IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

KARON HOWE AND ELMER LEE HOWE, JR.	)	
Plaintiffs,	)	
v.	)	**CIVIL ACTION NO:**
ALLERGAN INC. f/k/a INAMED CORPORATION f/k/a MCGHAN MEDICAL CORPORATION; ALLERGAN USA, INC., AND ALLERGAN PLC,	)	**COMPLAINT AND JURY DEMAND**
Defendants.	)	

COMPLAINT AND JURY DEMAND

NOW COMES Plaintiff Karon Howe and files her Original Complaint against Allergan Inc. f/k/a Inamed Corporation f/k/a McGhan Medical Corporation, Allergan USA Inc., and Allergan PLC and would respectfully show this Court as follows:

Parties

1. Plaintiff Karon Howe ("Plaintiff") is a citizen and resident of North Carolina and at all times relevant to this Complaint, including the surgical implantation of her McGhan textured breast implants and diagnosis and treatment of her BIA-ALCL, resided in Lenoir, Caldwell County, North Carolina.

2. Plaintiff Elmer Lee Howe, Jr. is a citizen and resident North Carolina and resides in Lenoir, Caldwell County, North Carolina.

3. Defendant Allergan PLC is a publicly-traded corporation whose headquarters is in Dublin, Ireland. Allergan's administrative headquarters in the United States are located in the states of

New Jersey and California. At all pertinent times, Allergan PLC did business in the State of North Carolina.

4. Defendant Allergan, Inc. is a wholly-owned subsidiary of Allergan PLC and is incorporated under the laws of Delaware with its principal place of business in Morris County, New Jersey. At all pertinent times, Allergan, Inc. did business in the State of North Carolina.

5. 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 Morris County, New Jersey and Irvine, California, where it's U.S. Medical Aesthetics division is located. At all pertinent times, Allergan, Inc. did business in the State of North Carolina and is, and has been, registered to do business in the State of North Carolina since 2008.

6. Inamed Corporation ("Inamed") f/k/a McGhan® Medical Corporation ("McGhan®") was incorporated under the laws of Delaware and its principal place of business was in Orange County, California. Upon information and belief, McGhan® changed its name to Inamed in 1986.

7. Inamed was a global surgical and medical device company engaged in the development, manufacturing and marketing of breast implants for the plastic and reconstructive surgery, aesthetic medicine and obesity markets. Inamed sold a variety of lifestyle products, including breast implants for cosmetic augmentation and breast implants for reconstructive surgery following a mastectomy.

8. McGhan® previously served the North American aesthetic medicine and reconstructive surgery markets. McGhan® developed, manufactured and sold plastic and reconstructive surgery breast implants (primarily saline-filled breast implants and tissue expanders). It sold primarily to plastic surgeons, dermatologists, cosmetic surgeons and other medical practitioners in the United States and Canada.

9. In March 2006, Allergan purchased substantially all of Inamed including Inamed's outstanding common stocks, as well as its wholly-owned subsidiary, McGhan®.

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

11. The combined acts and/or omissions of each Defendant resulted in injuries to the Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is also jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized, and/or ratified the conduct of each and every other Defendant.

12. Unless otherwise specified, Allergan Inc., Allergan USA, Inc. and Allergan PLC shall be collectively referred to as the "Allergan Defendants or Defendants."

Jurisdiction and Venue

13. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and the Defendants.

14. Venue in this Court is proper under 28 U.S.C. 1391(b)(2), as a substantial part of the events or omissions giving rise to the claim occurred in this judicial district, and because Defendant conducted substantial business in and derived substantial revenue from this district.

Tag-Along Action

15. This is a potential tag-along action and in accordance with 28 U.S.C. §14-7, it should be transferred to the United States District Court for New Jersey for inclusion in *In re, Allergan Biocell Textured Breast Implant Products Liability Litigation* MDL # 2921 (Hon. Brian R. Martinotti).

Introduction and Factual Background

16. Plaintiff Karon Howe had McGhan saline textured breast implants implanted in 1996 by her physician, Dr. Siciliano. Prior to making her decision to get these implants, Dr. Siciliano told her that textured implants, specifically those manufactured by McGhan, were a new and safe product on the market.

17. Based on representations of the safety of the products, Ms. Howe made a decision to undergo the procedure with the McGhan implants. She paid $10,000.00 for the implantation surgery.

18. In 2006, Allergan purchased McGhan and continued production and sale of McGhan's breast implants as part of a line of textured breast implants known as Allergan Biocell textured breast implants.

19. In June 2019, Ms. Howe returned to Dr. Siciliano for pain she was experiencing in her right breast. Dr. Siciliano determined the right implant was encapsulated, and pathology revealed anaplastic ALK-negative large cell lymphoma. Dr. Siciliano advised Ms. Howe that the cancer was caused by the implant. Notably, Ms. Howe has no history of cancer.

20. BIA-ALCL is *not* a breast cancer but a subtype of non-Hodgkin's lymphoma, a cancer of the immune system. It presents as a late-onset seroma in the breast (accumulation of fluid between the capsule and the implant, resulting in swelling of the breast) with high CD30 expression and an absence of anaplastic lymphoma kinase (ALK). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. This cancer is serious and can lead to death.

21. On July 24, 2019, the FDA issued a news release that announced the FDA-initiated recall of Allergan Biocell textured breast implants and Allergan Biocell tissue expanders:

> "Although the overall incidence of BIA-ALCL appears to be relatively low, once the evidence indicated that [Allergan's Biocell textured breast implant products] appeared to be directly linked to significant patient harm, including death, the FDA took action to alert the firm to new evidence indicating a recall is warranted to protect women's health,' said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D."[1]

22. On the same day, July 24, 2019, the FDA also reported updated data: "573 unique and pathologically confirmed BIA-ALCL" cases associated with textured breast implants with 33 confirmed deaths.[2]

23. On September 12, 2019, the FDA published an explanation of the July 24, 2019 recall of Allergan Biocell textured breast implants: "The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death**.**" FDA, *Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer*, https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (emphasis added).

Facts Specific to Breast Implants

a. The development of the modern breast augmentation implant and the Allergan Biocell textured breast implant.

24. Marketing for modern breast augmentation implants began in the 1960s. Early versions of implants were manufactured with thick shells to reduce rupture rates. However, a side effect of

[1] United States Food & Drug Administration, FDA News Release, *FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market* (July 24, 2019). Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan.

2 https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma. (emphasis added).

that design choice emerged, capsular contracture, which occurs from the growth of scar tissue around the implant (due to a foreign body reaction). Capsular contracture causes the surrounding tissue to thicken and constrict the implant, leading to pain and severe aesthetic problems.

25. In the 1970s, to reduce the incidence of capsular contracture, the first type of "texturing" in the form of a polyurethane foam coating on the implant shell emerged. These implants were ultimately removed from the market in 1991 due to an association between polyurethane and cancer. The texturing process evolved over the first two decades with different technologies, yet, the theory remained the same – the growth of tissue into the irregular spaces of the shell would prevent collagen and fibrous tissue from forming in excess around the implant capsule.

26. In 1987, McGhan introduced a breast implant with a textured surface named "Biocell." McGhan began marketing and selling the Biocell textured breast implant in 1988.

27. After acquiring McGhan, Allergan trademarked its texturing process "BIOCELL®." The textured surface is created by dipping a silicone capsule into salt crystals before it is dry. The surface is washed and cured, leaving behind a pitted surface with randomly sized pores.

b. Textured implants linked to cancer.

28. The first case of BIA-ALCL was reported in the Journal of Plastic and Reconstructive Surgery in 1997.

29. In November 2008, the Journal of the American Medical Association ("JAMA") published a retroactive analysis of 11 cases of ALCL between 1994 and 2006, and based upon preliminary findings, concluded that the evidence indicated an association between silicone breast prosthesis and ALCL. De Jong, Daphne (2008). Anaplastic Large-Cell Lymphoma in Women with Breast Implants, *JAMA: Journal of the American Medical Association*, 300(17), 2030-35.

30. On January 26, 2011, unbeknownst to Ms. Howe, the FDA released a report on BIA-ALCL,

identifying 27 cases and finding that"[b]ased on the published case studies and epidemiological research, ***the FDA believes that there is a possible association between breast implants and ALCL***."

31. The FDA further noted that, while it was not prepared to associate a particular type of breast implant with BIA-ALCL, "ALCL has been found more frequently in association with breast implants having a *textured* outer shell rather than a *smooth* outer shell."

32. In July 2014, the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") issued a Medical Device Alert "to further encourage healthcare professionals to report cases of ALCL in women who have breast implants or who have had them removed."

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

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

35. Several months after WHO's May 2016 designation, the National Comprehensive Cancer Network ("NCCN") released the first worldwide oncology standard for the disease.

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

37. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL, recognizing that "[a]t this, time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather

than those with smooth surfaces.

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

39. A July 2017 article stated that "[e]xperts have called for a common type of breast implant to be banned after it was revealed two people died and 23 developed the same type of cancer in the UK following breast enlargement surgery." Katie Forster, Calls to ban textured breast implants after two die and 23 develop same type of cancer, The Independent Online, July 10, 2017, available at https://www.independent.co.uk/news/health/breastimplants-cancer-ban-two-die-23-develop-same-type-textured-common-womenenlargement-cosmetic-a7832996.html.

40. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including 9 deaths.

41. A recent JAMA Oncology article concluded that "[b]reast implants are associated with increased risk of breast-ALCL", but the absolute risk has not been determined. Mintsje de Boer, et al., *Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast*. JAMA ONCOL. (published January 4, 2018). The Dutch epidemiological study reports the risk of developing breast-implant associated ALCL to be 421.8x higher in women with breast implants than in women with no implants, "implying an attributable risk approaching 100%."

42. On May 9, 2018, Australia's Therapeutic Goods Administration ("TGA") reported 72 cases of ALCL in Australian patients.

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

44. In its July 24, 2019, announcement recalling the product, the FDA stated that there are 573 cases of BIA-ALCL worldwide and that 33 people have died, a "significant increase" since the FDA's last update earlier in 2019—reflecting 116 new cases and 24 more deaths. The FDA stated that the risk of developing BIA-ALCL with Allergan Biocell textured implants is about six times that of becoming ill with textured implants from other manufacturers available in the U.S. The FDA noted that of the 573 cases of BIA-ALCL, 481, or more than 80%, were attributed to Allergan implants, and of the 33 deaths caused by BIA-ALCL, 12 of the 13 patients for whom the implant manufacturer was known had an Allergan implant when they were diagnosed. Dr. Amy Abernethy, principal FDA deputy commissioner, stated: "[b]ased on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "[o]nce the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

45. Despite Defendants knowledge of an association between their breast implants and anaplastic large cell lymphoma dating back into the mid-1990's, Defendants intentionally and purposefully failed to comply with their clearly-established post-market surveillance obligation, and in doing so have exposed many hundreds of thousands of women to life-altering and avoidable cancer and the risk thereof.

46. Ms. Howe's BIA-ALCL was caused by defective, unreasonably dangerous and adulterated Biocell textured breast implants that created an unreasonable risk of harm for users, including Ms. Howe.

47. Defendants' Biocell production procedure negligently produces overly textured rough implant shells, with potentially foreign and adulterated silicone particles, fragments, implant materials and residues on the implant surface. These foreign bodies trigger T-cell lymphoma and,

over time, ALCL.

c. Facts Specific to Plaintiff Karon Howe

48. In approximately 1996, Plaintiff Karon Howe was implanted with textured McGhan implants.

49. At the time the implants were placed into Ms. Howe's body, she was not advised, nor did she have any independent knowledge, that they were anything other than safe, life-long products. Nor was she advised that the product was associated with and/or known to cause BIA-ALCL. Moreover, she was not advised that there were safer alternatives available, namely smooth implants.

50. Ms. Howe was not advised of the risks associated with her implants, or that there was a safer alternative product, and had no independent knowledge that:

a. A significant risk of ALCL existed; or

b. A significant risk of BIA-ALCL existed; or

c. She might need future surgery to remove the implants in the future based on contracting ALCL and/or BIA-ALCL; or

d. She might need future imaging and/or diagnostic procedures to check for, or evaluate ALCL and/or BIA-ALCL.

51. In approximately 2019, Ms. Howe developed pain and deformity in her right breast tissue. After consulting with her physician the decision was made to explant the McGhan saline-filled textured implants.

52. On July 29, 2019, Plaintiff underwent a bilateral capsulectomy and explant of the McGhan saline-filled textured implants.

53. On August 5, 2019, Plaintiff's surgical pathology reports were completed and indicated that Ms. Howe had Breast Implant Associated-Anaplastic Large Cell Lymphoma.

54. On September 23, 2019, Ms. Howe returned for surgical re-exploration to rule out the presence of any additional capsule. At the time it was noted that a portion of the capsule was still present and that the tumor cells appeared to have escaped beyond the fibrous capsule and appeared to be infiltrating the adjacent fat stroma.

55. The additional pathology report confirmed that Ms. Howe had CD30 expression and was negative for ALK.

56. At the time the implants were placed into Ms. Howe's body, she was not advised, nor did she have any independent knowledge, that the breast implants were anything other than safe, life-long products. Nor was she advised that the product was associated with and/or known to cause BIA-ALCL and that she would require future surgery and treatments.

57. If Ms. Howe had been advised that implantation was associated with even the slightest risk of developing ALCL and/or BIA-ALCL she would not have proceeded with implantation.

58. Had the medical community been made aware of the existence of the true frequency, severity and significance of BIA-ALCL caused by the products, medical professionals and providers, including those who advised and served Plaintiff, would not have advised patients, including Plaintiff, to proceed with implantation of the products.

59. Due to the Defendants' failures to comply with their post-approval surveillance obligations, Ms. Howe did not suspect, nor did she have reason to suspect, that her injuries were caused by the breast implants, or by Defendants' tortious conduct.

60. Defendants, through their misrepresentations and omissions including their refusal or

reckless failures to disclose or report defects and significant events as required by federal law, and by state law which is parallel and does not impose duties or requirements materially different from those imposed by federal law, concealed from Plaintiff and her healthcare providers the true and significant risks associated with the products.

61. Defendants knew of the implants' defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Ms. Howe, in conscious and/or negligent disregard of the foreseeable harm caused by the breast implants.

62. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Ms. Howe, she suffered severe and permanent physical injuries. Ms. Howe endured substantial pain and suffering and had to undergo extensive medical and surgical procedures. Ms. Howe was forced to incur significant expenses for medical care and treatment as a direct and proximate result of Ms. Howe's injuries due to the breast implants. Ms. Howe suffered substantial economic loss, and have otherwise been physically, emotionally and economically injured.

63. She has since undergone radiation to the right breast and under her arm. She has had to travel to a BIA-ALCL specialist in Charlotte, North Carolina, for treatment. She has been told that, for a minimum of five years, she will have to regularly see her oncologist, have mammograms, PET scans, and CT scans, each expected to accumulate substantial medical bills. At this time, her right side is so sensitive she cannot bear to have a mammogram, complicating her treatment regimen.

The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Ms. Howe, and was wanton and reckless, thereby entitling Ms. Howe to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

Facts Pertaining to Plaintiff's Parallel Federal and State Law Claims

64. Plaintiff brings this action against Defendants for their failure to use reasonable care to warn consumers and healthcare providers of known or knowable product dangers and adverse events associated with textured breast implants. This claim is provided for by longstanding state court common law failure to warn which parallels Defendants' duty under federal-law and the Code of Federal Regulations 21 C.F.R. §803.50(a) (requiring a manufacturer of class III devices to file adverse event reports whenever the device may have caused or contributed to death or serious injury if it recurred) and 21 C.F.R. §814.84(b)(2) (requiring a manufacturer of a class III device to report new reports of data from any clinical investigations or studies involving the device, reports in the scientific literature concerning the device that are known or that should reasonably be known) and does not impose duties or requirements materially different from those imposed by federal law. The Defendants' duties under state common law, here North Carolina, precisely parallel the duties imposed by federal law and do not exist solely by virtue of the federal requirements.

65. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Upon enactment of the MDA, the FDA deemed saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process. The devices could be publicly sold so long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. §360e(d)(2).

66. In 1988, in response to growing safety concerns, the FDA re-classified both saline-filled

and silicone gel-filled breast implants as Class III devices.

67. In 1989, the FDA published a notice of intent to require submissions of a premarket approval application ("PMA") or completion of product development protocols ("PDPs') for these devices.

68. In 1992, the FDA determined that manufacturers had not adequately addressed public concerns about certain complications, such as implant rupture and silicone leakage. The FDA removed all silicone-filled breast implants from the market, and required manufacturers to submit premarket approval applications that contained data on safety and effectiveness. At this time, saline-filled breast implants remained on the market and any concerns regarding breast implants were unknown to Plaintiff.

69. In 1999, the FDA issued a final rule requiring PMAs for these devices to be filed with the FDA, or PDPs to be completed, within ninety (90) days. Thus, an approved PMA or PDP is now required to market all breast implants.

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

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

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

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

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

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

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

72. Where Conditional Premarket Approval ("CPMA") is granted, a device marketed by a manufacturer which fails to perform any requirements of the CPMA is considered to be adulterated under §501 of the FDCA and may not be further marketed.

a. The McGhan® Breast Implant PMA

73. In April 1992, the FDA entered into an agreement with McGhan setting forth the requirements for McGhan to conduct clinical trials of its silicone implant devices for use in reconstruction patients. Under the agreement, the FDA required that any clinical trial protocols be approved by the FDA and local Institutional Review Boards. The FDA also required McGhan to take all reasonable steps to ensure that it received informed consent from all patients prior to implantation of any evidence on a form consistent with that which had previously been approved by the FDA, and McGhan was to make sure all breast implants were labeled consistent with the agreement and the terms of the approved protocols.

74. McGhan was also required to submit data from the trials in accordance with an agreed schedule and take reasonable steps to ensure that participating physicians complied with the

protocols. Further, McGhan was required to cooperate with the FDA's review of the application and monitoring of the clinical trials.

75. The FDA also retained the power to terminate the study at any time if the data showed that continuation of the study was not necessary to, or in the interest of, the public health.

76. In March 1998, the FDA approved McGhan's study protocol, which was submitted pursuant to the 1992 agreement, subject to the FDA's inspection of McGhan's manufacturing facilities. In the same letter indicating approval, the FDA stated that McGhan's facility in Arklow, Ireland had been inspected and was found to be in compliance with regulations and therefore that facility could export silicone gel-filled mammary prostheses into the United States.

77. McGhan was further informed that it could begin enrolling patients in the study. This study was referred to as the "adjunct" study.

78. In addition to the adjunct study involving reconstruction patients, McGhan also applied for an investigational device exemption ("IDE") for use of the same devices for breast augmentation. The breast augmentation clinical trial was referred to as the "core" study and was approved by the FDA in 1998.

79. As the studies progressed, the FDA continued its oversight and considered a large volume of material submitted about the core and adjunct studies submitted by McGhan each year. The submissions in both included detailed manufacturing, chemical, physical, toxicological, and clinical information. McGhan noted that while the adjunct study was not being conducted under an IDE, the submissions it made relative thereto were structured to follow FDA guidelines for IDE clinical study annual reports.

80. Pursuant to FDA action in the second half of 1999, the FDA required any manufacturer wishing to continue to market saline-filled implants in the U.S. to file a PMA of such breast implants by November 17, 1999.

81. On August 19, 1999, the FDA required McGhan Medical to submit a PMA within 90 days.

82. On November 16, 1999, McGhan (now Inamed) filed a PMA for the "McGhan Medical RTV Saline-Filled Breast Implant" which was referred to an FDA Advisory Panel on general plastic surgery for review.

83. The Advisory Panel met in open session on March 1-3, 2000 to consider the applications. On May 10, 2000, the FDA announced that it had approved the application for PMA of four styles of McGhan saline-filled breast implants for augmentation in women age 18 and older and for reconstruction in women of any age. These breast implants were previously available in the U.S. marketplace as 510(k)-cleared devices.

84. As part of its 2000 approval, the FDA required McGhan to conduct multiple post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies included, among other things:

a. *10-year Post-Approval Studies* – To assess long-term clinical performance of the device. These studies were designed to follow women for 10 years after initial implantation.

b. *Retrieval Study* – To collect visual examination, physical, and histological data on explanted implants to determine the mode of failure of implants.

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

85. Notably, this approval was three years ***after*** the first case of BIA-ALCL was reported in a patient with a McGhan Medical RTV Saline-Filled Breast Implant (Style 168).

86. The Summary of Safety and Effectiveness Data ("SSED") and Directions for Use ("DFU") did not contain any mention of BIA-ALCL or anything related to this particular risk of lymphoma.

87. In December of 2002, Inamed sought PMA approval for its second generation of BIOCELL® textured breast implants. The SSED and DFU for this PMA likewise contained no mention of BIA-ALCL or risk of lymphoma.

88. In November 2006, after its acquisition of Inamed, Allergan received PMA approval for the second generation of BIOCELL® textured breast implants.

89. Allergan's PMA from the FDA on May 10, 2000 for the McGhan saline filled Biocell textured breast implants and on November 17, 2006 for Natrelle silicone gel-filled Biocell textured breast implants (PMA 20056), do not insulate Allergan from tort liability from parallel state law claims in this case. This is based on the Biocell implants having been at adulterated by negligent manufacturing, and Allergan having violated *post*-approval duties to report adverse events, clinical and laboratory studies and reports in the scientific literature. Allergan violated PMA requirements through negligent manufacturing, negligent failure to warn, and negligent failure to follow medical device laws, FDA regulations and the 2002 and 2010 PMAs.

90. Moreover, because the FDA had not been made aware of reports of BIA-ALCL until 2010, the PMAs in 2000 and 2006 did not consider any risk of BIA-ALCL and thus no failure to warn claim is preempted.

b. Obligations of a Manufacturer

91. 21 CFR §§ 814.80-814.84 sets forth the Federal post-approval requirements for a manufacturer, including requirements to monitor and report to the FDA any complaints about the product's performance or any adverse health consequences of which it becomes aware and that are or may be attributable to the

product.

92. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to medical device, rests with the manufacturer.

93. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, and to fully and promptly report all relevant information, specifically, but not limited to, foreseeable dangers with the product, to the FDA, the healthcare community, and consumers. An adequate warning mitigates the risk of harm posed by a product by allowing consumers to make informed choices about whether and how to encounter certain risks.

94. Adverse event reports date back to 1995 when the FDA created its adverse event reporting database, MAUDE (Manufacturer and User Facility Device Experience). MAUDE data is publicly available, but MAUDE searches are limited and do not allow for searches of multiple side effects. MAUDE also only returns 500 reports for any given search, making it difficult to analyze reporting patterns in any meaningful way.

95. "Alternative Summary Reports" ("ASR") for multiple adverse event reports all at one time under 21 CFR §803.19. The ASRs require less detail—for instance, they do not contain any report narrative describing the event—and were not publicly available through the MAUDE website. They were not available through a FOIA request. This exception was for well understood types of events and failure modes. "Since the program's inception in 1997, the FDA granted 108 such exemptions to individual manufacturers for certain well-known events associated with specific devices, which were often already described in the product labeling available to health care professionals and patients. The ASR Program allowed the FDA to more efficiently review reports of well-known, well-understood adverse events, so we could focus on identifying and taking action on new safety signals and less understood risks," Dr. Jeffrey Shuren, head of the FDA's Center for Devices & Radiological Health, said in prepared remarks. BIA-ALCL was no such "well-known" risk.

96. Post-approval requirements under both federal regulations and state law would have compelled reporting the association between the Biocell product and BIA-ALCL.

97. Not only was the association present in the literature, but Defendants' own adverse events highlighted the association, triggering the obligation under federal law and state law to communicate the risk in warnings information and to patients that may have received the implants in the past.

98. Under the PMA, Defendants' obligations included reporting to the FDA information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned. 21 CFR §803.50.

99. In violation of the law requiring Defendants to report adverse events to the FDA, and in order to conceal from doctors and the public the full extent of the risks of Biocell products, Defendants submitted adverse event reports with incorrect manufacturer names, including "Santa Barbara" and "Costa Rica."

100. On information and belief, Plaintiff believes there was a failure to report adverse events and a failure to timely report adverse events.

101. A review of both the MAUDE database and the ASR reports (released by the FDA in June of 2019) as of September 2019 revealed there were 1,298 reports of Allergan textured implants containing the term ALCL, lymphoma, CD30 and ALK testing.

102. Due to Defendants' unlawful reporting practices, medical professionals and consumers relying on the public reports would be unable to draw an accurate conclusion about the safety of Allergan devices including Plaintiff and her implanting physician.

103. Despite having knowledge and possession of evidence showing that the use of the textured breast implants was dangerous and likely to place consumers' health at serious risk, as will be

detailed further below, Defendants refused or recklessly failed to identify, disclose and warn of the health hazards and risks associated with the product, and about all adverse events which were known to them.

104. Instead, Defendants marketed, advertised and promoted the product while at the same time consciously refusing and/or negligently or recklessly failing to warn the FDA, health care providers where it would ultimately reach consumers.

105. Had Defendants substantially complied with their requirements under the PMA and controlling CFRs, Defendants' disclosures would have led to much wider knowledge of the risks associated with Defendants' products, including BIA-ALCL. Medical providers including Plaintiff's physicians would have warned about the risk of Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL") and had Ms. Howe been made aware of the risks associated with her implants, she would have avoided the product, and/or had it removed prior to developing cancer.

COUNT I

Negligence

106. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

107. Defendants, at all pertinent times, had a duty as a reasonably prudent manufacturer, to properly design, manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for the use of their breast implants.

108. Defendants owed a duty to Plaintiff to adequately warn her of the foreseeable risk of ALCL and/or BIA-ALCL associated with Defendants' Biocell textured breast implant products, and the resulting harm they would cause, and otherwise act as a reasonably prudent manufacturer under

similar circumstances.

109. Defendants, at all pertinent times, knew or in the exercise of reasonable care should have known, that their Biocell textured breast implants were of such a nature that they were not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure users. Even if Defendants did not discover the risk of ALCL and/or BIA-ALCL until after the Plaintiff started using the products, they failed to give warnings or take other steps to notify the Plaintiff and the public of the risk. Defendants also have a post-sale duty to warn and owed all implant users a duty of care to inform and update them concerning the risks of the product.

110. It was foreseeable that implantation could lead to an increased risk of BIA-ALCL. As such, Defendants knew or in the exercise of reasonable care should have known that their textured breast implants would cause serious injury. Defendants failed to disclose the known or knowable risks, which are not open or obvious, associated with their Biocell textured breast implant products, including BIA-ALCL. Defendants negligently, willfully and deliberately failed to avoid those consequences, and in so doing, acted in conscious disregard of the safety of Plaintiff.

111. At all pertinent times, Defendants knew or in the exercise of reasonable care should have known that the Biocell textured breast implants were unreasonably dangerous and defective when put to their reasonably anticipated uses.

112. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of their textured breast implants, including, but not limited to the following ways, each of which is a proximate cause of Plaintiff's

injuries:

a. Failing to warn Plaintiff of the hazards associated with the use of Defendants' Biocell textured breast implants, including the risk of ALCL and/or BIA-ALCL;

b. Failing to properly test the breast implants to determine adequacy and effectiveness or safety measures, if any, prior to releasing them for consumer use;

c. Failing to properly test the breast implants to determine the increased risk of ALCL and/or BIA-ALCL resulting from their normal and/or intended use;

d. Failing to inform ultimate users, such as Plaintiff, as to the safe and proper methods of handling and using the breast implants;

e. Failing to remove the breast implants from the market or adding proper warnings when Defendants knew or in the exercise of reasonable care should have known that the breast implants were defective;

f. Failing to advise users how to prevent or reduce exposure that caused an increase in ALCL and/or BIA-ALCL risk;

g. Failing to warn breast implant patients of the danger once implanted;

h. Marketing and labeling the breast implants as safe for all uses despite knowledge to the contrary; and

i. Failing to act like a reasonably prudent company under similar circumstances.

113. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied their Biocell textured breast implant products, that they were dangerous and unsafe for the use and purpose for which they were intended.

114. At all pertinent times, the Biocell textured breast implants were substantially in the same condition as when they left Defendants' possession.

115. Defendants had parallel duties under state and federal law pursuant to the federal post-approval requirements, to exercise reasonable care in providing adequate warnings about the risks and dangers of the Biocell textured breast implants, including the risk of developing BIA-ALCL, which was known or reasonably knowable to Defendants at the time of distribution, and that Defendants had come to know in light of adverse conditions and events experienced by patients in whom the Defendants' products were implanted.

116. Defendants breached their duty, pursuant to federal post-approval requirements, by failing to adequately warn Plaintiff and her physicians, either directly or by not timely and accurately reporting to regulatory authorities the risks of serious defects, adulterations and life-altering complications, including the development of BIA-ALCL, experienced by patients in whom the products were previously implanted.

117. Because Defendants failed to comply with their duties to discover and report adverse events to the FDA after pre-market approval, a requirement under federal law, they breached their duty to use reasonable care under North Carolina tort law regarding the duty of a manufacturer to provide adequate warnings. Additionally, because the FDA requirement regarding the submission of information regarding adverse events "is stated in general terms, and it applies to all devices that must undergo the [relevant] clearance process," this is "not the kind of federal requirement that can have a preemptive effect."

118. Within the scope of foreseeable risks associated with Defendants' negligence, Plaintiff purchased and used the Biocell textured breast implants that directly and proximately caused her to develop BIA-ALCL, to incur medical bills, lost wages, and to endure conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT II

Gross Negligence

119. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

120. Defendants' conduct was in conscious and intentional disregard for the rights, safety and welfare of the Plaintiff and those similarly situated. Defendants acted with reckless, willful and wanton disregard, intentional wrongdoing, and deliberate misconduct affecting the safety of others, including Plaintiff by marketing, manufacturing, advertising, promoting, and selling the Biocell textured breast implants, knowing that that use could lead to serious and life-threatening health problems like BIA-ALCL.

121. As a direct and proximate result of Defendants' reckless, willful and wanton disregard for the safety of their products, amounting to gross negligence, as alleged herein, as a direct and proximate cause of Defendants' gross negligence, Plaintiff developed BIA-ALCL, incurred medical bills, and experienced conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants join and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT III

Failure to Warn

122. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

123. Defendants were responsible as reasonably prudent manufacturers for designing, developing, manufacturing, assembling, marketing, testing, packaging, labeling, promoting, selling, and distributing the breast implant productsin the regular course of business.

124. Defendants' Biocell textured breast implants are defective and unreasonably dangerous to consumers, as the utility of the implants does not outweigh the danger of developing ALCL and/or BIA-ALCL.

125. Defendants' Biocell textured breast implants are defective in design and/or formulation, as they are not reasonably fit, suitable or safe for their intended, and the foreseeable risks including the development of ALCL and/or BIA-ALCL exceed the benefits associated with their design and formulation.

126. At all pertinent times, Defendants knew or in the exercise of reasonable care should have known, that use of their Biocell textured breast implants significantly increases the risk of BIA-ALCL.

127. At all pertinent times, Defendants knew or in the exercise of reasonable care should have known, that women receiving the Biocell textured breast implants neither had knowledge, nor were aware of the increased risk of BIA-ALCL.

128. At all pertinent times, including the time of sale and consumption, Defendants' Biocell textured breast implants were unreasonably dangerous and defective, given Defendants'

knowledge of the increased risk of ALCL and/or BIA-ALCL, risks which were reasonably foreseeable. Defendants failed to provide adequate warnings or instruction to consumers, including Plaintiff, regarding the increased risk of ALCL and/or BIA-ALCL associated with the use of the breast implants before implantation or after the implants were purchased and implanted. Defendants failed to properly and adequately warn and instruct Plaintiff as to the risks and benefits of the breast implants in light of her right and need for this information.

129. At all pertinent times to this action, Defendants' Biocell textured breast implants were defective, including but not limited to the following ways:

a. Failing to contain clear and concise warnings and/or instructions on the breast implants' packaging regarding the risk of BIA-ALCL;

b. Failing to include clear and concise warnings and/or instructions in the breast implants' advertisements to the medical professionals community, including those in print, or the web, on the radio, regarding the potential harmful effects, including the increased risk of BIA-ALCL, associated with the use of the breast implants;

c. Failing to alert the public to the specific dangers of the breast implants, including the increased risk of development of cancers including BIA-ALCL; and

d. Breaching express warranties and/or failing to conform to express factual representations upon which the Plaintiff justifiably relied in electing to use the breast implants;

130. The Biocell textured breast implants that were manufactured, designed, promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Plaintiff's physician without substantial change in the condition in which they were sold.

131. The defects, adulterations and increased risks inherent in the Biocell textured breast implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician. Neither Plaintiff nor her medical providers could have discovered the defects

in the exercise of reasonable care.

132. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

133. At all relevant times, Plaintiff's Biocell textured breast implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

134. Plaintiff was unaware of the dangers associated with implantation of the Biocell textured breast implants. The implants' use for breast augmentation was a reasonably foreseeable use in a manner normally intended by Defendants.

135. Had Plaintiff received a warning that implantation of the Biocell textured breast implants would significantly increase her risk of BIA-ALCL, she would not have used that product. Had she received the warning regarding the increased risk of BIA-ALCL while she had the implants, she would have taken steps to have the implants removed.

136. As a direct and proximate result of Defendants' failure to warn, Plaintiff developed BIA-ALCL, suffered severe and permanent physical injuries and significant pain and suffering. She incurred significant expenses for medical care and treatment.

137. Defendants knew or should have known that the breast implants were associated with or did actually in fact cause ALCL and/or BIA-ALCL.

138. Despite the fact that Defendants knew or should have known that implantation of the their textured breast implant products was unreasonably dangerous and was likely to seriously jeopardize the health of consuming patients, Defendants failed to warn of the risks associated with the product.

139. Defendants' failure to warn included, but was not limited to, its failure to report adverse events to the FDA. This failure to report is the same act and omission that violates parallel FDA

regulations, including but not limited to the statutory requirements regarding reporting adverse events found in sections 21 U.S.C. § 360i(a)(1)(A)-b and 21 C.F.R. § 803.50(a).

140. Specifically, Defendants were reporting serious adverse events, such as incidents of BIA-ALCL to the ASR database, rather than to the MAUDE database. The ASR was intended for reporting of well-established risks, only, not for reports of patient deaths or unusual adverse events such as BIA-ALCL.

141. Additionally, federal reporting rules require that adverse reports are submitted using identifying information regarding the manufacturer and the product at issue so the adverse event can be accurately tracked. As explained herein, above, Defendants failed to accurately report their company name on reports to the FDA through the ASR database, and also failed to report the name of the device at issue. Rather, the company listed their name as the city in which their manufacturing or sales facility was located, and the device as simply as "breast implant." There was no way for the FDA to tie the adverse event to the company or device itself.

142. As soon as the FDA was aware of the incidence of serious injuries and death that could be attributed to Defendants' textured breast implant devices, such as BIA-ALCL, the product was recalled from the market. Had the FDA been properly notified of the adverse events caused by Defendants' textured breast implant devices, in a timely and proper manner, as required by federal law and parallel state law, it is likely that the product would have been recalled earlier, and/or had significant changes made to the warnings and labelling to accurately notify and warn consumers and their physicians about the risks of serious adverse events related to Defendants' textured breast implant devices.

143. The defects, adulterations and increased risks inherent in the Biocell textured breast implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or

Plaintiff's physician. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the defects.

144. At all relevant times, Plaintiff's Allergan textured breast implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

145. The Biocell textured breast implants manufactured, designed, promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Plaintiff's physician without substantial change in the condition in which they were sold.

146. Defendants knew that their textured breast implant products would be used by the ordinary purchaser or user without inspection for defects and adulterations and without knowledge of the hazards involved in such use.

147. The Biocell textured breast implants, which were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, caused Plaintiff's injury of ALCL which would not have occurred but for the use of Defendants' textured breast implant products.

148. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Defendants' textured breast implant products. If Defendants had properly reported the adverse events to the FDA, as required under federal law, that information would have reached the implanting doctor in time to prevent the Plaintiff's injuries because the Plaintiff would not have chosen the Biocell textured breast implants knowing that the risks of ALCL was greater than Defendants' previously reported.

149. Because Defendants failed to comply with their duties to discover and report adverse events to the FDA after pre-market approval, a requirement under federal law, they breached their duty to use reasonable care under North Carolina tort law regarding the duty of a manufacturer to

provide adequate warnings. Additionally, because the FDA requirement regarding the submission of information regarding adverse events "is stated in general terms, and it applies to all devices that must undergo the [relevant] clearance process," this is "not the kind of federal requirement that can have a preemptive effect."

150. Thus, as a direct and proximate cause of Defendants' failure to report adverse events to the FDA, Plaintiff suffered and will continue to suffer severe physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

151. Defendants' lack of sufficient warnings about the dangers of use of their textured breast implant devices prior to, on, and after the date of Plaintiff's initial surgery was a substantial factor and a direct, legal, and concurrent cause of Plaintiff's injuries and damages as described herein above.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT IV

Breach of Express Warranty

152. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

153. Defendants marketed, manufactured, promoted, distributed and/or sold Biocell textured breast implants as safe for use by the public at large, including Plaintiff, who underwent a

procedure involving their implantation. Defendants knew the use for which the breast implants were intended and expressly warranted the products to be of merchantable quality, safe and fit for use.

154. Defendants further expressly warranted that the Biocell textured breast implants were of "premium" and "proven" quality with "mild tissue adherence."

155. Defendants' Biocell textured breast implants do not conform to these express warranties and representations because they are not premium, are not of proven quality, do not promote mild tissue adherence, and may produce serious side effects, including among other things, BIA-ALCL. Further, there was no information demonstrating that textured implants had better results or were safer than smooth implants at the time.

156. The Biocell textured breast implants did not conform to these express representations in violation of North Carolina General Statute §25-2-313, and North Carolina common law because the implants are not safe or effective, nor are they safer or more effective than other breast implants available, and they may produce serious side effects, including among other things, BIA-ALCL.

157. As a direct and proximate result of Allergan Defendants' breach of express warranty, Plaintiff developed BIA-ALCL, suffered severe and permanent physical injuries and significant pain and suffering. She incurred significant expenses for medical care and treatment.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT V

Breach of Implied Warranty

158. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

159. Defendants are merchants with respect to goods like the Biocell textured breast implants.

160. Defendants marketed, manufactured, promoted, distributed and/or sold the Biocell textured breast implants as safe for use by the public at large, including Plaintiff, who underwent a procedure involving their implantation.

161. Defendants knew or in the exercise of reasonable care should have known the use for which the Biocell textured breast implants were intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

162. The Biocell textured breast implants did not conform to these implied warranties in violation of North Carolina General Statutes §§ 25-2-314; 25-2-315 and North Carolina common law, as they were defective in design and manufacture and were therefore not fit for their intended uses and were not designed, manufactured, or sold in accordance with good design, manufacturing, or industry standards. The Biocell textured breast implants were not fit for their common, ordinary and intended uses because of the increased risk of BIA-ALCL. Therefore, Defendants have breached the implied warranty of merchantability as well as the implied warranty of fitness for a particular purpose. Such breaches by Defendants were a proximate cause of the injuries and damages sustained by Plaintiff.

163. When the Biocell textured breast implants were distributed into the stream of commerce and sold by Defendants they were unsafe for their intended use, and not of merchantable quality

as warranted by Defendants, as their use causes BIA-ALCL.

164. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff developed BIA-ALCL, suffered severe and permanent physical injuries and significant pain and suffering. She incurred significant expenses for medical care and treatment.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT VI

Negligent Misrepresentation

165. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

166. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public that the Biocell textured breast implants had been tested and found to be safe and effective. Defendants' also had a duty to provide accurate and complete information regarding the product. The representations made by Defendants, in fact, were false.

167. Defendants failed to exercise ordinary care in the representations concerning the Biocell textured breast implants because Defendants negligently misrepresented the products' high risk of unreasonable, dangerous, adverse side effects, including the risk of BIA-ALCL. Defendants negligently misrepresented claims regarding the safety and efficacy of the textured implants despite the lack of information regarding same.

168. Defendants' misrepresentations in promoting and marketing their breast implants created and reinforced a false impression as to the safety of their breast implant products, thereby placing

consumers at risk of serious and potentially lethal effects.

169. Defendants breached their duty in representing that the Biocell textured breast implants had no life-threatening side effects, and were safe for all reasonably intended uses.

170. At all relevant times, Defendants failed to exercise reasonable care in ascertaining or sharing information regarding the safe use of the Biocell textured breast implants, failed to disclose facts indicating that the implants were unreasonably dangerous and carcinogenic in nature, and otherwise failed to exercise reasonable care in communicating the information concerning the implants to Plaintiff, and/or concealed relevant facts that were known to them.

171. Defendants have a pecuniary interest in making false statements regarding the safety of their Biocell textured breast implant products.

172. These misrepresentations were made by Defendants with the intent to induce patients, like Plaintiff, to use Defendants' Biocell products.

173. At all times pertinent, Plaintiff justifiably relied on, and was ignorant of, the falsity and Defendants' misrepresentations and omissions. If the Defendants had disclosed true and accurate material facts concerning the risks, in particular the risk of developing ALCL and/or BIA-ALCL, Plaintiff would not have undergone surgery to implant the Biocell textured breast implant product.

174. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendant knew, and had reason to know, that the Breast Implants had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects.

175. Plaintiff's reliance upon the Defendants' misrepresentation and omissions was justified and

reasonable because, among other reasons, those misrepresentations and omissions were made by individuals and entities who were in a position to know the material facts concerning the Biocell textured breast implants and the association between them and the incidence of cancer, while Plaintiff was not in a position to know these material facts, and because Defendants failed to warn or otherwise provide notice to the consuming public as to the risks of these products, thereby inducing Plaintiff to use Defendants' Biocell textured breast implants in lieu of safer alternatives. At all relevant times, Defendants' corporate officers, directors, and/or managing agents knew of and ratified the acts of Defendants, as alleged herein.

176. As a direct, foreseeable and proximate result of Defendants' negligent misrepresentation, Plaintiff purchased and used the Biocell textured breast implants. As a direct and proximate result of such use, Plaintiff developed BIA-ALCL, incurred medical bills, lost wages, and endured conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT VII

Fraudulent Misrepresentation and Omission

177. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

178. Defendants, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of the Biocell textured breast implants described herein, owed a duty to provide accurate

and complete information regarding their products.

179. Defendants' fraudulently misrepresented information regarding their products including, but not limited to, their propensity to cause serious physical harm, including BIA-ALCL, and that the textured implants were as safe as smooth implants.

180. At all pertinent times, Defendants intentionally, willfully, and/or recklessly, with the intent to deceive, misrepresented and/or concealed material facts to consumers, including Plaintiff, related to the safety of the Biocell textured breast implants.

181. At all pertinent times, Defendants misrepresented and/or concealed material facts concerning the Biocell textured breast implants to consumers, including Plaintiff, with knowledge of the falsity of their misrepresentations.

182. Defendants were aware of the dangerous and defective condition of the Biocell textured breast implants and intentionally withheld this information from Plaintiff, the healthcare field, and the general public even though these significant dangers were not readily obvious to ordinary users.

183. Plaintiff justifiably relied upon the aforementioned misrepresentations and concealments made by the Defendants and used the Biocell textured breast implants as described herein.

184. As a direct and proximate result of Plaintiff's reliance, she sustained damages including the development of cancer, and was deprived of the opportunity of informed free choice in connection with the use of and exposure to Defendants' Biocell textured breast implants. As a direct and proximate result of Plaintiff's use of Defendants' products, she incurred medical bills, lost wages and endured conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees

and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT VIII

Fraudulent Concealment

185. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

186. Prior to and after Plaintiff's breast implant augmentation, Defendants fraudulently suppressed material information regarding the safety and efficacy of the Biocell textured breast implants and the availability of an alternative feasible safer design. Plaintiff believes the fraudulent misrepresentations and fraudulent concealment described herein were intentional.

187. Defendants intentionally concealed safety issues related to the Biocell textured breast implants in order to induce consumers, including Plaintiff, to purchase their products.

188. At the time Defendants concealed the fact that the Biocell textured breast implants were not safe as designed and marketed, they were under a duty to communicate this information to the general public in such a manner that the general public could appreciate the risks associated with using the products, generally.

189. Plaintiff relied upon Defendants' false and fraudulent misrepresentations and concealments regarding the safety of the Biocell textured breast implants.

190. As a direct and proximate result of Defendants' malicious and intentional concealment of material and information, Defendants proximately cause Plaintiffs' injuries.

191. Defendants' acts before, during and/or after the act causing Plaintiff's injuries prevented Plaintiff from discovering the injury or cause thereof. Plaintiff would have chosen not to get the implants or have them removed prior to contracting cancer if Defendants had not fraudulently

concealed the information.

192. As a direct and proximate result of Defendants' fraudulent concealment as described herein, Plaintiff suffered and continues to suffer from the damages for which she is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs and attorney's fees.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT IX

Violation of the North Carolina Consumer Fraud and Deceptive Business Practices Act (Violation of N.C.G.S. §§ 75-1.1 and 106-138) as to all Defendants

193. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

194. At all pertinent times, Defendants engaged in unlawful and deceptive acts and practices concerning the sale of the Biocell textured breast implants in violation of federal law and the North Carolina General Statutes §§ 75-1.1 and 106-138 in the manufacturing, distributing, marketing, promoting, and sale of the Biocell textured breast implants.

195. Defendants concealed the true risks of the Biocell textured breast implants.

196. Defendants' actions were negligent, knowing and willful, and/or wanton or reckless with respect to Plaintiff.

197. Defendants' intended for Plaintiff to rely on the concealment of the increased risk of BIA-ALCL in an effort to encourage sales of the Biocell textured breast implants.

198. Plaintiff would not have purchased, chosen or paid for all or part of the Biocell textured breast implants if she had known she would have a significantly higher risk for developing BIA-ALCL.

199. As a direct and proximate result of Defendants' deceptive trade practices in the marketing, promoting, selling, distributing, and advertising of the Biocell textured breast implants to consumers in the State of North Carolina, Plaintiff was harmed.

200. As a proximate result of Defendants' design, manufacture, marketing, sale and distribution of the Biocell textured breast implants, Plaintiff has been injured catastrophically, and has been caused severe pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

Wherefore, Plaintiff requests a judgment against Defendants jointly and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT X

Loss of Consortium

201. Plaintiffs re-allege and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

202. At the time Plaintiff was diagnosed with BIA-ALCL, she and Plaintiff Elmer Lee Howe, Jr. were husband and wife. Plaintiffs resided together and continue to reside together as husband and wife with all of the legal and natural consequences attendant to such marital status.

203. By reason of the negligence, gross negligence, recklessness and intentional conduct of Defendants, Plaintiff Elmer Lee Howe, Jr. has been caused to lose the comfort, companionship,

society, services and consortium caused by Ms. Howe's development of BIA-ALCL.

204. By reason of the foregoing, Plaintiff Elmer Lee Howe, Jr. demands judgment against Defendants for damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

COUNT XI

Punitive Damages

205. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the laws of North Carolina.

206. Defendants sold the Biocell textured breast implants to Plaintiff and other consumers throughout the United States without doing adequate testing to ensure that the implants were reasonably safe for their intended use.

207. Defendants sold the Biocell textured breast implants to Plaintiff and other consumers throughout the United States in spite of their knowledge that the implants caused the problems heretofore set forth in this Complaint, thereby causing the severe and debilitating injuries suffered by the Plaintiff.

208. At all times pertinent, Defendants knew or should have known that the Biocell textured breast implants were unreasonably dangerous with respect risk of BIA-ALCL, but continued manufacturing, marketing and selling the implants with reckless indifference to the rights of others, including Plaintiff.

209. At all times pertinent, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Biocell textured breast implants, including but not limited to information regarding the increased risk of developing ALCL and/or BIA-ALCL, as well as to minimize the true and accurate risk of injuries and complications caused by the products.

210. Defendants' misrepresentations included knowingly withholding material information from the consumers, including Plaintiff, concerning the safety and efficacy of the Biocell textured breast implants.

211. At all times pertinent, Defendants knew and intentionally and/or recklessly disregarded the fact that the Biocell textured breast implants cause debilitating and potentially lethal side effects with greater frequency than safer alternative breast implants and recklessly failed to advise the public of the same.

212. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Biocell textured breast implants despite available information demonstrating that the implants were likely to cause serious and potentially fatal side effects to users.

213. Defendants misled regulators, the medical community and the public at large, including Plaintiff, by making false and misleading representations about the safety of the Biocell textured breast implants. Defendants knowingly withheld and misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harms Plaintiff suffered.

214. Defendants' intentional, reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Biocell

textured breast implants against the benefits.

215. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed, believes and further alleges that Plaintiff and other members of the public will in the future be required to obtain further medical care and/or hospital care and medical services.

216. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles and the statutory provisions of the Plaintiff's respective home state and Defendants' home states.

217. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

Wherefore, Plaintiff requests a judgment against Defendants joint and severally for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief this Court deems just and appropriate, and demands trial by jury of all issues raised herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, reconstructive

surgery costs, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Pre-judgment interest;

5. Post-judgment interest;

6. Statutory damages as available;

7. Punitive damages as available;

8. Awarding Plaintiff reasonable attorneys' fees;

9. Awarding Plaintiff the costs of these proceedings; and

10. Such other and further relief as this Court deems just and proper.

Jury Demand

Demand is hereby made for trial by jury on all issues raised by these pleadings.

Respectfully Submitted,

MOTLEY RICE LLC

/s/ John D. Hurst

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