UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

STEPHANIE GRAYSON OHLER,	*	**CIVIL ACTION**
Plaintiff,	*	
	*	**No.**
versus	*	
	*	**JUDGE**
ALLERGAN USA, INC.,	*	
Defendant.	*	**MAGISTRATE JUDGE**

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COMPLAINT FOR DAMAGES

NOW INTO COURT, through undersigned counsel, comes Stephanie Grayson Ohler ("Plaintiff"), who in her original Complaint for Damages alleges as follows:

I. PARTIES

1. Stephanie Grayson Ohler ("Plaintiff"), at all times relevant, was/is a person of the full age of majority and a resident citizen of the State of Louisiana.

2. Allergan USA, Inc. ("Defendant") is a foreign corporation organized and existing under the laws of the State of Delaware, with its principal place of business located in Madison, New Jersey. At all times relevant, Allergan USA, Inc. was licensed to "do business," in the State of Louisiana.

II. SUBJECT MATTER JURISDICTION

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

III. PERSONAL JURISDICTION

4. Allergan USA, Inc. marketed, advertised, and sold medical devices, including its Natrelle BIOCELL Textured Breast Implants and Tissue Expanders in the Eastern District of Louisiana, which products were implanted into Plaintiff in the Eastern District of Louisiana. Because of these "minimum contacts," the assumption of jurisdiction over Allergan USA, Inc. will not offend traditional notions of fair play and substantial justice, and is fully consistent with the constitutional requirements of due process set forth in *International Shoe v. Washington*, 326 U.S. 310, 66 S.Ct. 154, 90 L.Ed.2d 95 (1945).

IV. VENUE

5. Venue is appropriate in the Eastern District of Louisiana pursuant to 28 U.S.C. § 1391(b)(2) because this is the District where a substantial part of the events or omissions giving rise to the claim occurred, including medical device implantation, as well as where a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred, and the cause of action arose.

V. FACTS REGARDING DEFENDANT'S BREAST IMPLANT PRODUCTS

Background

6. 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 pre-market approval under 21 U.S.C. § 360 before marketing the device to the public. The pre-market approval process allows the FDA to engage in scientific evaluations to determine if a Class III device is safe and effective.

7. 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, BIA-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.

8. 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.

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

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

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

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

The Product

13. 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 indicated 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.

14. 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.

15. 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.

16. Among the products affected by the FDA's recall are those implanted into Plaintiff, Allergan's Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile).

17. 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."*

18. 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

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

20. 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.

21. 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.

22. 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.

23. 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.

24. 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

25. Manufacturers selling medical devices in the United States have continuing obligations to comply with medical device reporting requirements. Consumers and medical personnel rely on the timely and accurate disclosures of information by medical device manufacturers in their decision making.

26. Breast implants are a Class III medical device.

27. 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. 35.21 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.*

28. 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 non-clinical 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.

29. 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.

30. 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.

31. 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.

32. 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.

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

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

35. 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.

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

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

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

39. 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.

40. 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."

41. 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.

42. 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.

43. 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.

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

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

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

47. 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.

48. 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.

49. 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 or select another product.

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

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

federal law.

VI. FACTS SPECIFIC TO PLAINTIFF

52. On January 31, 2014, Plaintiff underwent breast implant procedures performed by Brian Strand, M.D., at St. Tammany Hospital in Covington, Louisiana.

53. During the procedure, Dr. Strand implanted two of Defendant's Style 168 Natrelle BIOCELL rough textured saline-filled breast implants (the "product") into Plaintiff's body.

54. Plaintiff now suffers pain in the area of both breast implants, a known symptom of breast-implant associated anaplastic large cell lymphoma ("BIA-ALCL"), a type of non-Hodgkin's lymphoma (*i.e.*, cancer of the immune system).

55. Because of Medical Device Reports ("MDRs") reporting worldwide cases of BIA-ALCL and BIA-ALCL-related deaths associated with use of Allergan's BIOCELL textured breast implants, the U.S. Food and Drug Administration ("FDA") requested that Allergan recall its BIOCELL textured breast implants and tissue expanders.

56. Allergan has complied with the FDA's request and is removing these products from the global market. These products have the same BIOCELL textured surface (shell) which is a unique surface used only by Allergan.

57. During the first week of August 2020, while watching the cable channel television show "Botched," Plaintiff's mother Paula Townson viewed an episode concerning breast implant rejection. Ms. Townson then contacted her daughter (Plaintiff) to learn the make and style

of her daughter's breast implants. Ms. Townson then went online and learned of this medical product's association with breast-implant associated anaplastic large cell lymphoma ("BIA-ALCL").

58. During the week of August 24, 2020, Ms. Townson viewed a different episode of "Botched" during which the plastic surgeon physician informed his patient about rough-textured breast implants risk of cancer and told the patient that the implants needed to be removed as soon as possible. Ms. Townson promptly contacted the Plaintiff and informed her of this information. As a result, Plaintiff is presently scheduled to have her Style 168 Natrelle BIOCELL rough textured saline-filled breast implants removed on September 25, 2020.

59. Plaintiff has not received a copy of Allergan's August 9, 2019 letter advising of the FDA recall and of the cancer risk associated with its rough textured breast implants.

60. Plaintiff has suffered great anxiety after learning of very significant her risk of contracting breast-implant associated anaplastic large cell lymphoma.

VII. CAUSES OF ACTION

61. A claim for defect in construction or composition arises when a product is defective due to a mistake in the manufacturing process. The Louisiana Products Liability Act ("LPLA"), La. R.S. § 9:2500.51 *et seq*., does not create any manufacturing standards which are in addition to or alternative to those (if any) imposed by the FDA. Instead, the LPLA creates a parallel state law method of recovery for damages proximately caused by a characteristic of the product that rendered it unreasonably dangerous when such danger arose from a reasonable anticipated use of the product by the Plaintiff.

A. FIRST CAUSE OF ACTION UNDER LA. R.S. 9:2800.55:

UNREASONABLY DANGEROUS IN CONSTRUCTION OR COMPOSITION

62. Plaintiff repeats and re-alleges all of the above paragraphs as if each were set forth again *in extenso*.

63. The U.S. Food and Drug Administration, at 21 C.F.R. § 878.3540(a)(1), defines a "single-lumen" silicone gel-filled breast prosthesis as follows:

> "A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shall made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, filler, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to augment or reconstruct the female breast."

64. The U.S. Food and Drug Administration, at 21 C.F.R. § 878.3540© required "pre-market" approval of Defendant's *NATRELLE*® Silicone-Filled Breast Implants Smooth & BIOCELL® Texture before this product could be commercially distributed:

> "Date premarket approval application (PMA) is required. A PMA is required to be filed with the Food and Drug Administration on or before July 9, 1991 for any silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 9, 1991 been found to be substantially equivalent to a silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone gel-filled breast

prosthesis shall have an approved PMA in effect before being placed in commercial distribution."

65. Consistent with 21 C.F.R. § 878.3540©, Defendant, at page 4 of its April 6, 2009 "Directions for Use" of its *NATRELLE*® Silicone-Filled Breast Implants Smooth & BIOCELL® Texture initially described its product as follows:

> "*NATRELLE*® Silicone-Filled Breast Implants are constructed with barrier shell technology resulting in a low diffusion silicone elastomer shell and filled with a soft, cohesive silicone gel. All styles are single "lumen" round design and consist of a shell, a patch, and silicone gel fill. "*NATRELLE*® Silicone-Filled Breast Implants are dry heat sterilized and are available in both smooth and BIOCELL® surface texture."

66. Defendant, at page 5 of its February 13, 2013 "Directions for Use" for its BIOCELL® Texture "Natrelle Style 410 FX" breast implants,[1] updated the description of its product to differentiate between types of internal silicone gel, as follows:

> "***NATRELLE***®410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants are constructed with barrier shell technology and filled with a highly cohesive silicone gel. Allergan has approval for 2 types of silicone gel fillers: cohesive silicone gel and highly cohesive silicone gel. Allergan's cohesive silicone gel is softer than

[1] *See* the Directions for Use (Rec. Doc. 5-4), which is Exhibit "C" to Defendant's Motion to Dismiss (Rec. Doc. 5).

> Allergan's highly cohesive silicone gel. ***NATRELLE***® 410 Breast Implants are anatomically shaped and consist of a shell, patch, and highly cohesive silicone gel fill."

67. Based upon the foregoing representations by Defendant, on February 20, 2013 the U.S. Food and Drug Administration wrote that it had completed its review of the pre-market approval application ("PMA") for the "NATRELLE® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants", and informed Defendant that:

> "We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described above."

68. La. R.S. 9:2800.55 provides as follows:

> "A product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer.**"**

69. At the time it left Defendant's control, the NATRELLE® 410 device implanted into Plaintiff's right breast area deviated in a material way from other breast implants that had been approved by the U.S. Food and Drug Administration because this type of implant is associated with the development of anaplastic large cell lymphoma ("BIA-ALCL"), a type of non-Hodgkin's lymphoma (*i.e.*, cancer of the immune system) in women who have it implanted.

COUNT I

Manufacturing Defect Pursuant to La. R.S. 9:2800.55

70. Plaintiff incorporates the above allegations by reference.

71. Allergan designed, developed, tested, promoted, marketed, labeled, manufactured, distributed, and/or sold the BIOCELL textured implants that were implanted in Plaintiff.

72. Allergan had a duty to manufacture, design, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the BIOCELL textured implants with reasonable and due care for the safety and well-being of users, including Plaintiff.

73. The BIOCELL textured implants were defective and were in a condition that made them unreasonably dangerous *before* the implants left Allergan's possession, *i.e.*, they featured a condition that prompted the development of anaplastic large cell lymphoma ("BIA-ALCL"), a type of non-Hodgkin's lymphoma in women who have them implanted.

74. The manufacturing defect rendered all recalled models different from Allergan's intended result or from other identical units of the same product line. In particular, the recalled BIOCELL implants are not safe, have numerous and serious side effects, and cause severe and permanent injuries.

75. There are no specifications or performance standards for the manufacture of BIOCELL textured implants which included the causation of anaplastic large cell lymphoma ("BIA-ALCL"), a type of non-Hodgkin's lymphoma in women who have it implanted. Therefore, these implants were defective *ab initio*.

76. At the time the BIOCELL textured implants left Allergan's control, the implants contained

a physical characteristic which included the causation of anaplastic large cell lymphoma ("BIA-ALCL"), a type of non-Hodgkin's lymphoma in women who have it implanted.

77. At the time the BIOCELL textured implants left Allergan's control, the implants deviated in a material way from the other breast implant products manufactured by Allergan.

78. As a result of Allergan's defective construction or composition of BIOCELL textured implants, Plaintiff suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, fear of cancer and mental anguish, medical expenses, loss of enjoyment of life, lost wages, and ongoing medical monitoring costs.

COUNT II

Design Defect Pursuant to La. R.S. 9:2800.56

79. Plaintiff incorporates the above allegations by reference.

80. Allergan designed, developed, tested, promoted, marketed, labeled, manufactured, distributed, and/or sold the BIOCELL textured implants that were implanted in Plaintiff.

81. At all times relevant to this action, Allergan had a duty to manufacture, design, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the BIOCELL textured implants with reasonable and due care for the safety and well-being of users, including Plaintiff.

82. Plaintiff was a foreseeable user of BIOCELL textured implants.

83. The BIOCELL textured implants are defective in that the design of the implants causes an increased risk of developing BIA-ALCL.

84. The BIOCELL textured breast implants are defective because their risks and dangers outweigh any purported benefit.

85. At the time the BIOCELL textured implants left Allergan's control, Allergan knew that the defective condition of the implants made them unreasonably dangerous to users, including Plaintiff.

86. The BIOCELL textured implants were unreasonably dangerous when used by an ordinary user who used the implants as they were intended to be used, including Plaintiff.

87. Plaintiff could not, by the exercise of reasonable care, have discovered the defects of the BIOCELL textured implants mentioned herein.

88. The BIOCELL textured implants were dangerous to an extent beyond which would be contemplated by the ordinary user who purchased and/or used the products, including Plaintiff, because the design of the BIOCELL textured implants causes an increased risk of developing BIAALCL.

89. At the time that the BIOCELL textured implants left Allergan's control, an alternative design for the products existed that was capable of preventing Plaintiff's damages, and the gravity of the damage outweighed the minimal burden on Allergan of adopting such an alternative design.

90. As a result of Allergan's defective design of the BIOCELL textured breast implants, Plaintiff suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, mental anguish, medical expenses, surgical costs of removal of the products, loss of enjoyment of life, lost wages, and ongoing medical monitoring costs.

COUNT III

Failure to Warn Pursuant to La. R.S. 9:2800.57

91 Plaintiff incorporates the above allegations by reference.

92. Allergan designed, developed, tested, promoted, marketed, labeled, manufactured, distributed, and/or sold the BIOCELL textured implants that were implanted in Plaintiff.

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

94. Allergan knew, or should have known in the exercise of ordinary care, that the BIOCELL textured implants were unreasonably dangerous at the time the implants left Allergan's control and were received by Plaintiff, and the unreasonably dangerous nature of the implants was not generally known to the consumer.

95. Allergan failed to warn Plaintiff and her physicians about the dangers of the BIOCELL textured breast implants, *including the far greater comparative risk of using its implants versus competitors' implant products*, and the greatly increased risk of BIA-ALCL.

96. Allergan acquired this knowledge from the performance of extensive decades-long clinical studies, reviewing other scientific studies and literature, FDA communications, government reports, and complaints received from consumers, as well as other sources.

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

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

99. The BIOCELL textured breast implants were defective and unreasonably dangerous at the time the implants left Allergan's possession because the implants 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.

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

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

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

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

104. 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.

105. Had Plaintiff and her physician been provided the appropriate warnings about the increased risk of BIA-ALCL associated with BIOCELL textured breast implants, *and particularly the far greater comparative risk of using its implants versus competitors' implant products,* the Plaintiff and her physician would have been able to make an informed decision about using the product or selecting an alternative product.

106. As a result of Allergan's failures to adequately warn, Plaintiff suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, mental anguish, medical expenses, surgical costs of removal of the products, loss of enjoyment of life, lost

wages, and ongoing medical monitoring costs.

COUNT IV

Breach of Express Warranty Pursuant to La. R.S. 9:2800.58

107. Plaintiff incorporates the above allegations by reference.

108. Allergan designed, developed, tested, promoted, marketed, labeled, manufactured, distributed, and/or sold the BIOCELL textured implants that were implanted in Plaintiff.

109. Allergan expressly represented to Plaintiff, other consumers, and the medical community that the BIOCELL textured implants were safe and fit for their intended purposes, were of merchantable quality, did not produce any dangerous side effect, and had been adequately tested.

110. BIOCELL textured implants do not conform to Allergan's express representations because the products are not safe, have numerous and serious side effects, and cause severe and permanent injuries, including causing cancer.

111. At the time of the making of the express warranties, Allergan knew or should have known of the purpose for which the product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose.

112. The BIOCELL textured implants were unreasonably dangerous because the implants failed to conform to an express warranty of Allergan as provided by La. R.S. 9:2800.58.

113. At the time of the making of the express warranties, Allergan 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, like Plaintiff.

114. At all relevant times, BIOCELL textured implants did not perform as safely as an ordinary consumer and the medical community would expect, when used as intended or in a reasonably foreseeable manner.

115. Plaintiff, other consumers, and the medical community relied upon Allergan's express warranties.

116. Members of the medical community, including physicians and other healthcare providers, relied upon the representations and warranties of Allergan for use of BIOCELL textured implants.

117. Allergan breached the aforesaid express warranties, as its product was defective.

118. As a result of Allergan's breach of express warranty, Plaintiff suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, mental anguish, medical expenses, surgical costs of removal of the products, loss of enjoyment of life, lost wages, and ongoing medical monitoring costs.

COUNT V

Breach of Implied Warranty of Merchantability and Fitness

119. Plaintiff incorporates the above allegations by reference.

120. Allergan designed, developed, tested, promoted, marketed, labeled, manufactured, distributed, and/or sold the BIOCELL textured implants that were implanted in Plaintiff.

121. Allergan impliedly represented and warranted to the users of BIOCELL textured implants and their physicians, healthcare providers, and/or the FDA that BIOCELL textured implants were safe and merchantable quality and fit for the ordinary purpose for which said products were used.

122. At all relevant times, Allergan knew of the use for which BIOCELL textured implants were intended and impliedly warranted the products to be of merchantable quality and safe for such use.

123. Allergan was aware that consumers, including Plaintiff, would use BIOCELL textured implants in the manner intended.

124. Plaintiff, her physicians, and the medical community reasonably relied upon the judgment and sensibility of Allergan to sell BIOCELL textured implants only if the products were indeed of merchantable quality and safe for their intended use.

125. Allergan breached the implied warranty to consumers, including Plaintiff, as BIOCELL textured implants were not of merchantable quality or safe and fit for their intended use.

126. Consumers, including Plaintiff, and the medical community, reasonably relied upon Allergan's implied warranty for BIOCELL textured implants.

127. BIOCELL textured implants reached consumers, including Plaintiff, without substantial change in the condition in which the implants were manufactured and sold by Allergan.

128. The aforementioned representations and warranties were false, misleading, and inaccurate in that BIOCELL textured implants were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

129. BIOCELL textured implants were placed into the stream of commerce by Allergan in a defective, unsafe, and inherently dangerous condition and the implants were expected to and did reach users without substantial change in the condition in which the implants were sold.

130. Allergan breached the aforesaid implied warranties, as their BIOCELL textured implants were not fit for their intended purposes or uses.

131. As a result of Allergan's breach of implied warranty, Plaintiff has suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, mental anguish, medical expenses, surgical costs of removal of the products, loss of enjoyment of life, lost wages, and ongoing medical monitoring costs.

COUNT VI

Redhibition

132. Plaintiff incorporates the above allegations by reference.

133. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520.

134. Allergan sold and promoted BIOCELL textured implants, and BIOCELL textured implants possess a redhibitory defect because the products were not manufactured and marketed in accordance with industry standards and/or were unreasonably dangerous, as described above, which renders the products useless or so inconvenient that it must be presumed that the buyer would not have bought the products had she known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the products.

135. BIOCELL textured implants alternatively possess a redhibitory defect because the products were not manufactured and marketed in accordance with industry standard and/or were unreasonably dangerous, as described above, which diminishes the value of the products so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction in the purchase price of the products.

136. As the manufacturer of the products, under Louisiana law, Allergan is deemed to know that BIOCELL textured implants possessed a redhibitory defect. La. C.C. art. 2545.

137. Allergan is liable as a bad faith seller for selling defective products with knowledge of the defects, and thus, is liable to Plaintiff for the price of the products, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the products, and attorney's fees.

138. As a result of the redhibitory defects of Allergan's BIOCELL implants, Plaintiff has suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, mental anguish, medical expenses, surgical costs of removal of the products, loss of enjoyment of life, lost wages, and ongoing medical monitoring costs.

COUNT VII

Breach of Warranty of Fitness for Ordinary Use

139. Plaintiff incorporates the above allegations by reference.

140. In addition to warranting against redhibitory defects, Allergan warranted that BIOCELL textured implants were reasonably fit for their ordinary and intended use. La. C.C. art. 2524.

141. BIOCELL textured implants are not safe, have numerous and serious side effects, and cause severe and permanent injuries. As a result, Allergan's products are unfit and inherently dangerous for ordinary use.

142. As a result of Allergan's breach of warranty of fitness for ordinary use, Plaintiff has suffered damages and harm, including, but not limited to, personal injury, physical pain and suffering, mental anguish, medical expenses, surgical costs of removal of the products, loss of enjoyment of life, lost wages, and ongoing medical monitoring costs.

COUNT VIII

Medical Monitoring

143. Plaintiff incorporates the above allegations by reference.

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

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

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

VIII. JURY DEMAND

147. Plaintiff hereby demands a trial by jury as to all claims in this action.

IX. PRAYER FOR RELIEF

148. **WHEREFORE**, Plaintiff, Stephanie Grayson Ohler, prays that Defendant, Allergan USA, Inc., be served with Summons and a copy of the Complaint for Damages, that it serve its Answer thereto, and that after due proceedings had and the expiration of all legal delays:

A. That there be a Judgment entered holding Defendant liable unto Plaintiff for all money damages that are allowed by law, which are reasonable under these premises, exceed the sum or value of $75,000.00 exclusive of interest and costs, and include but not limited to general and special damages for:

(1) Past and future physical pain and suffering;

(2) Past and future mental anguish and distress;

(3) Past and future physical impairment;

(4) Past and future physical disfigurement;

(5) Past and future loss of enjoyment of life; and

(6) Past and future costs of medical care and treatment, including future medical monitoring costs.

B. That there also be an award of legal interest from the date of judicial demand until all money damages awarded in Judgment are fully paid;

C. That there also be an award of all costs allowed by Fed. R. Civ. P. 54(b) and 28 U.S.C. § 1920;

D. That there be trial by jury on all issues of fact and law triable to a jury; and

E. That the Court grant such other relief as the interests of justice may require.

Respectfully submitted,

/s/ Richard M. Martin, Jr.

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