal connection between the Defective Implants and BIA-ALCL, an association that was significantly greater than the risk posed by "other manufacturers' breast implants."

178. Further, from the dates of the design and manufacture of the Defective Implants through the present, Defendants continually acquired new information regarding the true risks with the Defective Implants and their clear causal connection to BIA-ALCL but failed to warn Plaintiffs, Class members, their physicians, the FDA, and other healthcare professionals by not submitting accurate adverse action reports and failing to unilaterally strengthen their warnings. Defendants' failure to identify, monitor, and report accurate adverse events made their warnings and/or disclosures inadequate.

179. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was permitted to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or

[65] *See Directions for Use: NATRELLE Silicone-Filled Breast Implants,* ALLERGAN (2017), https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/labeling/natrelleus/410implants/natrelle-410-dfu-l3717rev04.pdf.

information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

180. Despite Allergan's ability to unilaterally strengthen its warning regarding the newly acquired knowledge of the link between the Defective Implants and BIA-ALCL, it instead chose to actively conceal this knowledge and causal association through its manipulation of adverse event reports and other reporting data.

181. Had Defendants properly identified, monitored, and reported those adverse events, the FDA would have required it to add warnings to the label or otherwise disseminate the additional adverse event information to the implanting doctors at a minimum and would have required the Defective Implants to be recalled sooner. This is confirmed by the FDA's 2019 request that the Defective Implants be recalled and removed from the market once Allergan disclosed the true causal association between the Defective Implants and BIA-ALCL.

182. Moreover, if implanting physicians had been provided with the appropriate warnings regarding the causal connection between the Defective Implants and BIA-ALCL, they would have chosen to use an alternative product that did not present such a high risk of BIA-ALCL.

183. Defendants knew or should have known of the true risks with the Defective Implants but omitted to disclose these material facts to Plaintiffs, Class members, their physicians, the FDA, and other healthcare professionals by not submitting accurate adverse action reports. By submitting misleading adverse action reports, and concealing the risks associated with the Defective Implants, Defendants misrepresented and omitted facts regarding the true nature of the Defective Implants.

184. Plaintiffs and Class members would not have purchased, chosen, and/or paid for all or part of the Defective Implants had they known that they would be exposed to the risk of developing BIA-ALCL.

185. Defendants' misrepresentations and omissions have caused Plaintiffs and Class members damages in the form of surgical costs of removal of the products and/or the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

186. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT VI - UNJUST ENRICHMENT
On Behalf of the Class

187. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

188. Plaintiffs and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing Defective Implants from 2000 through July 24, 2019. Plaintiffs and Class members would not have purchased, chosen and/or paid for all or part of the Defective Implants had they known that they would be exposed to the risk of developing BIA-ALCL, while Defendants refuse to compensate them for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical fees, diagnostic fees, medical monitoring, invasive diagnostic procedures fees, and other costs and fees associated with retention of the Defective Implants. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiffs and the Class.

189. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiffs and the Class

members who developed and endure being exposed to the risk of developing a serious and deadly disease.

190. Defendants' retention of the benefit conferred upon them by Plaintiffs and the Class would be unjust and inequitable.

191. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT VII - MEDICAL MONITORING
On Behalf of the Class

192. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

193. Due to Defendants' actions and inactions in violation of federal law, medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of BIA-ALCL.

194. Plaintiffs and the Class are thus entitled to have Defendants pay for the costs of ongoing medical monitoring.

COUNT VIII - BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
On Behalf of the Class

195. Plaintiffs and the Class incorporate paragraphs 1 through 136 as though fully set forth herein.

196. By operation of law, Defendants, as manufacturers of the Defective Implants and as the providers of a limited warranty for the Defective Implants, impliedly warranted to Plaintiffs and the Class that the Defective Implants were of merchantable quality and safe for their ordinary and intended use in the human body.

197. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Defective Implants. At the point of sale, the Defective Implants—

while appearing normal—contained latent flaws rendering them unsuitable and unsafe for use in the human body.

198. Had Plaintiffs and the Class known the Defective Implants are unsafe for use in the human body, they would not have purchased them and had them implanted.

199. Defendants have refused to provide appropriate warranty relief notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Defective Implants would not present a substantial risk of bodily harm.

200. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request, individually and on behalf of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Florida Class defined above, and designate Plaintiffs as the class representative and Plaintiffs' counsel as counsel for the Class;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Plaintiffs and Class Members, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiffs and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims so triable.

Date: November 19, 2019

PODHURST ORSECK, P.A.
Counsel for M.P., S.S., and the Proposed Class
SunTrust International Center
One S.E. 3rd Avenue, Suite 2300
Miami, FL 33131

By: /s/ *Peter Prieto*
Peter Prieto (FBN 501492)
pprieto@podhurst.com
John Gravante, III (FBN 617113)
(to be admitted Pro Hac Vice)
jgravante@podhurst.com
Matthew Weinshall (FBN 84783)
mweinshall@podhurst.com
Alissa Del Riego (FBN 99742)
adelriego@podhurst.com