UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	Case No. 2:19-md-02921 (BRM) (JAD) MDL NO. 2921
	JUDGE BRIAN R. MARTINOTTI JUDGE JOSEPH A. DICKSON
SACHIKO JUNGBLUTH,	
Plaintiff,	
v.	
ALLERGAN INC. F/K/A INAMED CORPORATION F/K/A/ MCGHAN MEDICAL CORPORATION; ALLERGAN USA, INC; and ALLERGAN PLC,	DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 6
	Civil Action No:
Defendants.	

COMPLAINT

Plaintiff files this Complaint pursuant to CMO No. 6, and are to be bound by the rights, protections, privileges, and obligations of that CMO. In accordance with CMO No. 6, Plaintiff(s) hereby designate the United States District Court for the District of New Jersey as the place of remand as this case may have originally been filed there.

Plaintiff SACHIKO JUNGBLUTH, through her undersigned counsel, based on personal knowledge, investigation of counsel, and information and belief, allege as follows.

NATURE OF THE ACTION

1. Defendants Allergan, Inc., Allergan USA, Inc., and Allergan plc (collectively "Defendants" or "Allergan") manufacture and sell BIOCELL saline-filled and silicone-filled breast implants and tissue expanders ("BIOCELL").

2. On July 24, 2019, Allergan announced a worldwide recall of BIOCELL after the U.S. Food and Drug Administration ("FDA") called for the action following new information that Allergan's BIOCELL implants were tied to a vast majority of cases of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") not seen with other textured implants. Allergan announced that BIOCELL would no longer be sold or distributed in any market.

3. BIA-ALCL is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant; but in some cases, it can spread through the body.

4. A BIA-ALCL diagnosis is serious and can lead to death, especially if not diagnosed early or promptly treated.

5. BIA-ALCL symptoms include lumps, swelling in the breast, asymmetry around the breast implant, and pain around the breast implant. The recommended diagnostic testing for BIA-ALCL is invasive and includes ultrasound evaluation for fluid collection, breast masses, and enlarged regional lymph nodes and, in some cases, explant of the implant and surrounding scar tissue. A suspicious mass requires tissue biopsy and evaluation.

6. BIA-ALCL treatment includes removal of the implant and in some patients may also require treatment with chemotherapy and radiation treatment.

7. This is an action for personal injuries and economic damages suffered by SACHIKO JUNGBLUTH ("Plaintiff") as a direct and proximate result of the Allergan's negligent, fraudulent, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of the BIOCELL implants.

PARTIES

Plaintiffs

8. Plaintiff SACHIKO JUNGBLUTH is a resident of Houston, Texas.

9. Plaintiff SACHIKO JUNGBLUTH was implanted with bilateral BIOCELL Natrelle Silicone-Filled Textured breast implants on November 13, 2014. As a direct and proximate result of her BIOCELL implants, Plaintiff is at an increased risk of developing BIA-ALCL. Had Plaintiff been informed that BIOCELL would expose her to an increased risk of BIA-ALCL, she would have never had the BIOCELL implant installed.

10. Plaintiff's implants were subject to the July 24, 2019 worldwide recall due to the risk of it causing BIA-ALCL.

11. Plaintiff has incurred and will continue to require and incur expenses in connection with medical treatment as a result of these injuries, which were caused by Defendants' BIOCELL products, and their unlawful conduct with respect to BIOCELL's design, manufacture, marketing, distribution, and sale.

12. Plaintiff has endured and will continue to endure pain, suffering, mental anguish, and loss of enjoyment of life as a result of her injuries, has suffered lost earnings and/or a loss of earning capacity, and other injuries and damages to be proven at trial.

Defendants

13. Defendant Allergan plc is a publicly-traded corporation whose headquarters are in Dublin, Ireland. Allergan's administrative headquarters in the United States are located in the States of New Jersey and California.

14. Defendant Allergan, Inc., formerly known as Inamed Corporation ("Inamed"), and prior to that known as 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 in New Jersey.

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

16. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, and reference to "Allergan," "Defendant" or "Defendants" herein refers to each and every Defendant individually and collectively

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different States.

18. This Court has personal jurisdiction over Defendants because each Defendant's principal place of business is in New Jersey and Defendants conduct substantial business in Texas, New Jersey, and within this District. Defendants have sufficient minimum contacts with Texas and New Jersey and intentionally avail themselves of the consumers and markets within Texas and New Jersey through the promotion and sale of their products, including now-recalled BIOCELL.

19. Venue is properly set in this District pursuant to 28 U.S.C. § 1391(b) and (c), since each Defendant's principal place of business is in this judicial district.

FACTUAL ALLEGATIONS

I. Breast Implants and BIA-ALCL

20. Breast implants are prosthetic medical devices that are implanted under the breast tissue or under the chest muscle to increase (augment) breast size, change the contour of the breast, or to rebuild (reconstruct) breast tissue after mastectomy or other damage to the breast.

21. There are three general types of breast implant products, defined by their filler material: saline solution, silicone gel, and composite filler.

22. Breast implants are available in various sizes and can have either a smooth or textured shell.

23. In the United States, approximately 300,000 breast implants are placed per year.

24. Breast implant manufacturers utilize various and, at times proprietary, techniques to texture the surface of their implants. The "lost-salt technique" is utilized by the Defendants to create their BIOCELL products. The BIOCELL shell is created by dipping the implant into uncured silicone, but before the surface 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. BIOCELL implants and tissue expanders were designed to produce overhangs at the opening of the pores to promote greater tissue adherence.

25. In 2011, a summary of published studies, evidence, and reports was published that identified 27 cases of ALCL and concluded that there was an association between breast implants and ALCL. In January 2011, the FDA released a report on BIA-ALCL, listing as its primary finding the following: "[b]ased on the published case studies and epidemiological research, the FDA believes that there is a possible association between breast implants and ALCL." The FDA further noted that, while it was not prepared to associate a particular type of breast implant with

BIA-ALCL, "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."

26. The natural occurrence of ALCL is 1/300,000. However, the FDA recently cited studies that place the estimated current risk of BIA-ALCL in women with textured implants to be between 1:3,817 and 1:30,000. This is consistent with risks reported in Europe. A December 2016 update from Australia's Therapeutic Goods Administration ("TGA") reported a risk of 1:1,000 to 1:10,000 for textured implants.

27. In March 2015, an analysis identified 173 cases of ALCL. That same month, the French National Cancer Institute announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

28. On May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and classified it as a distinct clinical entity, separate from other categories of ALCL.

29. In November 2016, Australia's TGA convened an expert advisory panel to discuss the association between breast implants and ALCL and provide ongoing advice.

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

31. In May 2017, a global analysis of forty governmental databases identified 363 cases of BIA-ALCL with 258 being reported to the FDA.

32. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including nine deaths.

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

34. In its July 24, 2019 announcement recalling the product, the FDA stated that there are 573 cases of BIA-ALCL worldwide and that 33 people have died, a "significant increase" since the FDA's last update earlier in 2019—reflecting 116 new cases and 24 more deaths.

35. The FDA stated that the risk of developing BIA-ALCL with Allergan BIOCELL textured implants is about six times that of becoming ill with textured implants from other manufacturers available in the U.S.

36. The FDA noted that of the 573 cases of BIA-ALCL, 481, or more than 80%, were attributed to Allergan implants, and of the 33 deaths caused by BIA-ALCL, 12 of the 13 patients for whom the implant manufacturer was known had an Allergan implant when she was diagnosed. Dr. Amy Abernethy, principal FDA deputy commissioner, stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

II. Allegan's Attempts to Conceal the Risks of ALCL Associated with its Breast Implants

37. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Upon enactment of the MDA, the FDA deemed saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process. The devices could be publicly sold so long as manufacturers later provided "reasonable

assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2). In 1988, in response to growing safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices requiring premarket approval ("PMA").

38. In April 1991, upon final publication of new regulations, the FDA began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants. 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, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public.

39. A PMA application must contain certain information that is critical to the FDA's evaluation of the medical devices including "an identification, discussion, and analysis of any other data, information or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any sources, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience." 21 C.F.R. §814.20(8)(ii).

40. After the FDA approves a device, the FDA-required labeling sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing. The definition of labeling extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, Directions for Use ("DFU), and fillers.

41. In January 1992, because of safety and efficacy concerns, the FDA announced a voluntary moratorium on silicone gel-filled breast implants. The FDA requested manufactures to

stop supplying them and requested surgeons to stop implanting them while the FDA engaged in a further review of the implant devices.

42. 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 implant devices for use in reconstruction patients.

43. In March 1998, the FDA approved McGhan's study protocol, which allowed the manufacturer to begin enrolling patients in the study. This study was referred to as the "Adjunct Study" and it involved 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.

44. 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. It involved breast reconstruction, and revision (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.

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

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

47. 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 age 18 and older and for reconstruction in women of any age application, including Styles 163, 168, 363 and 468.

48. As a condition of Defendant's PMA, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Defendants were 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' labeling or (b) had been addressed by the device's labeling, but occurred with unexpected severity or frequency. 21 C.F.R. §814.32(a)(9).

49. According to the approval order, Defendants were 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 or similar device marketed by the manufacturer or importer would be likely cause or contribute to a death or serious injury if the malfunction were to reoccur.

50. In January 2002, McGhan, now known as Inamed Corporation, submitted to the FDA the first PMA for their silicone gel-filled breast implants.

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

52. In November 2006, Defendants' silicone-filled breast implants (under the brand name "Natrelle") received pre-market approval by the FDA under PMA number P020056.

53. As conditions of the 2006 approval, the FDA required Allergan to conduct six post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Allergan's Natrelle® Silicone-Filled breast implants 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 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 gelfilled breast implant patients, following them for 10 years.

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

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

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

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

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

55. After receiving premarket approval for a Class III device, manufacturers are subject to a continuous obligation to comply with Medical Device Reporting pursuant to 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a). Significant to this action, manufacturers are required to file adverse event reports with the FDA.

56. In February 2013, Defendants received pre-market approval of the 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants (also under the brand name "Natrelle") by the FDA under PMA number P040046.

57. In February 2013, the DFU for PMA P040046, reported ALCL under an "other reported condition."

58. As conditions of the 2006 and 2013 approvals, the FDA required Defendants to conduct six post-approval studies to characterize the long-term performance and safety of the devices.

59. Defendants' failure to comply with the FDA's post-approval requirements, which conditioned approval of PMAs P99074, P040046 and P020056, and the commercial distribution

of devices that were not in compliance with the requirements of the PMAs is a violation of the FFDCA.

60. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to any medical device, including BIOCELL Breast Implants, rests with the PMA applicant manufacturer.

61. 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.

62. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to medical devices, such as Allergan's Natrelle® Silicone-Filled breast implants, rests with the manufacturer.

63. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

64. According to the FDA, the purpose of filing the reports is to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments.[1]

65. These reports can be accessed on the FDA's Manufacturer and User Facility Device Experience ("MAUDE"). Running a search on MAUDE as of the date of this Complaint generates over 300 BIA-ALCL cases and approximately 1,400 injury reports.

[1] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (last visited December 19, 2019).

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

67. Equally as troubling, Allergan's practice was to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure" until 2017.[2]

68. This was done through filing "Alternative Summary Reports" ("ASR") for multiple adverse event reports all at one time, instead of filing an adverse event report for each individual adverse event. The ASRs require less detail and are not publicly available through the MAUDE website.

69. In 2017, the FDA no longer permitted the filing of ASRs. Prior to 2017, there were, on average, fewer than 200 breast implant injuries reported a year. In 2017, this number skyrocketed to 4,567 adverse events, and nearly doubled to 8,242 in the first half of 2018.

70. Due to Allergan's reporting practices, medical professionals and consumers relying on the public reports would be unable to draw an accurate conclusion about the safety of a particular medical device.

71. Indeed, Allergan reported a case of possible BIA-ALCL through a non-public ASR.[3]

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[2] *See* https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface (last visited December 19, 2019).
[3] *See*

72. Delayed reporting prevents the healthcare community and the public from timely learning of risks which inevitably play a part in their decision-making, including by both physicians and consumers, regarding treatments and procedures, and thereby exposes countless additional women to potential harm.

73. Allergan failed to report adverse events from the post-market approval studies commissioned as part of the implant's PMA approval that would have led to reports suggesting the devices' contribution to serious injury.

74. Had Defendants not intentionally failed to comply with their clearly-established post-market surveillance obligations, Plaintiff would have decided against implantation.

75. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to exercise reasonable care in adequately warning Plaintiff, and/or implanting medical professionals about the dangers of Allergan's Natrelle® Silicone-Filled breast implants, and about all adverse events of which Allergan became aware, and further, had a post-market duty to identify, monitor, and report all adverse events and all risks associated with the product.

76. Despite having knowledge and possession of evidence showing that the use of Allergan's textured breast implants was dangerous and likely to place consumers' health at serious risk, Allergan refused or recklessly failed to identify, disclose, and warn of the health hazards and risks associated with the product, and about all adverse events that were known to Allergan.

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 (last visited December 19, 2019) ("[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.").

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

78. From 2006 through the date of Plaintiffs' implants, Allergan continually acquired new information regarding the strong association between its Natrelle® and BIOCELL implants and the development of BIA-ALCL; an association that was significantly higher than any other textured breast implant.

79. Based on the newly acquired information, Allergan had an obligation to unilaterally make changes to the directions for use ("DFU") for its Natrelle® and BIOCELL implants to add or strengthen the warnings about the causal association between the product and the development of BIA-ALCL.

80. Rather than strengthen the information about the link between its product and BIA-ALCL, Allergan instead actively concealed its acquired knowledge of the causal link through its manipulation of adverse event reports and other public reports as described above.

81. Additionally, under applicable state laws, which do not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its Natrelle® and BIOCELL breast implant products. Allergan refused and recklessly and intentionally failed to do so.

82. Each of the deficiencies in Allergan's post-market compliance, including those described above, was 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.

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

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

III. Defendants' Worldwide Recall of BIOCELL Breast Implants and Tissue Expanders and Subsequent BIOCELL Replacement Warranty Program

85. On July 24, 2019, Defendants announced a voluntary worldwide withdrawal of unused stock of BIOCELL textured breast implants and tissue expanders from doctors' offices and hospitals, and a suspension of any future sales, which is part of the voluntary recall of BIOCELL textured breast implants and tissue expanders.

86. On July 30, 2019, Carrie Strom, Senior Vice President, U.S. Medical Aesthetics, sent a letter to "Allergan Plastic Surgery Customer[s]" outlining Defendants' BIOCELL Replacement Warranty, which provides reimbursement for up to $1,000 in diagnostic fees and up to $7,500 in surgical fees. Defendants will not be providing surgical fee assistance to revision patients.

87. Upon information and belief, the BIOCELL Replacement Warranty is deemed consideration for release of Defendants' liability and it requests those opting into this program to forever discharge Defendants and any related persons and entities from all claims arising out of the use of their BIOCELL products.

88. Defendants' BIOCELL Replacement program, which started on July 24, 2019 will last only until July 24, 2021.

89. 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.

90. Upon information and belief, women who have a recalled implant beyond the ConfidencePlus 10-year warranty period are not offered reimbursement in diagnostic fees or in surgical fees related to diagnosis and treating BIA-ALCL.

91. Defendants' July 24, 2019, recall and July 30, 2019, BIOCELL replacement program do not mitigate the damages to women who have or had BIOCELL devices in their bodies.

IV. Plaintiff's BIOCELL Implant and Resulting Harm

92. Plaintiff SACHIKO JUNGBLUTH is and was at all times alleged herein a citizen of the State of Texas.

93. Plaintiff was implanted with BIOCELL Natrelle Silicone-Filled Textured breast implants on November 13, 2014.

94. Plaintiff would not have purchased Allergan BIOCELL products had she been properly appraised of the risks of BIA-ALCL associated with BIOCELL or the risk of needing a revision surgery to remove and replace the BIOCELL implants.

95. Plaintiff is at an increased risk of developing BIA-ALCL and underwent revision surgery to remove the recalled BIOCELL implants.

V. Tolling of the Statute of Limitations and Estoppel

A. Discovery Rule Tolling

96. Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence, that her BIOCELL implants increased the risk of her incurring BIA-ALCL

97. Plaintiff did not know of or discover facts that would have caused a reasonable person to suspect that her injuries were caused by BIOCELL, or by Defendants' concealment of the fact that BIOCELL dramatically increased the risk of BIA-ALCL. The information linking BIA-ALCL was contained exclusively in articles that were published in scientific journals. Plaintiff did not have access to these scientific articles because they were behind a paywall. And even had the articles been more widely available, the significance of these highly technical articles would not have been apparent to Plaintiff.

98. Plaintiff could not have reasonably discovered the true extent of Defendants' deception about BIOCELL's safety until Defendants recalled her implants.

99. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent Concealment Tolling

100. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment throughout the period relevant to this action of the risk of BIA-ALCL from BIOCELL.

101. Instead of disclosing to consumers the link between BIOCELL and the BIA-ALCL, Defendants continued to manufacture and sell BIOCELL without disclosing this information on

the drug's label or elsewhere. Further, Defendants misled the public into believing BIOCELL was safe by repeatedly touting the safety of BIOCELL.

C. Estoppel

102. Defendants were under a continuous duty to disclose to Plaintiff the risk of BIA-ALCL exposure associated with BIOCELL.

103. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of BIOCELL and never updated the device's label to disclose this risk.

104. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

CAUSES OF ACTION

COUNT 1
NEGLIGENCE

105. Plaintiff incorporates by reference all preceding paragraphs.

106. Defendants owed Plaintiff a duty of care and to warn of any risks associated with the recalled BIOCELL implants. Defendants knew or should have known of the true risks with BIOCELL implants but failed to warn Plaintiff and her physicians by failing to submit accurate adverse action reports. By submitting misleading adverse event reports, and concealing the risks associated with the recalled BIOCELL implants, Defendants negligently violated their duty of care to Plaintiff and her doctors.

107. Defendants were negligent in the design, manufacture, sale, testing, and/or distribution of BIOCELL in that they: (a) failed to use due care in designing, formulating, developing, testing, manufacture, and sale of BIOCELL so as to avoid or warn against the described risks to consumers who used BIOCELL; (b) placed an unsafe product into the stream of commerce; and (c)

failed to discover or warn of the dangers associated with the use of BIOCELL despite having actual and/or constructive knowledge of such dangers.

108. Defendants' failure to provide adequate information and warning concerning the risk BIA-ALCL with the BIOCELL Implants and Tissue Expanders was a proximate cause of Plaintiff's increased risk of BIA-ALCL. But for Defendants' failure, Plaintiff would not be at an increased risk of BIA-ALCL.

109. Defendants' breach of duty caused Plaintiff 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.

110. Plaintiff would not have purchased, chosen, and/or paid for all or part of the BIOCELL implants had she known that she would be exposed to the risk of developing BIA-ALCL.

111. Had Defendants complied with their obligation to study, monitor, accurately and timely report the known information about the increased risk of developing BIA-ALCL, the latency period of developing BIA-ALCL after implantations, symptoms of BIG-ALCL, and the proper diagnosis of BIA-ALCL, Plaintiff's treating physicians would have communicated the information to her.

112. Upon information and belief, when the BIOCELL Breast Implants placed into Plaintiff's body were manufactured, Defendants had the technological capability to manufacture its Breast Implants in a reasonably safe manner that would not put her at an increased risk of BIA-ALCL.

113. Plaintiff suffered damages in an amount to be determined at trial.

COUNT 2
NEGLIGENT RECALL

114. Plaintiff incorporates by reference all preceding paragraphs.

115. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL products in the United States. That same day, Allergan voluntarily issued a worldwide recall of BIOCELL products.

116. In issuing a voluntary recall, Allergan assumed duties to Plaintiff to exercise reasonable care in issuing and implementing the recall.

117. Allergan breached its duties by failing to adequately warn Plaintiff of the dangers associated with the use of the recalled BIOCELL products and by refusing to pay for the surgical removal of Plaintiff's implants notwithstanding the clear connection between the recalled BIOCELL products and BIA-ALCL and the continuing risk the implants pose to Plaintiff's health.

118. As a direct result of Allergan's breach of duty, Plaintiff suffered harm in an amount to be determined at trial.

COUNT 3
STRICT LIABILITY - FAILURE TO WARN

119. Plaintiff incorporates by reference all preceding paragraphs.

120. Defendants had a duty to warn Plaintiff regarding the true risks associated with BIOCELL implants through submitting accurate adverse event reports as well as amending its warnings contained within the product DFUs.

121. Defendants failed to provide adequate warnings regarding the risks of BIA-ALCL.

122. Defendants supplied to Plaintiff documents including the DFU, Patient Labeling, Brochures, Device Tracking Forms, and/or Warranty documents concerning their BIOCELL products.

123. Plaintiff and her plastic surgeons who treated her had access to data concerning adverse events from the MAUDE database and Defendants' published studies.

124. Defendants had a duty to provide labeling to communicate Defendants' actual knowledge of the clear causal connection between its BIOCELL implants and BIA-ALCL, an association that was significantly greater than the risk posed by other manufacturers' breast implants.

125. Beginning in 1998, Defendants acquired and continued to acquire new information regarding the true risks with BIOCELL implants. Defendants knew the causal connection between their textured implants and BIA-ALCL before Plaintiff had the BIOCELL product implanted.

126. Beginning in 2006, Defendants continually acquired new information regarding the true risks with BIOCELL implants and their clear causal connection to BIA-ALCL but failed to warn Plaintiff and her physicians by not submitting accurate adverse action reports and failing to unilaterally strengthen their warnings. Defendants' failure to submit accurate adverse event reports made their warning inadequate and the implants defective.

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

128. Despite Allergan's obligation to unilaterally strengthen its warning regarding the knowledge of the link between BIOCELL 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.

129. The DFU, Patient Labeling, Brochures, Device Tracking Forms, Warranty documents and Defendants' published literature lacked information concerning what the Defendants knew about BIA-ALCL.

130. 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 BIOCELL implants to be recalled sooner. This is confirmed by the FDA's 2019 request that BIOCELL implants be recalled and removed from the market once Allergan disclosed the true causal association between the implants and BIA-ALCL.

131. The Defendants had a duty to disclose known risks to Plaintiff and her physicians. Despite the 2011 call from the FDA to determine how to identify safety signals that would better identify health risks associated with the breast implants, Defendants chose to submit ASRs until they were banned rather than report by way of MDRs which would have been publicly available. Defendants' failure to submit MDRs made their warning inadequate and accordingly rendered the implants defective.

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

133. Defendants' breach of their duty to warn have caused Plaintiff 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.

134. Plaintiff would not have purchased, chosen, and/or paid for all or part of the BIOCELL implants had she known that she would be exposed to the risk of developing BIA-ALCL.

135. Plaintiff and her plastic surgeons relied on Defendants' labeling and made her decision to use the BIOCELL device based on the information in the label. Had Defendants complied with their duties owed to Plaintiff, she would have decided against the textured implant, and would not be at an increased risk of developing BIA-ALCL.

136. As a direct and proximate result of Defendants' wrongful conduct Plaintiff has suffered bodily injury, and resulting pain and suffering, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of ability to earn money. The losses are either permanent or continuing and she will suffer those losses in the Plaintiff has also been injured by undergoing a surgery and implantation of a medical device and invasive diagnostic procedures, that she would not have had done if she was made aware of the true risks posed by the BIOCELL implants.

137. Plaintiff suffered damages in an amount to be determined at trial.

COUNT 4
UNJUST ENRICHMENT (In the Alternative)

138. Plaintiff incorporates by reference all preceding paragraphs.

139. Plaintiff conferred a tangible and material economic benefits upon Defendants by purchasing recalled BIOCELL implants. Plaintiff would not have purchased, chosen and/or paid for all or part of BIOCELL had she known that she would be exposed to the risk of developing BIA-ALCL, while Defendants refuse to pay for the surgical costs of removal of the products and/or compensate her sufficiently for the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

140. It would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff.

141. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff who is exposed to the risk of developing a serious and deadly disease.

142. Defendants' retention of the benefit conferred upon them by Plaintiff would be unjust and inequitable.

143. Plaintiff suffered damages in an amount to be determined at trial.

COUNT 5
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

144. Plaintiff incorporates by reference all preceding paragraphs.

145. Defendants were manufacturers and merchant sellers with respect to BIOCELL implants.

146. An implied warranty of fitness for human consumption runs from each Defendant to consumers like Plaintiff.

147. To induce the purchase and/or use of BIOCELL, Defendants' warranted to Plaintiff that the Defective Implants were of merchantable quality and safe for their ordinary and intended use in the human body.

148. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of recalled BIOCELL implants. At the point of sale, the while appearing normal—contained latent flaws rendering them unsuitable and unsafe for use in the human body.

149. Had Plaintiff known the recalled BIOCELL implants are unsafe for use in the human body, she would not have purchased them and had them implanted.

150. Plaintiff relied on the Defendants' skill or judgment to provide a safe implant product. The Defendants are in the business of designing, manufacturing, selling, and marketing breast implants.

151. The Defendants had reason to know that Plaintiff and/or her doctors would rely on the Defendants' skill or judgment.

152. Plaintiff reasonably expected, at the time of purchase, that the recalled BIOCELL implants would not present a substantial risk of bodily harm.

153. Defendants have refused to provide appropriate warranty relief notwithstanding the substantially increased risk of developing BIA-ALCL.

154. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff has sustained damages in an amount to be determined at trial.

COUNT 6
BREACH OF EXPRESS WARRANTY

155. Plaintiff incorporates by reference all preceding paragraphs.

156. Defendants were merchants and sellers with respect to BIOCELL.

157. In order to induce the purchase and implantation of BIOCELL, Defendants expressly warranted to potential users of BIOCELL that BIOCELL was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used. Express warranties were contained in direct to consumer advertising and other promotional and marketing campaigns, BIOCELL product information sheets given to patients with their surgery, the product labeling, and other public communications and representations.

158. Defendants expressly represented to Plaintiff, other consumers, and the medical community that BIOCELL implants were safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

159. BIOCELL does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to, developing BIA-ALCL.

160. At the time of the making of the express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of Defendants.

161. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

162. At all relevant times BIOCELL did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

163. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

164. Plaintiff was injured as a result of reliance upon Defendants' express warranties.

COUNT 7
NEW JERSEY PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A:58C-1, *et seq.*)

165. Plaintiff incorporates by reference all preceding paragraphs.

166. BIOCELL was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to

its propensity to permanent physical injuries including, but not limited to, developing BIA-ALCL and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of breast implants. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq.*

167. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

168. Plaintiff was prescribed and used the subject product for its intended purpose.

169. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

170. Defendants, as manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

171. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

172. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to BIA-ALCL.

173. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants

174. Defendants had a continuing duty to warn Plaintiff of the dangers associated with BIOCELL.

175. Had Plaintiff received adequate warnings regarding the risks of BIOCELL, she would not have used it and/or chosen a different course of treatment or different type of implant product.

176. Plaintiff suffered damages in an amount to be determined at trial.

COUNT 8
NEW JERSEY PRODUCT LIABILITY ACT — DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1, *et seq.*)

177. Plaintiff incorporates by reference all preceding paragraphs.

178. Defendants were at all relevant times the manufacturer and seller of the BIOCELL implants.

179. BIOCELL implants are defective in their design in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

180. At all times material to this action, BIOCELL implants were expected to reach, and did reach, consumers in Plaintiff's home state and throughout the United States, including receive by Plaintiff, without substantial change in the condition in which it was sold.

181. At all times material to this action, BIOCELL was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, BIOCELL contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting

Plaintiff to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing BIA-ALCL and other serious injuries and side effects;

b. When placed in the stream of commerce, BIOCELL was defective in design, making the use of BIOCELL more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other breast implants on the market;

c. The design defects of BIOCELL existed before it left the control of Defendants;

d. BIOCELL was insufficiently and inadequately tested;

e. BIOCELL caused harmful side effects that outweighed any potential utility; and

f. BIOCELL was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

182. Defendants' owed Plaintiff a duty to ensure that BIOCELL products were safe for their intended purpose, contained adequate warnings, and had a non-defective design. Defendants knew or should have known that BIOCELL implants created an increased risk of BIA-ALCL, in party due to their textured design, but failed to redesign the implants or warn Plaintiff and her physicians by failing to submit accurate adverse action reports.

183. By submitting misleading adverse event reports, and concealing the risks associated with the recalled BIOCELL implants, Defendants violated their duty of care to Plaintiff her doctors.

184. Defendants' breach of duty caused Plaintiff 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.

185. Plaintiff would not have purchased, chosen, and/or paid for all or part of the BIOCELL implants had she known that she would be exposed to the risk of developing BIA-ALCL.

186. Upon information and belief, when the BIOCELL Breast Implants placed into Plaintiff's body were manufactured, Defendants had the technological capability to manufacture its Breast Implants in a reasonably safe manner that would not put her at an increased risk of BIA-ALCL. At the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

187. Plaintiff suffered damages in an amount to be determined at trial.

COUNT 9
PUNITIVE DAMAGES

188. Plaintiff incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

189. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

190. As a direct and proximate result of Defendants' malicious, fraudulent, and/or intentional disregard of Plaintiff's rights, Plaintiff is entitled to punitive damages to punish Defendants and deter similar wrongdoing by others in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request judgment against all Defendants as follows:

1. For economic and non-economic damages, special damages, and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;
2. For actual or compensatory damages for the acts complained of herein in an amount to be determined by a jury and as provided by applicable law;
3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;
4. For exemplary and punitive damages sufficient to punish Defendants for the acts complained of herein and to deter Defendants and others from future wrongful practices, in an amount to be determined by a jury;
5. For an award of reasonable attorneys' fees, court costs, and other litigation expenses;
6. For prejudgment interest;
7. For post-judgment interest; and
8. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: August 19, 2020

Respectfully submitted,

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