IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT
EASTERN DIVISION

PAT BURRESS,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**No. _____**
	)	
ALLERGAN, INC., f/k/a INAMED CORPORATION, ALLERGAN USA, INC., ALLERGAN plc, MCGHAN MEDICAL CORPORATION, INAMED CORPORATION, ALLERGAN SALES, LLC,	)	
	)	
Defendants.	)	

COMPLAINT

Comes now the Plaintiff, by and through counsel, and would show the Court:

I. PARTIES, JURISDICTION AND VENUE

1. The Plaintiff, Pat Burress, is a resident of Alamo, Tennessee.

2. Defendant, Allergan, Inc., f/k/a Inamed Corporation, and f/k/a McGhan Medical Corporation, is a corporation formed under the laws of Delaware with a principal place of business located at 5 Giralda Farms, Dodge Drive, Madison, NJ 07940. It is a wholly owned subsidiary of Allergan plc.

3. Defendant, Allergan USA, Inc., is a corporation formed under the laws of Delaware with a principal place of business located at 5 Giralda Farms, Dodge Drive, Madison, NJ 07940. It is a wholly owned subsidiary of Allergan plc.

4. Defendant, Allergan plc, is a corporation formed under the laws of Delaware with a principal place of business located at 5 Giralda Farms, Dodge Drive, Madison, NJ

07940. It is a publicly traded corporation whose headquarters are located in Dublin, Ireland, with administrative headquarters in the United States in New Jersey and California.

5. Defendant, McGhan Medical Corporation, is a company that is previously part of Inamed Corporation. It previously served the North American aesthetic medicine and reconstructive surgery markets. McGhan developed, manufactured, and sold plastic and reconstructive surgery products, including saline-filled breast implants and tissue expanders, to plastic surgeons, dermatologists, cosmetic surgeons and other practitioners in the United States and Canada.

6. Defendant, Inamed Corporation, is a company purchased substantially by Allergan engaged in the development, manufacturing, and marketing of products for the plastic and reconstructive surgery, aesthetic medicine and obesity markets. It sold a variety of lifestyle products, including breast implants for cosmetic augmentation and breast implants for reconstructive surgery following a mastectomy. In March 2006, Allergan purchased substantially all of Inamed including Inamed's outstanding common stocks and wholly owned subsidiary, McGhan Medical Corporation.

7. Defendant, Allergan Sales, LLC, is a Delaware Limited Liability Company formed in 2002, engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, or selling for profit, BIOCELL© textured breast implants. It also manages Allergan plc's business operations, and maintains its principal execute office at 2525 Dupont Drive, Irvine, California.

8. Jurisdiction in this matter is based upon 28 U.S.C. 1332, diversity jurisdiction.

9. Venue is appropriate in this Court pursuant to 28 U.S.C. 1391(b)(2), as the substantial part of the acts giving rise to Plaintiff's claims occurred in this District and Defendants are subject to personal jurisdiction in this District.

II. PREDICATE FACTS

10. Breast implants are prosthetic products used to change the size, shape and contour of a woman's breast. These are available in various sizes, with either smooth or textured shells. The three general types of implants are defined by the filler solution: saline solution, silicone gel solution, and composite filler solution.

11. Nationally, about 300,000 total implants are placed annually in the United States. From 2000 to 2016, the number of breast augmentations rose 37% and reconstructions post mastectomy rose 39%.

12. In 2011, a summary of published articles, studies, evidence and reports identified 27 cases of ALCL, and concluded that there existed an association between breast implants and ALCL.

13. In January 2011, the FDA released a report on BIA-ALCL, listing as its primary finding, that it believed there was a possible association between breast implants and ALCL. The FDA further noted that, while it was not prepared to associate a particular type of 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."

14. While naturally, ALCL occurs in every 1 of 300,000 women, the FDA recently cited to studies placing the estimated current risk of BIA-ALCL in women with textured implants to be between 1 in 3,817 and 1 in 30,000.

15. In March 2015, an analysis identified 173 cases of ALCL. In May of 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.

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

17. In May 2017, a total of 363 cases were identified, with 258 reported to the FDA.

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

19. Defendant Allergan plc ("Allergan") manufactures and sells NATRELLE BIOCELL© saline-filled and silicone filled breast implants and tissue expanders ("BIOCELL ©").

20. Allergan's Natrelle® silicone-filled breast implants are Class III medical devices receiving pre-market approval by the FDA in November 2006.

21. As conditions of the approval, the FDA required Allergan to conduct six post-approval studies to characterize the long term performance and safety of the devices.

22. After receiving premarket approval for a Class III device, manufacturers, including Allergan, are required to undertake a continuous obligation to comply with Medical Device Reporting pursuant to 21 USC 360i(a)(1) and 21 CFR 803.50(a). Manufacturers are required to file adverse event reports with the FDA.

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

24. Approximately 1,400 injury reports have been filed related to Allergan implants, and 300 BIA-ALCL cases.

25. In order to conceal the extent of the adverse events, Allergan reported adverse event reports with incorrect manufacturer names, including "Santa Barbra" and "Costa Rica" instead of under the name "Allergan." As a result, consumers, healthcare professionals, and the FDA were unable to detect trends in the products of Allergan, and whether the products were safe and effective.

26. Allergan also developed a pattern and practice of reporting adverse events as "Alternative Summary Reports" for multiple events at one time, instead of filing an adverse event report for each individual adverse event.

27. In 2017, the FDA ceased the permit the filing of Alternative Summary Reports. Prior to this, on average, less than 200 breast implant injuries were annually reported.

After this, in 2017, the number reported was 4,567 adverse events, and 8,242 in 2018.

28. Due to these reporting practices, medical professionals and consumers relying on the public reports were unable to draw an accurate conclusion about the safety of a particular medical device.

29. Under state law, including Tennessee, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

30. Delayed reporting prevents the healthcare community and public from timely learning and evaluating the risks which play a crucial role in decision making, including both physicians and consumers, regarding treatments and procedures, and thereby exposes countless additional women to potential harm.

31. Allergan failed to report adverse events from the post-market approval studies commissioned as part of the implants preliminary approval that would have led to reports suggesting the correlation between the implants and serious injury.

32. Had defendants not failed to comply with their clearly demarcated obligations post market, Plaintiff would have more likely than not decided against implantation.

33. Under applicable state law, Allergan had a duty to exercise reasonable care in adequately warning the Plaintiff about the dangers of Allergan's Natrelle® Silicone Filled breast implants, and all about the adverse events of which Allergan became aware, and further, had a post market duty to identify , monitor and report all adverse events and all risks associated with the product.

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

35. At no point in time did Allergan revise its product labeling after becoming aware of otherwise undisclosed dangers in its Natrelle® and BIOCELL© breast implant products. Allergan refused and recklessly and intentionally failed to do so.

36. Allergan's insufficient follow up rates and inadequate data, establish and confirm the reckless and intentional disregard for the safety of consumers, including Plaintiff.

37. Notwithstanding the knowledge it had, as well as the failure to comply with post-market approval requirements, Allergan continued to commercially distribute its Natrelle® and BIOCELL© breast implants.

38. Had Allergan substantially complied with the PMA, rather than underperforming as set forth above, Allergan's disclosures would have led to much wider knowledge of the risks associated with the Allergan products. In addition, the physician and patient labeling would have materially changed over time, and patients, including Plaintiff, would not have purchased or implants Allergan's products.

39. Unknown to Plaintiff, on or about July 24, 2019, Allergan announced a worldwide recall of BIOCELL© after the U.S. Food and Drug Administration ("FDA") called for the action following new information that Allergan's BIOCELL © implants were tied to a vast majority of cases of breast implant- associated anaplastic large cell

lymphoma ("BIA-ALCL") not seen with other textured implants. Allergan announced that BIOCELL © would no longer be sold or distributed in any market.

40. BIA-ALCL is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread through the body. Even if an individual's risk of developing BIA-ALCL is considered low, this cancer is serious and can lead to death, especially if not treated promptly. BIA-ALCL can be treated with surgery to remove the implant and surrounding scar tissue and in some patients, and may also require treatment with chemotherapy and radiation treatment. The recommended diagnostic testing for BIA-ALCL is invasive. The Directions for Use ("DFU") for physicians provide in pertinent part: "When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL." The symptoms of BIA-ALCL may occur well after the surgical incision has healed, often years after the implant placement.

41. In its announcement, the FDA stated that there are 573 cases of BIA-ALCL worldwide and 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: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence indicated that a specific manufacturer's products appeared to be directly linked to significant patient harm, including death, the FDA took action."

42. The recalled BIOCELL© products include the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046. The textured style includes Style 410MF, which was the style implanted in the Plaintiff.

43. Plaintiff, prior to the recall, paid for and received Natrelle 410 MF 420cc implants in both breasts, Ref MF-410420, SN 20913887 (left) and SN 21055859 (right), in Jackson, TN.

44. On or about August 13, 2019, for the first time, Plaintiff became aware of the recalled product. By letter dated August 12, 2019, Plaintiff's physician advised her that the breast implant manufacturer Allergan had issued a "voluntary withdrawal" of its Biocell textured breast implants and tissues from the market. The letter went on to advise the Plaintiff that "BIA-ALCL is not breast cancer. It is an uncommon-but-treatable type of non-Hodgkin's lymphoma that can develop around breast implants. To date, there have been no confirmed cases of BIA-ALCL in women who have had only "smooth surface" breast implants or tissue expanders." Exhibit A hereto.

45. At no time did Allergan provide surgical fee assistance for individuals, including Plaintiff, to have breast implant revision and removal of the implants.

46. Plaintiff had her implants removed a short time later, at her own cost and expense.

47. Allergan received a substantial benefit from selling thousands of the recalled BIOCELL© products from 2006 through July 24, 2019 to unsuspecting individuals, including Plaintiff, who were exposed to the risk of developing BIA-ALCL, a serious and deadly disease.

48. Plaintiff expended her own funds, out of pocket, to have the implants removed after being notified by her physician of the recall.

49. Plaintiff would not have had the recalled BIOCELL© products implanted had she known prior to the procedure that implantation with NatrelleTM would subject her to the risk of contracting BIA-ALCL and the costs associated with removal, surgical and diagnostic fees, medical monitoring, lost wages, and invasive diagnostic procedures to detect BIA-ALCL.

50. After the explantation of the implants, Plaintiff suffered intense pain, missed work, and deals with the stretched tissue and physical scars from the two surgeries.

III. CAUSES OF ACTION

A. STRICT LIABILITY - FAILURE TO WARN

51. All paragraphs set forth in 1-49 hereinabove are incorporated herein as if incorporated verbatim.

52. Defendants had a duty to warn Plaintiff about the true risks associated with the BIOCELL© Natrelle 410MF implants through the submission of accurate adverse event reports and amendment of the warning labels contained within the product.

53. The warnings contained within the product at the time of implantation failed to relay the extent of the danger, as well as Allergan's actual knowledge of the causal connection between its BIOCELL© implants and BIA-ALCL, which it had known since 2006.

54. Despite the ability to update its warnings, it instead chose to actively conceal this knowledge of the link between the implants and BIA-ALCL, and failed to update the warnings.

55. Defendants' breached their duty to warn to the Plaintiff, by failing to update their warnings with actual knowledge.

56. Had Plaintiff been made aware of the warnings, she more likely than not, would have declined to have the products implanted.

57. As a direct and proximate result, Plaintiff was caused injury, including chronic inflammation, heightened risk of injury, medical bills, implant and explant bills, pain and suffering, lost wages, and other compensatory damages in an amount to be determined by a jury, not to exceed $500,000.

B. NEGLIGENCE

58. All paragraphs set forth in 1-56 hereinabove are incorporated herein as if incorporated verbatim.

59. Defendants owed Plaintiff a duty of care and to warn of any and all risks associated with the recalled BIOCELL© products. Defendants knew or should have known of the true risks with BIOCELL© implants but failed to warn Plaintiff of these, by failing to submit and/or concealing misleading adverse event reports, and concealing the risks associated with the recalled BIOCELL© implants.

60. Defendants breached the duty of care it owed to Plaintiff by its actions.

61. As a direct and proximate result, Plaintiff was caused injury, including chronic inflammation, heightened risk of injury, medical bills, implant and explant bills, pain and suffering, lost wages, and other compensatory damages in an amount to be determined by a jury, not to exceed $500,000.

C. UNJUST ENRICHMENT

62. All paragraphs set forth in 1-60 hereinabove are incorporated herein as if incorporated verbatim.

63. Plaintiff conferred an economic benefit upon the Defendants by the purchase of the recalled implants. Plaintiff, had she known the true risks, would more likely than not, not purchased, chosen and/or paid for all of the implants and associated surgery.

64. Now, Defendants refuse to compensate Plaintiff for the surgical costs of removal of the products, the pain and suffering experienced, the disfigurement, scarring, lost wages, surgical and diagnostic fees, medical monitoring associated with the products.

65. Under these circumstances, it is inequitable to confer such an economic benefit upon the Defendants at the expense of Plaintiff.

66. As a direct and proximate result, Plaintiff has been caused injury, including chronic inflammation, heightened risk of injury, medical bills, implant and explant bills, pain and suffering, lost wages, and other compensatory damages in an amount to be determined by a jury, not to exceed $500,000.

D. MISREPRESENTATION

67. All paragraphs set forth in 1-65 hereinabove are incorporated herein as if incorporated verbatim.

68. Defendants made representations to the Plaintiff and medical professionals, as well as the FDA, about the safety of the BIOCELL© implants, including the two Plaintiff had implanted.

69. At the time the Defendants made such representations, it either had actual knowledge or a reckless disregard that such statements were untrue.

70. The Plaintiff relief on the Defendants' representations, to her detriment.

71. As a direct and proximate result, Plaintiff has been caused injury, including chronic inflammation, heightened risk of injury, medical bills, implant and explant bills, pain and suffering, lost wages, and other compensatory damages in an amount to be determined by a jury, not to exceed $500,000.

E. DAMAGES

72. As a direct and proximate result, Plaintiff has been caused injury, including chronic inflammation, heightened risk of future injury, disfigurement, medical bills, implant and explant bills, pain and suffering, lost wages, and other compensatory damages in an amount to be determined by a jury, not to exceed $500,000.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that this Court:

1. Require the Defendants to answer this Complaint;

2. Award all compensatory damages in favor of Plaintiff and against Defendants, jointly and severally;

3. Award in favor of Plaintiff and against Defendants, reasonable attorneys' fees, costs and court costs;

4. Award any and all other relief to which this Plaintiff may be entitled.

5. Plaintiff reserves the right to amend her *ad damnum* and her complaint as further and other facts become known.

RESPECTFULLY SUBMITTED August 11, 2020.

HARRIS SHELTON HANOVER WALSH, PLLC

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The undersigned recognizes that our office is surety for all ordinary court costs and taxes pursuant to Tenn. Code Ann.§20-12-120 not to exceed One Thousand Dollars ($1,000.00).

HARRIS SHELTON HANOVER WALSH, PLLC

BY: ___/s/Amber Griffin Shaw