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Counsel for Plaintiff C.C. on behalf of herself and all others similarly situated

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

C.C., individually and on behalf of all others similarly situated,

Plaintiff,

v.

ALLERGAN, INC. f/k/a INAMED CORPORATION; ALLERGAN USA, INC.; ALLERGAN plc; and DOES 1 through 20, inclusive,

Defendants.

Case No. 4:19-cv-6347

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff C.C. brings this Class Action Complaint against Defendants ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., and ALLERGAN plc (collectively "Defendants" or "Allergan"), on behalf of herself and all other others similarly situated, and alleges as follows:

INTRODUCTION

1. Plaintiff brings this class action against Allergan for manufacturing and selling BIOCELL textured breast implants and tissue expanders that expose women to a higher risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system. Although it knew of the increased risks of BIA-ALCL as early as 2011, Allergan failed to warn women considering their implants. Although Allergan has now issued a recall pursuant to FDA's directive, it refuses to take full responsibility and refuses to cover the significant costs associated with removal and replacement of the defective devices and medical monitoring, among other damages.

2. Following a request by the FDA, Allergan announced a worldwide recall of all BIOCELL textured breast implants and tissue expanders on July 14, 2019. The models included in the recall are:

- **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
- 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 410FM
  - Style 410FF
  - Style 410MM
  - Style 410 MF
  - Style 410 FL
  - Style 410 ML
  - Style 410 LL
  - Style 410 LM

- Style 410 LF
- Style 410 FX
- Style 410 MX
- Style 410 LX

- **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)

3. Allergen has refused to pay for the removal of the recalled products or any of the consequences of additional surgery that women who choose removal will have to undergo, or for medical monitoring of the substantially increased risk of BIA-ALCL that all women implanted with the devices have been subjected to.

4. Prior to issuing a request for the recall, the Food and Drug Administration ("FDA") had received reports establishing that BIOCELL implants and expanders were associated with an increase in reported cases of BIA-ALCL: 573 cases of BIA-ALCL worldwide including 33 deaths. Of the 573 known cases of BIA-ALCL, 481 (or about 84%) were attributed to Allergan products, and of the 33 reported deaths, "12 of the 13 patients for which the manufacturer of the implant is known are confirmed to have an Allergan breast implant[.]" According to the FDA, the risk of BIA-ALCL is six times higher with Allergan's textured implants than textured implants from other manufacturers.

5. Plaintiff brings this Action to make Allergan take responsibility for exposing women to a higher risk of BIA-ALCL and to make all women implanted with these defective devices whole by covering all costs associated with the removal, replacement, and recovery, medical monitoring, and all damages arising out of the sale and implanting of these defective devices.

PARTIES

6. Plaintiff is an individual who resides in Dublin, California.

7. Given the sensitivity of their claims and the nature of the medical products and services at issue, Plaintiff is proceeding under a pseudonym in this litigation to protect her privacy. If required by the Court, Plaintiff will seek permission to use a pseudonym.

8. Defendant ALLERGAN plc is a publicly traded corporation headquartered in Dublin, Ireland. It has administrative headquarters for the United States in New Jersey. ALLERGAN plc also maintains a large presence in Irvine, California, where its U.S. Medical Aesthetics division responsible for breast implants is now based, including thousands of employees and large offices and research and development facilities.

9. Defendant ALLERGAN, INC. f/k/a INAMED CORPORATION, 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. ALLERGAN, INC. f/k/a INAMED CORPORATION was previously headquartered in Irvine, California.

10. 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.

11. Plaintiff is unaware of the true names, capacities, relationship and extent of participation in the conduct alleged herein, of the Defendants sued herein as DOES 1 through 20, but are informed and believe that said Defendants are legally responsible for the wrongful conduct alleged herein and therefore sue these Defendants by fictitious names. Plaintiff will amend this complaint to allege the true names and capacities of the DOES Defendants when ascertained.

JURISDICTION AND VENUE

12. This Court has jurisdiction over Plaintiff's claims under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds $5 million exclusive of interest and costs. Some Class Members and Defendants are citizens of different states. There are at least 100 putative Class Members throughout the State of California.

13. This Court has personal jurisdiction over Defendants because they have sufficient minimum contacts in California to render the exercise of jurisdiction by this Court proper and fair. Allergan researched, designed, tested, manufactured, and carried out comprehensive decade-long clinical trials for the recalled BIOCELL products in

California. Allergan's U.S. Medical Aesthetics division, which is responsible for the development and sale of breast implants, including the recalled BIOCELL products, is based in California. Senior Vice President, U.S. Medical Aesthetics, Carrie Strom is also based in California.

14. Venue properly lies in this District pursuant to 28 U.S.C. § 1391(b)(2) and (b)(3) because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District, and because Defendants are subject to personal jurisdiction within this District.

15. Plaintiff is informed and believes that each Defendant acted in all respects pertinent to this action as the agent of the other Defendants, carried out a joint scheme, business plan or policy in all respects pertinent hereto, and the acts of each Defendant are legally attributable to the other Defendants.

FACTUAL ALLEGATIONS

I. The Parties

16. On November 6, 1997, Plaintiff received Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), style 468, BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants. They are included on the list of recalled BIOCELL implants, and she paid approximately $5,000 for the implants and procedure.

17. Plaintiff has begun exhibiting symptoms associated with BIA-ALCL, including a change in the shape of her right breast (asymmetry), and a change in the size of both breasts.

18. Plaintiff would not have had and/or selected these implants had she known prior to the procedure that they would subject her to the significantly greater risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other fees and procedures to detect and treat BIA-ALCL.

19. Plaintiff wants Allergan to fully pay for the removal of her implants, but Allergan has refused to pay for any surgical costs associated with the recall or medical monitoring of the greatly increased risk of BIA-ALCL.

20. Allergan manufactures and sells BIOCELL breast implants and tissue expanders. Allergan's BIOCELL line of implants are a type of breast implant and tissue expander that are textured to reduce the likelihood of common complications like capsular contracture.

21. The products that were recalled include:

- **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
  - 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
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  - Style TRX, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
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- 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 410FM
  - Style 410FF
  - Style 410MM
  - Style 410 MF
  - Style 410 FL
  - Style 410 ML
  - Style 410 LL
  - Style 410 LM
  - Style 410 LF
  - Style 410 FX
  - Style 410 MX
  - Style 410 LX
- **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)

II. Allergan's Textured Implants Greatly Increase the Risk of Cancer

22. The FDA has confirmed 457 cases of BIA-ALCL in the United States, all linked to textured breast implants. The current lifetime risk of BIA-ALCL runs between 1 in 3,817 and 1 in 30,000. The American Society of Plastic Surgeons estimates the current

risk of BIA-ALCL to be between 1 in 2,207 and 1 in 86,029 for women with textured implants.

23. On March 21, 2017, the FDA stated "[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." In May 2017, a global analysis of about forty governmental databases showed 363 cases of BIA-ALCL, 258 of which were reported to the FDA.

24. 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 recalled implants and tissue expanders.

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

26. In February 2019, the FDA sent a letter to health care providers across the United States warning them about the link between textured breast implants and BIA-ALCL.

27. It was not until July 24, 2019 that Allergan announced a worldwide recall of all BIOCELL textured breast implants and tissue expanders. It waited this long despite knowing for years about the growing data that these devices were unsafe and could cause cancer. And it did not properly disclose this information to patients.

III. The Recalled Implants Are from California

28. Many of the BIOCELL breast implants that have been recalled were originally designed, tested, and manufactured in California.

29. McGhan (later acquired by Allergan) was once a leading manufacturer of breast implants, and made several of the devices recalled by Allergan. The recalled devices include Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant). The company was based in Santa Barbara County, California. In 1985, it became a subsidiary of a publicly held company called First American Corporation, which later changed its name to Inamed Corporation.

30. Inamed (later acquired by Allergan) also made several of the devices recalled by Allergan including Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants). This company was also based in Santa Barbara, California, where it maintained its offices and headquarters, performed research and development, and had its manufacturing facilities, including a 225,000 square foot facility. Inamed also maintained large offices, manufacturing, and distribution facilities in Carpinteria, California and Fremont, California. Inamed manufactured some of its breast implant products in Santa Barbara, California.

31. In March 2006, Allergan acquired Inamed and its wholly owned subsidiary, McGhan for approximately $3.2 billion. Allergan acquired the BIOCELL trademark and assumed the liability risks for its past and present manufacturing of breast implant products.

32. In October 2006, Allergan publicly announced that Inamed's Santa Barbara facilities would serve as its national center for research and development in medical aesthetics, which included breast implants. In addition, Allergan maintained secondary manufacturing facilities for the recalled BIOCELL products in Santa Barbara, California.

33. In 2013, Allergan filed a Summary of Safety and Effectiveness Data ("SSED") with the FDA, and listed its research and development facility in Santa Barbara County. The facility is about 105,000 square feet.

34. The respective SSEDs for the devices subject to the recall show that employees in Santa Barbara, California were responsible for seeking FDA approval for these products.

35. The Directions for Use ("DFU") containing important product and patient information for the recalled BIOCELL products, were conceived of, reviewed, and approved by Allergan in Santa Barbara and/or in Irvine, California. The relevant DFUs list either a Santa Barbara or Irvine, California address for Inamed and Allergan.

36. Allergan's Medical Aesthetics division responsible for its BIOCELL breast implants and overseeing the recall, including the deficient replacement warranty, is now based in Irvine, California.

IV. Allergan Failed to Disclose the Risks of Its Implants to Patients

37. Patients and their physicians are entitled to know the potential risks of textured implants. Yet, Allergan did not properly make these disclosures. Since at least 2011 when it was first reported by the FDA, Allergan knew about the link between its BIOCELL implants and BIA-ALCL.

38. Indeed, since April 1991, the FDA has required breast implant manufacturers to obtain premarket approval for breast implants through the Premarket Approval Applications ("PMAs") process, which allows the FDA to evaluate the safety and effectiveness of medical devices. This process includes known investigations showing whether or not the device is safe and effective, and other data relevant for evaluating the safety and effectiveness of the device that is known or should reasonably be known to the manufacturer.

39. In 2000, Inamed began conducting a 10-year study to assess the performance and safety of the McGhan Medical RTV Saline-Filled Breast Implant. In 2006, Allergan began long-term studies for its Inamed Silicone-Filled Breast Implants to determine any health concerns including cancer.

40. Allergan is required to file adverse event reports with the FDA, and has the responsibility for timely communicating complete and accurate safety information. It is further obligated to monitor all reasonably available information and clinical experiences.

41. The FDA publishes adverse event reports in a public, searchable database called the Manufacturer and End User Facility Device Experience database or "MAUDE" which is updated monthly.

42. It has been reported that instead of accurately reporting adverse events individually each time an injury occurred, Allergan sought to "bury evidence of ruptures

and other injuries by reporting them as routine events that did not require public disclosure." It did this by filing Alternative Summary Reports ("ASR").

43. For nearly two decades, the FDA has allowed manufacturers to submit quarterly spreadsheets through the Alternative Summary Reports Program, summarizing reports of common problems of approved devices. ASRs cannot include severe or unexpected events or injuries necessitating remedial action, which should still be disclosed to the public through MAUDE. Yet, it is believed that these incidents were kept hidden in ASRs.

44. In fact, in 2017 when the FDA began implementing more rigorous reporting requirements, there was a dramatic increase in the number of adverse events related to breast implant injuries. It went from 200 a year, to 4,567 in 2017 and 8,242 in the first half of 2018.

45. In an effort to increase transparency, on June 21, 2019, the FDA formally ended the Alternative Summary Reporting Program. The FDA said the surge in reports reflected the change in its requirements, rather than a new public health issue.

46. Accurate reporting of adverse events is critical to ensure that the public is adequately and timely notified of potential problems with a medical device. This includes devices manufactured and sold by Allergan.

47. The general public, including physicians and patients, receive information from databases like the MAUDE. Researchers, including those studying connections between breast implants and cancer and other health issues, also use the MAUDE database in their studies of defective medical devices.

48. Upon information and belief, Allergan used the Alternative Summary Reporting Program instead of MAUDE, and as a result, failed to disclose the risks of its medical devices, including those at issue in this litigation.

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

50. Allergan continually received new information showing the connection between its textured breast implants and BIA-ALCL and that the risk associated with its BIOCELL breast implants was significantly greater than its competitors. Yet, it failed to properly disclose this information.

51. Allergan failed to comply with the conditions of the PMAs by failing to fulfill its obligations to accurately and promptly report adverse events and continuing to sell the recalled BIOCELL products.

52. Had Allergan complied with its obligations under federal law, the disclosure of the connection between BIOCELL breast implants and BIA-ALCL would have allowed patients including Plaintiff, and her treating physician to make an informed decision regarding whether to use other implants.

CLASS ACTION ALLEGATIONS

53. Plaintiff brings this action in her individual capacity and as a class action pursuant to Federal Rule of Civil Procedure 23 on behalf of the following proposed nationwide class and state subclass:

> **Nationwide Class**: All individuals in the United States who implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA.
>
> **California Subclass**: All individuals who implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA while in California.

54. Excluded from the Class are Defendants, as well as their officers, employees, agents or affiliates, and any judge who presides over this action, as well as all past and present employees, officers and directors of Defendants. Plaintiff reserves the right to expand, limit, modify, or amend the Class and definitions, including the addition of one or more subclasses, in connection with their motion for class certification, or at any other time, based upon, *inter alia*, changing circumstances and/or new facts obtained during discovery.

55. The Class meets the requirements of Federal Rules of Civil Procedure 23(a) and 23(b)(1), (b)(2), and (b)(3) for all of the following reasons.

56. **Numerosity** – Although the exact number of Class members is uncertain, and can only be ascertained through appropriate discovery, the number is great enough such that joinder is impracticable. The disposition of the claims of these Class members in a single action will provide substantial benefits to all parties and the Court. Information concerning the exact size of the putative class is within the possession of Defendants. The parties will be able to identify each member of the Class after Defendants' document production and/or related discovery.

57. **Commonality** – Common questions of fact and law exist as to all Class members and predominate over any questions that affect only individual Class members, including by example only and without limitation, the following:

a. Whether the recalled BIOCELL products significantly increase the risk of developing BIA-ALCL;

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

c. Whether Allergan was negligent in selling BIOCELL recalled products;

d. Whether Allergan failed to warn consumers regarding the risks of the recalled BIOCELL products;

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

f. Whether Allergan breached implied warranties connected with the recalled BIOCELL products;

g. Whether Allergan's practices constitute unfair acts or practices under the Unfair Competition Law;

h. Whether Plaintiff and class members are entitled to equitable relief, including injunctive relief; and

i. Whether Plaintiff and class members are entitled to damages or other monetary relief, and if so, in what amount.

58. **Typicality –** All of Plaintiff's claims are typical of the claims of the proposed Class they seek to represent in that: Plaintiff, like all class members, was implanted with recalled BIOCELL products and faces an increased risk of BIA-ALCL; Plaintiff's claims arise from the same practice or course of conduct that forms the basis of the Class claims; Plaintiff's claims are based upon the same legal and remedial theories as the proposed Class and involve similar factual circumstances; there is no antagonism between the interests of Plaintiff and absent Class members; the injuries that Plaintiff suffered are similar to the injuries that Class members have suffered.

59. **Adequacy** – Plaintiff will fairly and adequately represent the Class in that: (1) there is no conflict between Plaintiff's claims and those of other Class members; (2) Plaintiff has retained counsel who are skilled and experienced in class actions and who will vigorously prosecute this litigation; (3) Plaintiff's claims are typical of the claims of Class members.

60. **Predominance –** The proposed action meets the requirements of Federal Rule of Civil Procedure 23(b)(3) because questions of law and fact common to the Class predominate over any questions which may affect only individual Class members.

61. **Superiority** – A class action is superior to all other methods available for the fair and efficient adjudication of this controversy. Because the amount of each individual class member's claim is small relative to the complexity of the litigation, and given Allergan's financial resources, no class member would be likely to pursue legal redress individually for the violations detailed herein. A class action would also streamline the determination of common claims or issues in this case. Conversely, individual suits would create the potential for inconsistent or contradictory rulings. By contrast, a class action presents fewer management difficulties, allows claims to be heard which would otherwise go unheard, and allows comprehensive supervision by a single court.

62. Injunctive Relief - Class certification is also appropriate under Rule 23(b)(2) because Allergan acted and refused to act on grounds generally applicable to

the class, making appropriate final injunctive relief with respect to the class as a whole.

FIRST CAUSE OF ACTION
STRICT LIABILITY—FAILURE TO WARN

63. Plaintiff re-alleges and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

64. Allergan manufactured, distributed, and/or sold the BIOCELL breast implants that were implanted in Plaintiff.

65. Allergan had a duty to warn Plaintiff and her physicians about the dangers of the recalled BIOCELL products which it knew, or in the exercise of ordinary care, should have known, at the time the recalled BIOCELL products left Allergan's control.

66. The BIOCELL breast implants had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific and medical community at the time of the manufacture, distribution, or sale of the implant.

67. Allergan failed to warn Plaintiff and her physicians about the serious risk of using its recalled BIOCELL products, including the greatly increased risk of BIA-ALCL. At the time Plaintiff received her implants, Allergan was aware of the clear causal connection between its BIOCELL breast implants but did not disclose this information or warn of the significantly greater risk of BIA-ALCL associated with its implants. Allergan obtained this knowledge from performing extensive decades-long clinical studies, reviewing scientific studies and literature, FDA communications, government reports, and from complaints from consumers, among other sources. Rather than disclose the truth, Allergan, in violation of federal law, attempted to conceal the true facts by not reporting all adverse events to the FDA and by filing ASRs to avoid public reporting on MAUDE.

68. Allergan also failed to warn Plaintiff and the public by not submitting accurate adverse event reports that patients and physicians rely on to make informed decisions about selecting the type of breast implants.

69. The recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession because they did not contain adequate warnings, including the greatly increased risk of developing BIA-ALCL.

70. The potential risks presented a substantial danger to Plaintiff and ordinary consumers when used or misused in an intended or reasonably foreseeable way.

71. Plaintiff and ordinary consumers would have not recognized the potential for risks.

72. Allergan failed to adequately warn or instruct concerning the potential risks of recalled BIOCELL products.

73. It was foreseeable to Allergan that failure to adequately warn about the risks of its recalled BIOCELL products would cause irreparable harm to those who had the products implanted in their bodies, including the types of emotional distress suffered by Plaintiff.

74. As a result of Allergan's failures to adequately warn, Plaintiff was harmed as described herein including physical pain and emotional distress. The lack of sufficient warnings was a substantial factor in causing Plaintiff's harm. If Plaintiff and her physician had been provided with the appropriate warnings regarding the causal connection between BIOCELL implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL.

75. Allergan's breach of its duty to warn has caused Plaintiff damages including surgical costs of removal of the products, ongoing medical monitoring, and other medical expenses.

SECOND CAUSE OF ACTION
NEGLIGENCE

76. Plaintiff re-alleges and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

77. Allergan has a continuing duty to monitor the recalled BIOCELL products to discover and report to the FDA any complaints about product

performance and safety. Allergan also has a continuing duty to provide warnings and instructions regarding potential safety hazards associated with the use of its products.

78. Allergan breached these duties by failing to provide timely and adequate reports regarding the safety hazards associated with the recalled BIOCELL products, including the close causal connection to BIA-ALCL. Through numerous adverse reports, consumer complaints, scientific research and literature, internal clinical research, and communications from the FDA and international governmental organizations that Allergan monitored, Allergan was aware of the clear connection between the recalled BIOCELL products and BIA-ALCL, and that its textured breast implants posed a significantly greater risk than competing textured breast implants.

79. Although Allergan knew or should have known that the recalled BIOCELL products posed a serious risk of bodily harm to consumers, Allergan continued to manufacture and market them to consumers and failed to comply with applicable FDA reporting and monitoring requirements.

80. Had Allergan properly and timely reported the adverse events to the FDA as required under federal law, material information regarding the true risk of the recalled BIOCELL products, including the substantially greater risk of developing BIA-ALCL, would have reached Plaintiff and her treating medical professionals in time to avoid her injuries.

81. Allergan knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of its failure to exercise ordinary care and comply with FDA reporting and monitoring requirements, including emotional distress.

82. As a direct result of Allergan's breach of duty, Plaintiff has suffered harm in an amount to be determined at trial, including severe emotional distress.

THIRD CAUSE OF ACTION
NEGLIGENT RECALL

83. Plaintiff re-alleges and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

84. 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.

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

86. 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.

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

FOURTH CAUSE OF ACTION
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

88. Plaintiff incorporates the above allegations by reference.

89. By operations of law, Allergan, as manufacturer of the recalled BIOCELL products and as the provider of the Limited Warranty, impliedly warranted to Plaintiff that the implants she was purchasing were of merchantable quality and safe for their ordinary and intended use in the human body as an aesthetic breast enhancement.

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

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

92. Allergan has refused to provide appropriate warranty relief, as it will not provide surgical fee assistance to patients notwithstanding the substantially increased risk

of developing BIA-ALCL. Plaintiff reasonably expected that her implants would not present a substantial risk of bodily harm at the time of purchase.

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

FIFTH CAUSE OF ACTION
VIOLATION OF THE CALIFORNIA UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §17200, *et seq.* ("UCL")

94. Plaintiff incorporate the above allegations by reference.

95. Plaintiff brings this claim on behalf of the California Subclass.

96. The UCL proscribes acts of unfair competition including "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200.

97. Allergan's conduct is unfair in violation of the UCL, because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

98. Allergan acted in an immoral, unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner, including as follows:

a. Selling recalled BIOCELL products that it knew to present a substantially greater risk of developing BIA-ALCL than competing textured breast implants;

b. Concealing the clear connection between its BIOCELL products and BIA-ALCL from the FDA, consumers, and medical professionals;

c. Failing to disclose that the recalled BIOCELL products have a substantially greater risk of developing BIA-ALCL than competing textured breast implants and;

d. Minimizing the scope of the risks associated with using the recalled BIOCELL products in communications with the public.

99. The gravity of harm resulting from Allergan's unfair conduct outweighs any potential utility. The practice of selling breast implants that present a substantial health

risk to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

100. The harm from Allergan's conduct was not reasonably avoidable by consumers because only Allergan was aware of the true facts concerning its BIOCELL implants and BIA-ALCL, and Allergan did not disclose them, despite receiving information establishing a causal connection between the BIOCELL products and BIA-ALCL from clinical testing, medical literature and studies, communications from the FDA and international agencies, and consumer complaints. Plaintiff did not know of and had no reasonable means of discovering the true risk of using BIOCELL implants.

101. There were reasonably available alternatives that would further Allergan's business interest of satisfying and retaining its customers while maintaining profitability, such as: (1) completely and accurately disclosing adverse events to the public; (2) acknowledging the significantly greater risk of BIA-ALCL with its recalled BIOCELL products and paying for surgery to remove the implants for patients with recalled implants; and (3) disclosing the true extent of the risk of BIA-ALCL to prospective purchasers.

102. Plaintiff suffered injury in fact, including lost money or property, as a result of Allergan's unfair acts. Absent Allergan's unfair conduct, Plaintiff would not have selected Allergan implants.

103. Through its unfair conduct, Allergan acquired money that Plaintiff once had an ownership interest in either directly or through Plaintiff's medical professionals.

104. Plaintiff accordingly seeks appropriate relief under the UCL, including (a) restitution in full and (b) such orders or judgments as may be necessary to enjoin Allergan from continuing its unfair practices. Plaintiff also seeks reasonable attorneys' fees and costs under applicable law, including California Code of Civil Procedure section 1021.5.

SIXTH CAUSE OF ACTION
MEDICAL MONITORING

105. Plaintiff incorporates the above allegations by reference.

106. As a result of exposure to the recalled BIOCELL products, the need for

future monitoring is reasonably certain. Allergan's textured implants significantly increase the risk of BIA-ALCL.

107. Medical monitoring is therefore reasonable in order to properly diagnose the symptoms of BIA-ALCL particularly as it can become fatal when not treated in a timely manner.

108. Plaintiff is therefore entitled to have Allergan pay for the costs of ongoing medical monitoring.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf all others similarly situated, request that the Court enter judgment against Defendants as follows:

A. An order certifying this action as a class action under Federal Rule of Civil Procedure 23, defining the Class as requested herein, appointing the undersigned as Class Counsel, and finding that Plaintiff is a proper representative of the Class herein;

B. Award Plaintiff compensatory, restitutionary, rescissory, general, consequential, punitive and/or exemplary damages in an amount to be determined at trial;

C. Enter an injunction against Allergan and its officers, agents, successors, employees, representatives, assigns, and any and all persons acting in concert with them, to: (1) ensure Allergan's compliance with California Business and Professions Code section 17200, *et seq.*; and (2) require them to implement a medical monitoring program for Plaintiff and class members;

D. Retain jurisdiction over this action to ensure Allergan complies with such a decree;

E. Enter other appropriate equitable relief;

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

G. Pre-judgment and post-judgment interest as provided by law; and

H. Such other and further relief that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury of all issues so triable.

AHDOOT & WOLFSON, PC

Dated: October 4, 2019

/s/ Tina Wolfson

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