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Clerk, U.S. District Court, ILCD

IN THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF ILLINOIS

LANA TAUBEN, on behalf of herself and all others similarly situated, Plaintiffs,	)	
v.	)	Case No. _____
ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., and ALLERGAN plc. Defendants.	)	CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Lana Tauben ("Plaintiff"), on behalf of herself and all others similarly situated, brings this action against Defendants Allergan, Inc., Allergan USA, Inc., and Allergan plc (hereinafter collectively "Allergan"). Allergan manufactures and sells BIOCELL saline-filled and silicone-filled breast implants and tissue expanders ("BIOCELL" or "BIOCELL textured implants"). Plaintiff alleges Allergan's BICOELL textured breast implants have increased her risk of developing breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"). 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 cases of BIA-ALCL.

PARTIES

1. Plaintiff was a citizen and resident of Champaign County, Illinois at all times relevant to this action.

2. Plaintiff has received two sets of implants from Allergan. She received her first set of implants in November 2016. However, these implants were removed in July 2017, because she

had significant problems with pain and swelling around the implants. During the second surgery to remove her implants, Plaintiff received a second set of implants. These implants were manufactured by Defendants and were the Naturelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants FX.

3. These implants were later recalled by the FDA on July 24, 2019. At the time of the procedure in July 2017, Plaintiff lived in Illinois. Plaintiff would not have had the recalled BIOCELL product implanted had she known prior to her surgery that the BIOCELL textured implants increased her risk of contracting BIA-ALCL, in addition to the costs associated with surgical removal of the implants. Plaintiff seeks removal of the BIOCELL textured implants at Defendants' full expense.

4. Defendant Allergan plc is a corporation with its headquarters in Dublin, Ireland. Defendant Allergan plc's principal place of business is located at: 5 Giralda Farms, Dodge Dr., Madison, New Jersey 07940.

5. Defendant Allergan, Inc., formerly known as Inamed Corporation and prior to that, McGhan Medical Corporation, is a wholly owned subsidiary of Allergan plc. Defendant Allergan, Inc., is incorporated under the laws of Delaware and has its principal place of business located at: 5 Giralda Farms, Dodge Dr., Madison, New Jersey 07940.[1] The research and development center, as well as the secondary manufacturing facility, for Allergan's BIOCELL textured implants is located in Santa Barbara, California.

[1] In March 2006, Allergen acquired Inamed and its wholly owned subsidiary McGhan for approximately $3.2 billion. During this acquisition, Allergen also acquired the BIOCELL trademark and assumed the risks associated with these products.

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

7. At all relevant times, each Defendant acted as the agent and alter ego of the other.

8. Any reference to "Allergan," "Defendant," or "Defendants" herein refers to each and every Defendant individually and collectively.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this matter pursuant to the Class Action Fairness Act, 28 U.C.S. § 1332, because the proposed class action: (1) has at least 100 class members; (2) the combined claims of class members exceeds $5,000,000.00, exclusive of interests, attorneys' fees, and costs; and (3) Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2).

10. This Court has specific personal jurisdiction over Allergan because Allergan conducts substantial business in Illinois and within this District. Allergan has sufficient minimum contacts with Illinois and intentionally avails itself of the consumers and markets within Illinois through the promotion and sale of the BIOCELL textured breast implants. Plaintiff's breast implant surgery using the BIOCELL textured implants manufactured by Allergan occurred in Illinois.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to these claims occurred in this venue.

FACTUAL ALLEGATIONS

Background

12. Breast implants are medical devices that are implanted under the breast tissue to increase breast size or replace breast tissue that has been removed. Tissue expanders are a type of inflatable breast implant which stretches skin and muscle to make room for a permanent implant in the future. Tissue expanders are often used in breast reconstruction surgeries.

13. Breast implants were first introduced in the 1960s. In 1976, Congress passed the Medical Device Amendment to the Federal Food, Drug and Cosmetic Act which allowed the FDA to review and approve new medical devices, including breast implants.

14. The FDA uses a three-tiered organizational system to classify medical devices, Class I, II, and III, based on the device's safety risks. Generally, the greater the safety risk, the greater the regulatory control asserted by the FDA and the higher the class listing. A Class I medical device has low to moderate risk to the user. Examples of Class I devices are elastic bandages, stethoscopes, and bedpans. A Class II medical device has a moderate to high risk to the user. Examples of a Class II medical device include electric powered wheelchairs and pregnancy test kits. A Class III medical device has a high risk to the patient or user. Examples of Class III devices are pacemakers and breast implants. Class III medical devices are considered, by the FDA, to create the greatest risk to human safety and necessitate the need for special controls. One of these special controls is the requirement to obtain premarket approval under 21 U.S.C. § 360 before marketing the device to the public. The premarket approval process allows the FDA to engage in scientific evaluations to determine if a Class III device is safe and effective.

The Product

15. In January 2011, the FDA identified a link between breast implants and BIA-ALCL. BIA-ALCL is a type of non-Hodgkin's lymphoma, a cancer of the immune system. BIA-ALCL is not breast cancer, although in most cases, BI-ALCL is found in the scar tissue and fluid near the breast implant. In some cases, the cancer will spread throughout the body to other systems.

16. The main symptoms of BIA-ALCL are persistent swelling or enlargement of a patient's breast or surrounding tissue that develops a year or more after breast implant surgery, lumps in the breast or armpit, pain, rash, redness, hardening of the breast, or changes in the shape or size of the breast.

17. BIA-ALCL is a serious cancer and can be fatal, especially if not diagnosed early or promptly treated.

18. BIA-ALCL can be treated by surgically removing the implant and surrounding scar tissue. Some patients may also require chemotherapy and radiation treatments.

19. The symptoms of BIA-ALCL may occur years after the implant placement.

20. The diagnostic testing recommended to determine if BIA-ALCL is present is invasive.

21. On July 24, 2019, the FDA issued a worldwide Class I Recall of BIOCELL textured implants. A Class I Recall is the most series type of recall and indicates that use of the recalled product may cause serious injury or death. The FDA issued this recall because the BIOCELL implants were tied to a large majority of cases of BIA-ALCL. The risk of developing BIA-ALCL is greatly increased if the patient has textured implants. The FDA announced the risk of BIA-ALCL in women with textured implants ranges from 1:3,817 and 1:30,000.

22. The FDA determined the risk of developing BIA-ALCL was six times higher with Allergan's BIOCELL textured implants when compared with textured implants from other manufacturers.

23. On July 24, 2019, in its recall statement, the FDA stated there are 573 cases of BIA-ALCL worldwide. Of those 573 cases, 33 people have died as a result of BIA-ALCL. This is a "significant increase" since the FDA's last update earlier in 2019 which found there were 116 new cases of BIA-ALCL and 24 deaths. Of the 573 individuals with BIA-ALCL, 481, or 83.9%, had Allergan's BIOCELL implants. Of the 33 deaths caused by BIA-ALCL, 12 of the 13 patients where the implant manufacturer was known had Allergan's BIOCELL textured implants.

24. The products affected by the FDA's recall are as follows:

- **Style Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled Mammary Implant). 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). 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**. 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 that have BIOCELL texturing originally cleared as:
  - Natrelle 133 Plus Tissue Expander (K143354)
  - Natrelle 133 Tissue Expander with Suture Tabs (K102806).

25. Prior to the FDA's recall on July 24, 2019, numerous studies documented the risk of developing BIA-ALCL in association with BIOCELL textured breast implants. The American Society of Plastic Surgeons estimates that the current risk of BIA-ALCL for women with textured implants ranges from 1:2,207 and 1:86,029. In March 2015, the French National Cancer Institute claimed "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant." On March 21, 2017, the FDA updated its 2011 warning and stated "[t]he risk of BIA-ALCL is higher for textured surface implants versus smooth surface implants."

26. In December 2018, Allergan's BIOCELL textured implants lost their European certification and were suspended from the European and Brazilian markets. Allergan textured implants were banned in France in April 2019. Allergan's BIOCELL textured implants were banned in Canada in May 2019.

The Warranty

27. On July 24, 2019, Allergan announced that BIOCELL textured breast implants would no longer be sold or distributed in any market.

28. On July 30, 2019, Allergan announced it has created a BIOCELL Replacement Warranty for all customers that currently have BIOCELL textured implants ("the Warranty"). The Warranty provides that Allergan will provide Allergan smooth implants to replace the BIOCELL textured implants. However, Allergan will not provide any surgical fee assistance or

reimbursement for the surgery to remove the BIOCELL textured implants and replace them with Allergan smooth implants. The Warranty will run for 24 months, until July 24, 2021, and will apply only to revision surgeries on or after the date of the FDA's recall, July 24, 2019.

29. The Warranty is insufficient because it does not provide for surgical fee assistance for breast implant revision and instead only provides free smooth Allergan implant replacement.

30. If a customer with a BIOCELL textured implant is diagnosed with BIA-ALCL, under the NATRELLE Confidence Plus Warranty, the customer will be reimbursed for diagnostic fees up to $1,000 and up to $7,500 in surgical fees related to diagnosing and treating BIA-ALCL.

31. The Confidence Plus Warranty is wholly insufficient as it applies to customers who are diagnosed with BIA-ALCL. The Warranty's reimbursement of $1,000 for diagnostic fees and $7,500 for surgical removal and cancer treatment is entirely too low concerning the expensive and invasive nature of surgery and cancer treatment.

32. As a result of Allergan's conduct, including refusal to pay for the removal of the recalled BIOCELL implants and the increased risk of developing BIA-ALCL, Plaintiff will be forced to expend substantial amounts of money for surgery, medical monitoring, diagnostic testing, and other medical expenses.

The Concealment

33. Manufacturers selling medical devices in the United States have continuing obligations to comply with medical device reporting requirements.

34. Consumers and medical personnel rely on the timely and accurate disclosures of information by medical device manufacturers in their decision making.

35. Breast implants are a Class III medical device.

36. The FDA requires that a Class III medical device receive premarket approval ("PMA") from the FDA before it can be marketed. A PMA application provides regulatory and scientific information to the FDA demonstrating the safety and effectiveness of the device. PMA is the strictest type of medical device marketing application due to the increased risk associated with Class III medical devices. A PMA application will not be approved if it is incomplete, inaccurate, inconsistent, omits critical information, or is poorly organized. If a Class III medical device fails to receive PMA, it cannot be marketed. The failure to comply with, or withhold information from, a PMA application is cause for withdrawal of the application.

37. 21 C.F.R. § 803.50(a) requires a manufacturer to report to the FDA any information that is reasonably known that may reasonably suggest a device may have caused or contributed to series injury or death within 30 calendar days after learning such information. Information is "reasonably known" if the information can be obtained by contacting "a user facility, importer or other initial reporter;" in the manufacturer's possession; or "can be obtain[ed] by analysis, testing, or other evaluation of the device." 21 C.F.R. § 803.50(b). If information is found, the manufacturer must investigate each reported event and evaluate the cause. *Id.*

38. Manufacturers selling medical devices in the United States must also provide periodic reports to the FDA, including "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably could be known to the applicant" and "[r]eports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant." 21 C.F.R. § 814.84.

39. The FDA publishes adverse events reports concerning findings of products in a database called the Manufacturer and User Facility Device Experience database ("MAUDE"). This database is available to the public.

40. Allergan's BIOCELL textured implants received premarket approval from the FDA in November 2006. After receiving premarket approval for a Class III device, a manufacturer has a duty to file adverse event reports with the FDA. 21 U.S.C. § 360(a)(1) and 21 C.F.R. § 803.50(a). The primary responsibility for timely and accurately reporting events to the FDA concerning the safety and effectiveness of a medical device is with the manufacturer. These reports are to be submitted to MAUDE.

41. Accordingly, Allergen is required to file adverse event reports with the FDA in connection with medical devices it produces. Allergen also is obligated to timely communicate any safety information concerning its medical devices to the FDA. Allergen is obligated to monitor all reasonably available information and clinical studies concerning its medical devices.

42. Allergan has known about the connection between its textured implants and the increased risk of developing BIA-ALCL since at least 2011. During the late 1990s and early 2000s, McGhan (later Inamed) began long-term clinical studies on their silicone breast implants. In 2000, Inamed, began a ten-year study to determine the safety and performance of the McGhan Medical RTV Saline-Filled Breast Implant. In 2006, Allergan purchased Inamed and began several long-term studies to assess the performance of their breast implants, including any health or safety risks, including cancer risks. Additionally, as a condition of this premarket approval, the FDA required Allergan to conduct six post-approval studies to determine the long-term safety of these implants.

43. However, Allergan did not disclose the connection between the BIOCELL textured implants and BIA-ALCL to the FDA or the public.

44. Allergan did not accurately report adverse events each time an injury or malfunction occurred concerning the BIOCELL textured implants.

45. Until 2017, Allergan buried evidence of ruptures and other injuries with its implants by reporting these as routine events that did not require any public disclosure. Allergan hid these incidents in "Alternative Summary Reports" ("ASR"), which are not required to be reported to MAUDE. The ASR program was intended to exclude severe or unexpected events or injuries. Severe or unexpected events or injuries are required to be reported through MAUDE.

46. Allergan manipulated the ASR program to hide these serious events from public disclosure.

47. Allergen used the ASR program to disclose adverse event reports that were required to be disclosed to the public through MAUDE.

48. Allergen buried serious events in non-public ASR reports, including a possible case of BIA-ALCL.

49. Further substantiating that severe breast implant events were buried in the ASR program, the FDA began implementing more rigorous reporting requirements in 2017 and there was a dramatic increase in the number of adverse events related to breast implant injuries – from 200 in a single year to 4,567 in 2017 and 8,242 in the first six months of 2018.

50. The FDA even acknowledges there was a "transparency issue" until recently with the reporting of adverse event reports. The FDA said the increase in adverse event reports reflected the FDA's implemented change in reporting requirements in 2017 and not "a new public health issue."

51. The FDA relies on accurate reporting of adverse events to monitor the safety of medical devices. The general public, medical personnel, and researchers rely on MAUDE to monitor the safety of medical devices.

52. Because Allergan deceptively and inaccurately used ASR instead of MAUDE to report adverse incidents, Allergan misled the FDA, medical personnel, researchers, its customers, and the general public. As a result, Allergan's customers were exposed to harm.

53. Additionally, Allergan did not report to the FDA adverse events from its required post-market approval studies. These post-market approval studies indicate that the recalled BIOCELL textured implants have caused or contributed to death and/or serious injury by increasing the risk of BIA-ALCL.

54. Allergan continuously received new information showing the connection between its textured breast implants and the significantly increased risk of developing BIA-ALCL.

55. Allergan failed to comply with the conditions of the PMA application.

56. Allergan violated federal law by failing to accurately and promptly report adverse events.

57. Allergan also violated applicable state laws, which do not impose duties or requirements different from those imposed by federal law. Therefore, under both state and federal law, Allergan was required to promptly report any information indicative of a serious injury associated with one of its medical devices.

58. Because Allergan failed to file adverse event reports, consumers, medical personnel, and the FDA were unable to detect trends in Allergan's products. This deprived the market and consumers of the information necessary to make an informed decision about whether Allergan's products were safe and effective.

59. If Allergan had complied with its obligations under federal law, the disclosure of the risk of BIA-ALCL and BIOCELL textured implants would have allowed Plaintiff and her surgeon to make an informed decision whether to use the BIOCELL implants.

60. Allergan acted recklessly and with intentional disregard for the safety of Plaintiff and its customers.

61. In addition to Allergan's failure to comply with reporting requirements, Allegan continued to distribute the textured implants commercially. This distribution was a violation of federal law.

CLASS ALLEGATIONS

62. Plaintiff brings this action on her own behalf and on behalf of the following class pursuant to the Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

> All individuals with implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA while in Illinois.

63. Excluded from the Class are Allergan, their parents, subsidiaries, affiliates, officers and directors, any entity in which Allergan has a controlling interest, all class members who timely elect to be excluded, governmental entities, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members. Plaintiff reserves the right to modify, change, or expand the class definition based on facts learned through discovery and further investigation.

64. Numerosity: Members of the Class are so numerous that individual joinder is impracticable. Plaintiff is informed to believe the proposed Class contains at least thousands of individuals who have the recalled BIOCELL textured breast implants. Therefore, the Class is sufficiently numerous to make joinder impracticable, if not impossible. While the precise number

of Class members is unknown to Plaintiff at this point, the Class members are readily ascertainable and can be identified via Allergan's records.

65. Existence and Predominance of Common Questions of Law and Fact: Common questions of law and fact exist to all members of the Class. These questions predominate over question affecting only individual Class members. These common legal questions include, but are not limited to:

- Whether Allergan was negligent in selling the BIOCELL textured implants;
- Whether Allergan failed to warn consumers of the risks associated with the BIOCELL textured implants;
- Whether Allergan violated federal standards and requirements for the marketing, warning, and reporting of the recalled BIOCELL products;
- Whether Allergan breached implied warranties connected with the recalled BIOCELL products;
- Whether Allergan's conduct constitutes unfair acts or practices under Illinois law;
- Whether Plaintiff and Class members are entitled to equitable relief, including injunctive relief; and
- Whether Plaintiff and Class members are entitled to damages and monetary relief, and if so, in what amount.

These questions, as well as others, are common to the Class and predominate over questions affecting only individual members of the Class.

66. Typicality: Plaintiff's claims are typical of the claims of all members of the Class who have the recalled BIOCELL textured breast implants.

67. Adequacy: Plaintiff is an adequate representative of the Class because Plaintiff's interests do not conflict with the interests of the Class that Plaintiff seeks to represent. Plaintiff's counsel is highly experienced in complex class action litigation. The interests of the Class will be fairly and adequately represented by Plaintiff and her counsel.

68. Superiority: A class action is the superior method for fair and efficient adjudication. The injuries suffered by each Class member is relatively small in comparison with the burden, expense, and time dedicated to individual prosecution. The litigation will be complex and extensive, and it would be very difficult for the Class to individually redress Allergan's actions. Further, individual litigation poses a risk of inconsistent or contradictory judgments and increases the delay and expense to all parties and the courts. Class actions present far less management difficulties and provides judicial efficiency and removes the risk of inconsistent judgments in courts.

69. 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.

CAUSES OF ACTION

COUNT I
STRICT LIABILITY – FAILURE TO WARN

70. Plaintiff incorporates the above allegations by reference.

71. Allergan manufactured, distributed, and/or sold the BIOCELL textured breast implants that Plaintiff has.

72. Allergan had a duty to warn Plaintiff and her physician about the significantly increased risk of developing BIA-ALCL in connection with the BIOCELL textured implants.

73. Allergan knew, or should have known in the exercise of ordinary care, that the BIOCELL textured breast implants were unreasonably dangerous at the time the implants left Allergan's control and were received by Plaintiff, and their unreasonably dangerous nature was not generally known to the consumer. Allergan acquired this knowledge from the performance of extensive studies, reviewing other scientific studies, complaints received from consumers, as well as other sources. Further, the BIOCELL textured breast implants' health risks were known in the scientific and medical community at the time of their manufacture, distribution, or sale.

74. Allergan, in violation of federal law, attempted to conceal this information by not making adverse event reports to the FDA.

75. Allergan, in violation of federal law, filed ASR reports to avoid the public reporting of adverse event reports on MAUDE.

76. The BIOCELL textured breast implants were defective and unreasonably dangerous at the time they left Allergan's possession because they did not contain adequate warnings, including the lack of warning concerning the significantly increased risk of developing BIA-ALCL associated with the BIOCELL textured implants.

77. Allergan failed to warn Plaintiff and her physician about the dangers of the BIOCELL textured breast implants.

78. Plaintiff and ordinary consumers would not have recognized the potential for the risk of developing BIA-ALCL from the BIOCELL textured breast implants.

79. The potential risks of the BIOCELL textured implants presented and continue to present a substantial danger to Plaintiff and ordinary consumers when used or misused in an intended or reasonably foreseeable way.

80. Allergan failed to adequately warn or instruct concerning the risks of BIOCELL textured breast implants.

81. It was foreseeable that Allergan's failure to adequately warn about the risks associated with the BIOCELL textured breast implants would cause irreparable harm to those who had the products implanted, including the types of emotional distress incurred by Plaintiff.

82. As a result of Allergan's failure to adequately warn of the risks associated with BIOCELL textured implants, Plaintiff was harmed as described herein including physical pain and emotional distress. The lack of sufficient warning was a substantial factor in causing Plaintiff's harm. Had Plaintiff and her physician been provided the appropriate warnings about the increased risk of BIA-ALCL associated with BIOCELL textured breast implants, Plaintiff and her physician would have been able to make an informed decision about using the product or an selecting an alternative product.

83. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT II
NEGLIGENCE

84. Plaintiff incorporates the above allegations by reference.

85. Allergan has a continuing duty to monitor its medical devices, including the BIOCELL textured breast implants, and report any complaints or findings about product performance and safety to the FDA timely and accurately. Allergan also has a continuing duty to provide warnings and instructions regarding potential safety hazards associated with the use of its products.

86. Allergan breached these duties by failing to provide timely and adequate reports regarding potential safety hazards associated with the use of the BIOCELL textured breast implants, including the increased risk of developing BIA-ALCL. Allergan was on notice to this

risk through adverse reports, consumer complaints, scientific research and literature, internal clinical research, and communications from the FDA and international governmental organizations that Allergan monitored.

87. Allergan was aware that Allergan's brand of implants imposed a significantly greater risk than competing textured breast implants for the development of BIA-ALCL.

88. Allergan's breach of its duty to warn has caused Plaintiff damages including surgical costs for removal of the BIOCELL textured breast implants, medical monitoring, invasive diagnostic procedures, and other medical expenses.

89. By submitting misleading adverse event reports and concealing the risks associated with the BIOCELL textured breast implants, Allergan negligently violated its duty of care to Plaintiff.

90. Although Allergan knew, or should have known, of the increased risk of BIA-ALCL associated with the BIOCELL textured breast implants and the significant risk of harm to consumers, Allergan continued to manufacture and market the BIOCELL textured breast implants to the public.

91. Allergan failed to comply with applicable FDA and reporting requirements.

92. If Allergan had properly and timely reported the adverse events to the FDA as required under federal law, Plaintiff and her physician would have become aware of the significantly increased risk of developing BIA-ALCL with the BIOCELL textured breast implants in time to avoid her injuries.

93. Allergan knew or should have known that consumers like Plaintiff would foreseeably suffer injuries as a result of Allergan's failure to exercise ordinary care and comply with the FDA's reporting requirements, including emotional distress.

94. Allergan's breach of duty caused Plaintiff damages in the form of surgical costs for removal of the products, medical monitoring, and/or invasive diagnostic procedures associated with the BIOCELL© textured breast implants.

95. As a direct and proximate result of Allergan's breach of duty, Plaintiff and the Class have suffered harm in an amount to be determined at trial, including severe emotional distress.

COUNT III
NEGLIGENT RECALL

96. Plaintiff incorporates the above allegations by reference.

97. On July 24, 2019, the FDA requested that Allergan recall the BIOCELL textured breast implants in the United States.

98. On that same day, Allergan issued a worldwide recall of the BIOCELL textured breast implants.

99. By issuing a recall, Allergan assumed duties to Plaintiff to exercise reasonable care in issuing and implementing the recall.

100. Allergan breached its duty by failing to adequately warn Plaintiff of the increased risk of developing BIA-ALCL in connection with the BIOCELL textured breast implants.

101. Allergan breached its duty by refusing to pay for the surgical removal of Plaintiff's implants despite the increased risk of developing BIA-ALCL associated with her implants.

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

COUNT IV
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

103. Plaintiff incorporates the above allegations by reference.

104. Allergan is a manufacturer and seller of the BIOCELL textured breast implants.

105. As the manufacturer, Allergan impliedly warranted to Plaintiff that the implants were of merchantable quality and safe for their ordinary and intended use.

106. Allergan breached the implied warranty of merchantability in connection with the sale and distribution of the BIOCELL textured breast implants because the products, at the time of sale, contained hidden flaws that rendered them unsafe for their ordinary use.

107. If Plaintiff had known the BIOCELL textured breast implants were unsafe for ordinary use, they would not have chosen them for purchase. It was reasonable for Plaintiff not to know that the BIOCELL textured breast implants would present an increased risk of developing BIA-ALCL at the time of their purchase.

108. Allergan has refused, and continues to refuse, to provide adequate warranty relief because Allergan will not pay for surgery for customers, including Plaintiff, to have the BIOCELL textured breast implants removed.

109. 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.

COUNT V
ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

110. Plaintiff incorporates the above allegations by reference.

111. Allergan engaged in unlawful and deceptive acts and practices concerning the sale of the BIOCELL textured breast implants in violation of federal law and the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS § 505/10a.

112. Allergan concealed the true risks of the BIOCELL textured breast implants.

113. Allergan's actions were negligent, knowing and willful, and/or wanton or reckless with respect to the rights of Plaintiff and the Class.

114. Allergen intended Plaintiff to rely on the concealment of the increased risk of BIA-ALCL in an effort to encourage sales of the BIOCELL textured implants.

115. Plaintiff and the Class would not have purchased, chosen, or paid for all or part of the BIOCELL textured breast implants if they knew they would have a significantly higher risk of developing BIA-ALCL.

116. As a direct and proximate result of Allergan's deceptive actions, Plaintiff and the Class suffered an ascertainable loss of money or property, including the costs associated with removal of the BIOCELL textured breast implants, diagnostic fees, and medical monitoring costs associated with retention of the products.

117. Plaintiff Class seek relief under the ICFA, including but not limited to, injunctive relief, damages, restitution, punitive damages, attorneys' fees, and costs.

COUNT VI
MEDICAL MONITORING

118. Plaintiff incorporates the above allegations by reference.

119. Medical monitoring is, to a reasonable degree of medical certainty, required to detect the BIA-ALCL cancer in Plaintiff.

120. Medical monitoring is reasonable to properly diagnose the symptoms of BIA-ALCL. This is particularly important because BIA-ALCL is less likely to be fatal if diagnosed and treated early in the disease's progression.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests, individually and on behalf of the Class, that this Court:

A. Certify the Class under Fed. R. Civ. P. 23(a), (b)(1), (b)(2), (b)(3), and/or (c)(4), as appropriate; appoint Plaintiff as Class Representative; and appoint the undersigned counsel as Class Counsel;

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

C. Award prejudgment interest as permitted by law;

D. 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 the Illinois Consumer Fraud and Deceptive Business Practices Act, and (2) require them to implement a medical monitoring program for Plaintiffs and Class members;

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

F. Enter other appropriate equitable relief;

G. Award pre-judgment interest and post-judgment interest on such monetary relief; and

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

DEMAND FOR JURY TRIAL

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

DATE: September 20, 2019

Respectfully submitted:

THE BAUMSTARK FIRM LLC

/s/ Luke A. Baumstark
Luke A. Baumstark, IL Bar No: 6301453
815 Geyer Avenue
St. Louis, Missouri 63104
Tel: (314) 492-6290
Fax: (314) 492-6348
luke@baumstarkfirm.com

-and-

Matthew L. Dameron (*pro hac vice forthcoming*)
Courtney M. Stout (*pro hac vice forthcoming*)
WILLIAMS DIRKS DAMERON LLC
1100 Main Street, Suite 2600
Kansas City, Missouri 64105
Tel: (816) 945-7110
Fax: (816) 945-7118
matt@williamsdirks.com
cstout@williamsdirks.com

-and-

Mandy M. Shell (*pro hac vice forthcoming*)
SHELL LAW & TAX
1656 Washington, Suite 140
Kansas City, Missouri 64108
Tel: (816) 399-5030
Fax: (816) 205-8420
mshell@shell-law.com
Attorneys for Plaintiff and the Proposed Class