IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF LOUISIANA SHREVEPORT DIVISION

CHRISTINE DOWNEY and DRAKE ALLEN DOWNEY,	)	
	)	
Plaintiffs,	)	
v.	)	Case No.
_____	)	
ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., ALLERGAN PLC AND ABBVIE, INC.	)	
	)	JURY TRIAL DEMANDED
Defendants.	)	

COMPLAINT

Plaintiffs, CHRISTINE DOWNEY and DRAKE ALLEN DOWNEY, based on information and belief, and for causes of action against the Defendants ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., ALLERGAN PLC and ABBVIE, INC. each of them, hereby alleges as follows:

INTRODUCTION

1. Plaintiffs, CHRISTINE DOWNEY and DRAKE ALLEN DOWNEY, bring this action against Defendants ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., ALLERGAN, PLC and ABBVIE, INC., (hereinafter, collectively referred to as "Defendants" or "Allergan"), in relation to the design, manufacture, marketing, labeling and distribution of McGhan® Breast Implants, the pervasive, reckless and continuous failure to comport with the Premarket Approval Application (''PMA") requirements imposed by the Food & Drug Administration ("FDA"), and failure to warn consumers of the known dangers and known adverse events associated with the use of this product.

2. Defendant Allergan, formerly known as Inamed Corporation ("Inamed") and prior to that known as McGhan Medical Corporation ("McGhan"), is a global leader in aesthetic medicine, and a market leader in breast aesthetics as set forth herein.

3. Plaintiffs bring this action against Defendants in relation to the design, manufacture, marketing, and distribution of McGhan® Breast Implants, the repeated failure to follow the requirements imposed by FDA, failure to warn consumers and healthcare providers of known dangers and known adverse events, and reckless violation of state law, including the laws of the State of Louisiana.

PARTIES

4. Plaintiff, Christine Downey and her husband Drake Allen Downey, are and at all material times, residents of Princeton, Bossier Parish, Louisiana.

5. Allergan, Inc. f/k/a Inamed Corporation is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

6. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey. Allergan USA, Inc. is registered with the Louisiana Secretary of State to conduct business in Louisiana and at all pertinent times alleged herein conducted business within the State of Louisiana.

7. Allergan PLC is a publicly-traded corporation headquartered in Dublin, Ireland. Allergan plc's administrative headquarters in the United States are located in New Jersey and California.

8. Abbvie, Inc. is a publicly-traded corporation headquartered in North Chicago, Illinois. Abbvie acquired Allergan in May of 2020.

Allergan's Relationship to McGhan Medical Corporation and Inamed Corporation

1. McGhan Medical Corporation ("McGhan") previously served the North American aesthetic medicine and reconstructive surgery markets. McGhan developed, manufactured and sold plastic and reconstructive surgery (PRS) products, primarily saline-filled breast implants and tissue expanders. McGhan sold its products primarily to plastic surgeons, dermatologists, cosmetic surgeons, reconstructive surgeons, and other medical practitioners in the United States and Canada.

2. Upon information and belief, McGhan changed its name to Inamed Corporation ("Inamed") in or around 1986.

3. Inamed Corporation is incorporated under the laws of Delaware, and its principal place of business is in Orange County, California.

4. Inamed was a global surgical and medical device company engaged in the development, manufacturing, and marketing of products for 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.

5. In March 2006, Allergan purchased substantially all of Inamed, including Inamed's outstanding common stocks and Inamed's wholly-owned subsidiary,

McGhan.

Allergan Defendants: Agents, Alter Egos and Joint Tortfeasors

6. At all relevant times, Defendants acted as agents and alter-egos of each other and engaged in acts leading to the placement of Defendants' products into the stream of commerce in the State of Louisiana and resulting in Plaintiff's personal injuries in the State of Louisiana as alleged herein.

7. The combined acts and/or omissions of each Defendant resulted in injuries to the Plaintiff in the State of Louisiana. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is 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.

8. At all relevant times, Defendants acted in concert with one another to fraudulently convey false and misleading information concerning the McGhan® Breast Implants and concealed the risks of serious adverse events associated with the implants from Plaintiff, the public, physicians, and other healthcare providers. But for the Defendants' actions, Plaintiff, Christine Downey , would not have suffered the severe injuries and harms that resulted from implantation of the McGhan® Breast Implants into Plaintiff's body.

9. Defendant Allergan is a leading breast implant manufacturer, having collected approximately $400 million in net revenue in 2017 alone from the sale of breast implants.

10. At all relevant times, Defendants acted in concert with one another to

fraudulently convey false and misleading information concerning the McGhan® Breast Implants, and concealed the risks of serious adverse events associated with its breast implant products from Plaintiff, the public, physicians, and other healthcare providers resulting in severe personal injuries to Plaintiff in the State of Louisiana.

11. But for the Defendants' actions, Plaintiff, Christine Downey , would not have suffered severe injuries and harms that resulted from implantation of the McGhan® Breast Implants into her body. Defendants at all relevant times engaged directly or indirectly in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting selling and introducing into the stream of commerce in the State of Louisiana their products, including the breast implants that injured plaintiff in the State of Louisiana.

12. At all material times, Defendants maintained systematic and continuous contacts within this jurisdiction, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district. Defendants received substantial financial gain as a result of designing, formulating, testing, packaging, labeling, producing, assembling, advertising, marketing, promoting, distributing, manufacturing, and/or selling the breast implant products within this jurisdiction.

JURISDICTION AND VENUE

13. This Honorable Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because complete diversity of citizenship exists between the Plaintiff and the Defendants, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district as alleged herein.

14. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTS REGARDING ALLERGAN ND MCGHAN® SALINE FILLED BREAST IMPLANTS

A. General Information Relating to Breast Implants

15. Silicones, which are also called polysiloxanes, are polymers that include a synthetic compound made up of repeating chains of alternating silicon and oxygen atoms, frequently combined with carbon and/or hydrogen. Silicones are typically heat-resistant and rubber-like, and are used in sealants, adhesives, lubricants, medicine, cooking utensils, and thermal and electrical insulation. Being purely synthetic, silicones do not exist in nature

16. A breast implant is a prosthetic product used to change the size, shape, and/or contour of a woman's breast. There are three general types of breast implant products, defined by their filler material: saline solution, silicone gel, and composite filler.

17. Silicone gel-filled breast implants have a silicone outer shell that is filled with silicone gel. They are available in various sizes and can have either a smooth or textured shell. Silicone gel-filled breast implants are approved for breast augmentation in women age 22 or older and for breast reconstruction in women of any age.

18. 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).

19. 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 requiring premarket approval ("PMA").

20. In April 1991, upon final publication of new regulations, FDA began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants.

21. 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.

22. 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 be 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.

23. 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.

24. In November 1991, the FDA held an Advisory Panel meeting to discuss several PMAs for silicone gel-filled breast implants. While the Advisory Panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, they unanimously recommended that the FDA permit the implants to remain on the market.

25. In January 1992, the FDA announced a voluntary moratorium on silicone gel- filled breast implants, requesting that the manufacturers stop supplying them and that surgeons stop implanting them while the FDA engaged in a further review of the products' safety and effectiveness.

26. In April 1992, the FDA determined that none of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support premarket approval for silicone breast implants. From that time, implantation of the products in the United States was limited to reconstruction and revision patients.

B. Information Specific to McGhan Gel-Filled and Saline-Filled Breast Implants

27. In 1991, McGhan, a predecessor corporation to Inamed and Allergan,

Inc., applied for premarket approval for various styles of implants. The FDA denied approval of the application for use of such devices for the augmentation of healthy female breasts, but also determined there was a public health need for the devices to be available for reconstruction patients.

28. In April 1992, the FDA entered into an agreement with McGhan setting forth the requirements for McGhan to conduct clinical trials of the 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 device on a form consistent with that which had previously been approved by the FDA, and McGhan was to make sure all products were labeled consistent with the agreement and the terms of the approved protocols.

29. 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.

30. 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.

31. 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.

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

33. 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.

34. 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.

35. 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 an application for pre-market approval of such products by November 17, 1999. McGhan was among the three manufacturers of saline-filled breast implants whose PMA applications were accepted for filing; and, in accordance with FDA regulations, each of the three applications was referred to an FDA Advisory Panel on general and plastic surgery.

36. The Advisory Panel met in open session on March 1-3, 2000 to consider the applications.

37. On May 10, 2000, the FDA announced that it had approved McGhan's application for PMA of four styles of saline-filled breast implants for augmentation in women age 18 and older and for reconstruction in women of any age. These products were previously available in the U.S. marketplace as 510(k) devices.

38. As conditions of the 2000 approval, the FDA required McGhan to conduct four post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for the McGhan Breast Implants included:

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.

d. Mechanical Testing

39. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as the McGhan Breast Implants, rests with the manufacturer.

40. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

41. Also under state law, which does not impose duties or requirements

materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

42. When monitoring and reporting adverse events, especially those indicating an association between their product and breast cancer, ALCL and/or BIA-ALCL, as required by federal regulations, Louisiana, and New Jersey law, time is of the essence.

43. Delayed reporting prevents the healthcare community and the public from timely learning of risks which must inevitably play a part in their decision-making, by both physicians and consumers, regarding treatments and procedures, and thereby expose countless additional women to potential harm.

44. Defendants' specific obligations after the PMA include, but are not limited to:

a. 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];

b. Monitoring the product and reporting to the FDA any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 CFR §814];

c. Submitting an adverse event report within 10 days of receiving knowledge of an adverse reaction, side effect, injury . . . that is attributable to the device [21 CFR §814.82(a)(9) and PMA];

d. Submitting a PMA supplement for the following:

- When unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification [PMA Conditions of Approval and 21 CFR §814.39]

- Labeling changes except for those that add to or strengthen a contraindication, warning, precaution or information about an adverse reaction for which there is reasonable evidence of a

causal association [21 CFR §814.39(a)(2) and §814.39(d)(2)(i)];

- for any listed or material changes to the product [21 CFR §814.39];

e. Establishing and implementing a quality policy which all aspects of the manufacturer's operations must meet [21 CFR §820.20];

f. Establishing and maintaining procedures for validating the device design, including testing of production units under actual or stimulated use conditions, and creation of a risk plan and conduction of risk analyses [21 CFR §820.30];

f. Documenting all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues [21 CFR §820.100];

g. Establishing internal procedures for reviewing complaints and event reports [21 CFR §§820.198, 820.100, 820.20];

h. Establishing Quality Management System (QMS) procedures to assess potential causes of quality problems, including non-conforming products [21 CFR §§820.70 and 820.90];

i. Reporting on Post-Approval Studies in a timely fashion [21 CFR §814.80]; and

j. Advertising the device accurately and truthfully [21 CPR §801].

45. Defendants violated other federal requirements including the requirements to:

a. establish and maintain a quality system. [21 C.F.R. 820.5];

b. provide for management responsibility [21 C.F.R. 820.20];

c. provide for quality audits [21 C.F.R. 820.22];

d. establish and maintain procedures to control the design of the device in ordered to ensure that specified design requirements are met [21 C.F.R. 820.30];

e. establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonable be anticipated to have an adverse effect on product quality [21 C.F.R. § 820.70(e)];

f. establish and maintain procedures for acceptance activities, including inspections, tests, or other verification activities [21 C.F.R 820.80];

g. identify the "conformance or nonconformance of product with acceptance criteria ... throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed" [21 C.F.R 820.86];

h. establish and maintain procedures to control product that fails to conform with specified requirements, including the evaluation of non-conforming products [21 C.F.R. § 820.90(a)];

i. establish and maintain procedures for implementing corrective and preventive action including:

i. identifying the cause of product nonconformities,
ii. identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems,
iii. ensuring that information related to quality problems or nonconforming product is disseminated to hose directly responsible for assuring. [21 C.F.R. § 820.100(a)(1)-(7)].

46. Defendants failed to report adverse events from the post market approval studies commissioned as part of the implant's PMA approval, which would have led to reports suggesting the device's contribution to serious injury, such as those suffered by Plaintiff, Christine Downey .

47. Had Defendants not intentionally failed to comply with their clearly-established post-market surveillance obligations, Plaintiff, Christine Downey , would have decided against implantation and her injuries would not have occurred.

48. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Inamed/Allergan had a duty to exercise reasonable care in adequately and timely warning Plaintiff and Plaintiff's implanting surgeon

about the dangers of the McGhan Breast Implants, and about all adverse events of which Defendants became aware, and had a post-market duty to identify, monitor and report all adverse events and all risks associated with the product.

49. Despite having knowledge and possession of evidence showing that the use of the McGhan 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 Defendants.

50. Instead, Defendants marketed, advertised and promoted the product while at the same time consciously refusing and/or recklessly failing to monitor, warn, or otherwise ensure the safety and efficacy for users of the McGhan Breast Implants.

51. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Defendants had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its McGhan Breast Implants. Defendants recklessly failed to do so.

52. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Defendants were required at all material times to promptly report any information suggesting that one of its products may have contributed to a serious injury, or had malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

53. The PMA provided as follows:

> Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

54. Defendants' insufficient follow-up rates and inadequate data, as detailed above,

establish and confirm Defendants' reckless and intentional disregard for the safety of thousands of women, including Plaintiff.

55. Each of the above-cited deficiencies in Defendants' post-market compliance, including those described above, was a "failure to comply with the conditions of approval" and each constituted a ground for withdrawal of the PMA. Defendants' conduct separately violated their duties under the law.

56. Notwithstanding Defendants' failures to comply with post-approval requirements, including the failures described above, Defendants continued to commercially distribute the McGhan Breast Implant products. As expressly provided in the PMA, such distribution was a violation of federal law.

57. Had Defendants substantially complied with the PMA, rather than flagrantly under-performing the post-approval requirements as alleged above, Defendants' disclosures would have led to much wider knowledge of the risks associated with Defendants' products. In addition, Defendants' physician and patient labeling would have materially changed over time, and patients including Plaintiff, and medical providers including Plaintiff's physicians, would not in ignorance have purchased or implanted Defendants' products, including, but not limited to, the causative association to Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA- ALCL").

58. Specifically, Defendants knew or should have known that the new breast implants, specifically the textured-design models, were associated with Anaplastic Large Cell Lymphoma.

59. To protect the McGhan® brand, the Defendants intentionally failed in their post-approval study and conditions of approval, and thereby consciously and deliberately

concealed its knowledge of known safety risks from the FDA, the medical community, including Plaintiff's surgeon, and the public at large. Additionally, the Defendants ignored the available scientific studies and publications indicating an association between textured breast implants and Anaplastic Large Cell Lymphoma.

60. Defendants also have a duty to exercise reasonable care in the manufacture, development, design, marketing, labeling, distributing, and sale of the product after it was approved for sale by the FDA in 2000, which does not impose duties or requirements materially different from those imposed by federal law. Defendants failed or refused to do so.

61. At material times, Defendants routinely maintained manufacturing facilities that failed to comply with applicable law and regulations in relation to:

a. The lack of approved software and systems;

b. The use of nonconforming products;

c. Documents which failed to include data or statistical rationale to support sampling plans used to test saline and gel-filled products;

d. The failure to initiate or take corrective action to reassess the results and adjust the values of product bioburden samples;

e. The omission of any reference in Defendants' reporting to its manufacturing processes as a potential cause of product failures relating to the inability to sterilize the product;

f. The omission of any reference in Defendants' reporting to its manufacturing processes as a potential cause of product failures relating to finished products which showed an "absence of material" or a "fail[ure] to contain gel";

g. The failure to adhere to an appropriate Environmental Monitoring Program;

h. Deficiencies in Defendants' sampling methods for finished product testing;

i. Deficiencies in Defendants' risk analyses and its investigation of non-conformances;

j. Deficiencies in Defendants' environmental monitoring control procedures; and

k. Citations to incomplete data and missing statistical or technical rationales to justify the performance of finished product testing.

62. These deviations contributed to faulty manufacture of McGhan® Breast Implants which were textured, prone to rupture and which were thus defective and adulterated.

63. Allergan failed to warn consumers, healthcare providers, including Plaintiff's surgeon, and the FDA that ALCL and BIA-ALCL, and symptomatology attenuated thereto, was a potential risk of McGhan® Breast Implants, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk.

64. The risk of ALCL or BIA-ALCL was not disclosed or discussed in the product's consumer labeling, despite the availability of substantial evidence that an association existed and was established by at least 2008, but probably much earlier, as further detailed below.

65. Defendants knew of the manufacturing failures, and multiple risks associated with implants design, and consciously responded by terminating the studies required within post market surveillance, in favor of self-serving research that it could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

66. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the McGhan Breast Implants, the public's knowledge of the risks associated with the McGhan Breast Implants were seriously hampered and delayed. This endangered patient safety, including the safety of Plaintiff, Christine

Downey .

BREAST IMPLANT–ASSOCIATED ANAPLASTIC LARGE-CELL LYMPHOMA

67. Approximately 300,000 total breast implants are placed per year in the U.S. From 2000 to 2016, the number of breast augmentations in the United States rose 37%, and reconstructions after mastectomy rose 39%.

68. Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL") is a rare T-cell lymphoma that can develop following breast implant implantation. It is a type of non-Hodgkin's lymphoma, a cancer of the cells of the immune system.

69. The most common presenting symptom for BIA-ALCL is a swollen breast caused by the formation of a delayed unilateral idiopathic seroma occurring between the implant surface and the breast capsule.

70. Upon information and belief, the first case of anaplastic large cell lymphoma (ALCL) in association with silicone breast implants was diagnosed in the early 1990's.

71. In November 2008, 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.

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

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

74. 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*.

75. 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.

76. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL.

77. In the Updated Safety Alert, the FDA recognized 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."

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

79. 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/breast-implants-cancer-ban-two-die-23-develop-same-type-textured-common-women-enlargement-cosmetic-a7832996.html

80. 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."

81. 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.

82. 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).

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

84. In 2019, the FDA began preparing for public hearings on this issue and told ICIJ in a statement pertaining to the 2019 hearing, "[t]his will help inform FDA as to whether we should take additional actions to protect patient safety including a black box label warning, a ban on textured implants, a patient safety checklist, or other steps." Available at:

https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/.

85. The French regulatory body ANSM (Agence Nationale de Sécurité du Méedicament et des produits de santé) will also be holding an open hearing in February of 2019 to hear from health professionals and implant wearers before making a ruling on the safety of textured implants. "In the meantime, the ANSM recommends that health professionals rather use implants with a smooth surface." Available at:

https://www.afp.com/en/news/15/france-review-safety-lymphoma-linked-breast-implants-doc-1b06ve1.

86. On February 12, 2019, Health Canada announced that it would be updated its safety review of breast implants. https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69052a-eng.php

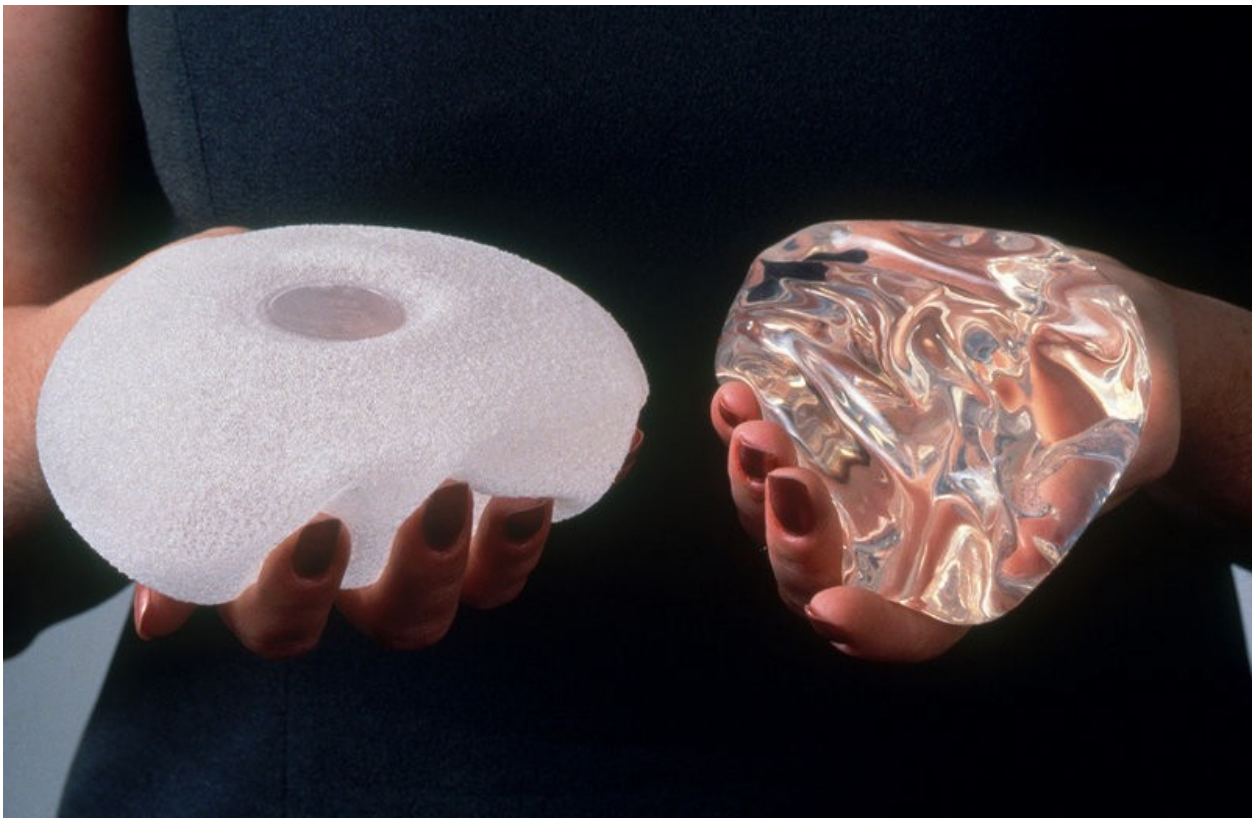
87. On July 11, 2019, The Australian Therapeutic Goods Administration (TGA) announced a completed assessment of textured breast implants in Australia. The TGA proposed regulatory action pertaining to textured implants, including proposed cancellation of Allergan Natrelle implants. https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma

88. On July 24, 2019, the FDA requested that Allergan recall all BIOCELL textured breast implants and tissue expanders marketed in the U.S. based on newly submitted Medical Device Reports reporting worldwide cases of BIA-ALCL and BIA-ALCL-related deaths associated with these devices. Shortly thereafter, Allergan notified the FDA that it would recall its BIOCELL products. https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue

89. The natural occurrence of this cancer is 1/300,000. However, FDA recently cited to 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

90. Upon information and belief, BIA-ALCL is mainly associated with textured breast

implants; however, there have been cases of BIA-ALCL in women with smooth implants.



91. Despite Defendants' knowledge of an association between breast implants and ALCL dating back to the 1990's, Defendants purposefully failed to comply with their clearly-established post-market surveillance obligations and in doing so have exposed many hundreds of thousands of women to life-altering and avoidable cancer.

92. While ANSM's recommendation against the use of textured implants due to the risk of BIA-ALCL is the first of its kind for a country's regulatory body, it is not new. Many plastic surgeons in the United States have publicly denounced the use of textured implants for this reason including, but not limited to, the following plastic surgeons: Eric Swanson, M.D., David A. Hidalgo, M.D., and Mark Clemens, M.D., F.A.C.S.

FACTS SPECIFIC TO CHRISTINE DOWNEY

93. In 2000 Plaintiff Christine Downey was diagnosed with bilateral breast cancer at LSU (Feist Weiler) in Shreveport La. Christine Downey and her physician decided upon textured saline implants for her breast reconstruction, augmentation and had them implanted by a plastic surgeon in Shreveport, Louisiana.

94. At the time the McGhan Breast Implants were placed into Christine Downey 's body, she was not advised, nor did she have any independent knowledge, that the McGhan Breast Implants were anything other than safe, life-long products. Nor was she advised that the product was associated and/or known to cause BIA-ALCL.

95. Christine Downey was not advised, 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 upon contracting ALCL and/or BIA-ALCL; or

d. She might need future surgery and/or chemotherapy and radiation, or

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

f. The chemicals with which Defendants fill the McGhan Breast Implants contains compounds and metals which are toxic to the human body; or

g. Smooth implants were a safer available alternative to textured implants.

96. In December of 2011, Ms. Downey presented with pain and swelling in her left breast. Plaintiff underwent mammogram and ultrasound imaging, the latter of which revealed fluid around the left implant, though the implant appeared intact.

97. Doctors initially speculated that the original implant might be a double lumen implant because of the appearance of fluid in absence of rupture. This theory was

disproved as a late December 2011 MRI revealed bilateral breast implants without signs of rupture. In February of 2012 Plaintiff had a plastic surgery consultation, and subsequently had an explant of the left saline breast implant, along with left-side replacement with silicone implant. Fine needle aspiration and excision biopsies of the left breast capsule were done.

98. The FNA pathology/cytology report on 4/18/2012 was consistent with atypical lymphoid proliferation expressing CD30 and CD45, negative for ALK-1 and positive for LCA. The excision biopsy of the left breast capsule revealed anaplastic large cell lymphoma, ALK-1 negative.

99. In mid-2019, Christine Downey noticed that one of her two breasts was enlarged.

100. On October 30, 2019, Christine Downey underwent ultrasound-guided aspiration of peri-implant fluid, which "revealed **Breast Implant Associated Anaplastic Large Cell Lymphoma**." (emphasis added).

101. Christine Downey has suffered and is continuing to suffer debilitating side effects from BIA-ALCL, surgery, hospitalization, including fatigue, pain, loss of income, financial ruin, and physical deformities, with which she will be forced to live for the rest of her life.

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

103. Had Christine Downey 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 of the Products.

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

105. Due to the Defendants' repeated failure to comply with their post-approval surveillance obligation, Christine Downey did not suspect, nor did she have reason to suspect, that she was at risk of injury, or that her her injuries were caused by the McGhan® breast implants, or by Defendants' tortious conduct.

106. Moreover, both at the time of her explantation and at the time of her diagnosis and treatment for anaplastic large cell lymphoma, Christine Downey was not aware that her breast implants were a significant and likely cause of her anaplastic large cell lymphoma.

107. While Plaintiff's treating physicians may, or may not, have learned of the existence of an association between breast implants and an increased risk of breast-ALCL, per sources described in paragraphs 67-88, supra, Plaintiff was never advised by her physicians of that association. Plaintiff Christine Downey only became aware of the link between her cancer and her implant use within one year of the filing of this complaint.

108. 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 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 Products.

109. At all times material herein, Drake Allen Downey was the husband of Plaintiff Christine Downey, and a partner and help mate during her injuries, diagnosis, and treatments. Not only has he suffered from watching the ijjury to his loved one, his wife's battle with Breast Implant-Associated Anaplastic Large-Cell Lymphoma cancer has resulted in his suffering all of the seven factors under Louisiana law comprising a loss of consortium claim.

110. All conditions precedent to filing this action have occurred, or have been satisfied or waived.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

111. Plaintiff hereby incorporates by reference all other paragraphs in this Complaint as if set forth fully herein.

112. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and other consumers the true risks associated with the McGhan® Breast Implants.

113. As a result of Defendants' actions, Plaintiff was unaware, and could not reasonably know or have learned through reasonable diligence, that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

114. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of the McGhan® Breast Implants.

115. Defendants were under a duty to disclose the true character, quality and nature of the McGhan® Breast Implants because this was non-public information over which they continue to have exclusive control. Defendants knew that this information was not available to Plaintiff, her medical providers and/or her health facilities, yet they failed to disclose the information to the public.

116. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purposes of marketing and promoting a profitable product, notwithstanding the known or reasonably knowable risks.

117. Plaintiff, consumers, and medical professionals could not have afforded to and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and they were forced to rely on Defendants' representations

PUNITIVE DAMAGES UNDER CHOICE OF LAW

118. Defendants' manufacture, marketing, promotion, distribution and sale of a defective product and their failure to provide adequate warnings and instructions concerning its hazards was willful, wanton, reckless and without regard for the public's safety and welfare.

119. Defendants knowingly withheld information, and affirmatively misrepresented information, required to be submitted by federal law, to Plaintiff, the medical community and the public at large, of the safety of McGhan® Breast Implants.

120. Defendants downplayed, understated and/or disregarded their knowledge of the

serious and permanent side effects and risks associated with the use of McGhan® Breast Implants. despite available information demonstrating that McGhan® Breast Implants were likely to cause serious and potentially fatal side effects to users.

121. At all times relevant hereto, Defendants knew of the defective nature of their McGhan® Breast Implants, and continued to design, manufacture, market, label, and sell McGhan® Breast Implants so as to maximize sales and profits at the expense of public health and safety, with wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by McGhan® Breast Implants, including Plaintiff who did suffer such harm.

122. Defendants misled regulators, the medical community and the public at large, including Plaintiff, by making false and misleading representations about the safety of McGhan® Breast Implants. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiff.

123. As a direct and proximate result of Defendants' reckless, willful and wanton acts in disregard of the safety of the public generally and of Plaintiff in particular, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

CAUSES OF ACTION

COUNT I:
BREACH OF DUTY IN THE MANUFACTURE UNDER THE LOUISIANA PRODUCTS LIABLITY ACT (LPLA)
(Against All Defendants)

124. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

125. At all material times, Defendants owed Plaintiff Christine Downey a duty to use reasonable care, pursuant to the federal post-approval requirements, to discover dangerous qualities and characteristics present on the McGhan® Breast Implants as a result of manufacturing flaws and a deficiency in quality control.

126. Defendants owed Plaintiff a duty to use reasonable care in the production (manufacture) and sale (marketing) of McGhan® Breast Implants.

127. Defendants owed Plaintiff a duty to use reasonable care in conducting and reporting on post-approval studies, monitoring, testing, and adequately warning of the dangers, including the development of BIA-ALCL, related to McGhan® Breast Implants.

128. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted McGhan® Breast Implants, including the devices which were implanted into Plaintiff Christine Downey .

129. Plaintiff was implanted with McGhan® Breast Implants which were defective, dangerous and adulterated upon manufacture, and without adequate warnings, in violation of state law, which does not impose duties or requirements materially different from those imposed by federal law including the PMA post approval specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

130. Defendants had a duty under 21 C.F.R. § 820.70(e) to establish and maintain

procedures to prevent contamination of equipment or product by substances that could reasonable be anticipated to have an adverse effect on product quality.

131. Defendants violated the duties owed to Plaintiff by:

h. failing to establish and maintain procedures to prevent the contamination of McGhan® Breast Implants by substances that could cause an adverse effect on purchasers, including Plaintiff;

i. failing to use exercise ordinary care in the manufacturing and marketing of McGhan® Breast Implants when they contained contaminants and/or bacteria in violation of the FDA requirements and standards as set forth in the Facts section of this Complaint;

j. placing breast implants into the stream of commerce that were not sterile;

k. failing to warn Plaintiff's physician and Plaintiff of the risk that the breast implants were contaminated and could result in serious bodily injury.

132. Defendants violated the parallel state duty of a manufacturer not to distribute a product in a defective and unreasonably dangerous condition pursuant to under Louisiana law.

133. Defendants had parallel duties under state and federal law to exercise reasonable care in establishing and maintaining procedures to prevent the contamination of their products that could be dangerous and have adverse effects on consumers.

134. Defendants breached their parallel duties by failing to establish and maintain procedures to prevent contamination of their breast implants.

135. Defendants' violations caused the McGhan® Breast Implants to be sold to Plaintiff Christine Downey in a contaminated and dangerous condition which caused her to develop and suffer from BIA-ALCL.

136. Defendants' specific actions which constitute breaches of these duties to Plaintiff include: failing to timely and accurately report adverse events regarding the McGhan® Breast Implants; failing to report the McGhan® Breast Implants' failure to meet performance specifications and expectations under the PMA and FDA requirements; failing to revise and update product labeling to reflect Defendants' current knowledge of BIA-ALCL; receiving but failing to warn or report to the FDA and the medical community Defendants' knowledge and information regarding complaints and specific events about McGhan® Breast Implants causing BIA-ALCL, and additional injuries including:

l. Adverse events requiring removal;

m. Persistent and/or chronic inflammation or autoimmune impacts;

n. suspected cancer linked to breast implants;

o. ALCL diagnoses linked to breast implants; and,

p. BIA-ALCL diagnoses linked to breast implants.

137. Defendants disseminated false information by deliberately engaging in false and misleading sales and marketing tactics touting the aesthetic beauty of breast augmentation while minimizing and/or avoiding the risks, which only later, after causing avoidable injury, reached physicians, the medical community, and the public.

138. At all material times, Defendants knew and intended that the medical community and/or patients would rely upon Defendants' disseminated information in deciding whether to purchase and/or implant McGhan® Breast Implants.

139. At all material times, Defendants knew and intended that patients who were implanted with McGhan® Breast Implants would, in reliance on false information, be placed in

unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to McGhan® Breast Implants, causing them to develop cancer requiring future removal surgeries and to suffer debilitating injuries and conditions, and emotional turmoil attenuated thereto.

140. Plaintiff and/or Plaintiff's physicians reasonably relied on Defendants' negligent misrepresentations and omissions, as Defendants intended, and would not have made the same decision(s) if provided the required information.

141. As a proximate and foreseeable result of the foregoing misrepresentations by Defendant, Plaintiff has suffered and will continue to suffer from BIA-ALCL and its accompanying symptoms including, but not limited to, severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

142. For each of the statutes and regulations cited in this Complaint, Plaintiff Christine Downey is within the class of persons the statutes and regulations are intended to protect, and Plaintiff's injuries are of the type of harm these statutes and regulations are designed to prevent. Defendants were negligent in their development, promotion, marketing, manufacture, distribution, sale and/or post-market surveillance of McGhan® Breast Implants in one or more of the following ways:

q. Failing to identify the risk of BIA-ALCL in a timely manner;

r. Failing to warn of the risk of BIA-ALCL;

s. Designing, manufacturing, distributing and selling McGhan® Breast Implants that are dangerous to the consuming public;

t. Designing, manufacturing, distributing and selling McGhan® Breast Implants which differ from the specifications set forth in the PMA, its Supplements, and the Conditions of Approval;

u. Failing to conduct regular risk analyses of McGhan® Breast Implants; and,

v. Failing to exercise reasonable care in the manufacturing, inspection, testing, and quality control processes.

143. As a proximate and legal result of Defendants' failure to exercise reasonable care in the warning, design, manufacture, distribution and sale of the McGhan® Breast Implants implanted into Plaintiff, Plaintiff has suffered and will continue to suffer severe from BIA-ALCL and its accompanying symptoms including physical injuries, pain and suffering, severe emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Christine Downey demands judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper and appropriate.

COUNT II:

MANUFACTURING AND DESIGN DEFECT UNDER LSA-RS 9:2800.55 AND LSA-RS 9:2800.56

(Against All Defendants)

144. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

145. At all material times, Defendants were engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting McGhan® Breast Implants, including those which were implanted into Plaintiff Christine

Downey.

146. Plaintiff was implanted with McGhan® Breast Implants which were defective, dangerous and adulterated upon manufacture as they were contaminated and were manufactured with nonconforming materials and uncertified components in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

147. McGhan® Breast Implants were adulterated as a result of being manufactured in violation of FDA regulations and requirements, particularly 21 C.F.R § 820.70(e), such that manufacturing residuals and contaminants and/or bacteria remained on the implants after their manufacture.

148. At all material times, Defendants knew the contaminated and adulterated products would be surgically implanted into the bodies of members of the general public, including Plaintiff.

149. Plaintiff's McGhan® Breast Implants were defective and adulterated at the time of sale and distribution, and at the time they left Defendants' possession, and Defendants failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and that the product was susceptible to causing ALCL and/or BIA-ALCL as suffered by Plaintiff Christine Downey .

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

151. The defects, adulterations and increased risks inherent in McGhan® 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.

152. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants when consenting to the implantation of McGhan® Breast Implants.

153. At all relevant times, Plaintiff's McGhan® Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

154. The McGhan® 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.

155. Defendants knew that McGhan® Breast Implants 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.

156. McGhan® Breast Implants, which were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, and caused Plaintiff's injury of BIA-ALCL, which would not have occurred but for the use of McGhan® Breast Implants.

157. As a proximate result and/or substantial factor of McGhan® Breast Implants' defective and adulterated condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Christine Downey demands judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory

and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper and appropriate.

COUNT III: INADEQUATE WARNING UNDER LSA-RS-9:2800.57
(Against All Defendants)

158. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

159. At all material times, Defendants were engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting McGhan® Breast Implants.

160. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted McGhan® Breast Implants, including those which were implanted into Plaintiff Christine Downey .

161. Plaintiff was implanted with McGhan® Breast Implants which were defective, dangerous and adulterated upon manufacture, and which were manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

162. At all material times, Defendants intended for the McGhan® Breast Implants to be surgically implanted into the bodies of members of the general public, including

Plaintiff, and knew the product would be surgically implanted into members of the general public, including Plaintiff.

163. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects, adulterations and life-altering complications such as the development of BIA-ALCL described in this Complaint, rendering the device defective and unreasonably dangerous.

164. Additionally, Defendants had a parallel duty to adequately warn Plaintiff, pursuant to federal and state requirements, of any dangerous condition of its products and failed to do so.

165. Defendants violated the parallel state and federal duty to warn by failing to adequately warn Plaintiff Christine Downey 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.

166. Defendants also failed to revise the Product's labeling to give warnings consistent with adverse event information which was known or available to Defendants at the time of distribution, and failed to warn Plaintiff of information which became known or available to Defendants after implantation into Plaintiff.

167. Notwithstanding the Defendants' knowledge of the defective condition of its product, they failed to adequately warn the medical community and consumers of the product, including Plaintiff and his healthcare providers, of the dangers and risk of harm associated with the use and administration of its breast implant.

168. A reasonably prudent manufacturer would have warned of these characteristics and its

danger to users, and Defendants' failure to do so renders defendant liable for all damages caused by Defendants' subsequent failure to use reasonable care to provide adequate warning of the danger to Plaintiff and other users of the product.

169. Defendants knew or should have known that there was a significant risk that its McGhan® Breast Implants caused, and did in fact increase the risk of contracting, BIA-ALCL. Defendants deliberately refused to disclose this information to FDA, the medical community and the public.

170. Despite the fact that Defendants knew or should have known that implantation of McGhan® Breast Implants was unreasonably dangerous and was associated with an increased risk of serious injury to consuming patients, Defendants failed to monitor and warn of the defects, adulterations, health hazards and increased risks associated with the product.

171. The defects, adulterations and increased risks inherent in McGhan® 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.

172. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants when she consented to the implantation of McGhan® Breast Implants.

173. At all relevant times, Plaintiff's McGhan® Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

174. The McGhan® Breast Implants manufactured, designed, promoted, marketed, distributed, and sold by Defendant were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were

sold.

175. Defendants knew that McGhan® Breast Implants 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. After Defendants ad started shipping product that had left its control, they acquired knowledge of characteristics of the product that might cause damage and the danger of such characteristic, and is liable for damage caused by a subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product since that knowledge of the characteristics and its danger to users was acquired.

176. The defective and adulterated product was a substantial contributing factor in bringing about or did in fact cause the injuries to Plaintiff that would not have occurred but for the use of McGhan® Breast Implants.

177. 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 McGhan® Breast Implants.

178. As a proximate result and/or substantial factor of McGhan® Breast Implants defective and adulterated condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff, Christine Downey, demands judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory

and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper and appropriate.

COUNT IV:

NON-CONFORMITY TO EXPRESS WARRANTY UNDER LSA-RS-9:2800.58

(Against All Defendants)

179. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

180. Defendants in their manufacturing, design, distribution, marketing and promotion of McGhan® Breast Implants voluntarily made implied and express warranties that the McGhan® Breast Implants were safe and effective for Plaintiff and members of the public generally.

181. Defendants breached the implied warranty of merchantability as McGhan® Breast Implants were unfit for their ordinary purpose and were manufactured in a manner that made them unreasonably dangerous.

182. Additionally, Defendants breached their express warranties of McGhan® Breast Implants by advertising them as safe, effective, fit and proper for their intended use.

183. Defendants further expressly warranted to Plaintiff and Plaintiff's physicians that their McGhan® Breast Implants were safer and more effective than other breast implants, were safe and long-lasting.

184. The requirements of truthful, accurate, and non-misleading warranties do not impose any different or additional requirements on defendants as required by federal law.

185. McGhan® Breast Implants do not conform to these implied or express warranties and representations because McGhan® Breast Implants are not safe or effective for their ordinary purpose, 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.

186. Plaintiff and Plaintiff's physician relied upon Defendants' voluntary express and implied warranties that the McGhan® Breast Implants were safe and effective for use.

187. Defendants breach of warranties directly caused Plaintiff and Plaintiff's physician to choose McGhan® Breast Implants and have them implanted which was the direct and proximate cause of Plaintiff's development of BIA-ALCL and profound injuries resulting therefrom.

188. Plaintiff's injuries are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff Christine Downey and Drake Allen Downey demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

DEMAND FOR JURY TRIAL

The Plaintiff demands trial by a jury on all of the triable issues of this complaint.

Dated: August 3, 2020

Respectfully submitted,

/s Richard L. Root
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