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30-2020-01154383-CU-PL-CJC - ROA # 2 - DAVID H. YAMASAKI, Clerk of the Court By Valerie Hammer, Deputy Clerk.

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SUPERIOR COURT FOR THE STATE OF CALIFORNIA
COUNTY OF ORANGE

ASSIGNED FOR ALL PURPOSES TO: Judge Sheila Fell

SUSAN MROWIEC, individually,

Plaintiff,

v.

ALLERGAN, INC. f/k/a INAMED CORPORATION f/k/a McGHAN MEDICAL CORPORATION, a Delaware corporation with its principal place of business in California; ALLERGAN HOLDCO U.S. INC., a Delaware corporation with its principal place of business in California; ALLERGAN HOLDINGS, INC., a Delaware corporation with its principal place of business in California; ALLERGAN SALES, LLC, a Delaware corporation with its principal place of business in California; ALLERGAN USA, INC., a Delaware corporation with its principal place of business in California; ALLERGAN plc, a foreign corporation with its principal place of business in California; and DOES 1 through 100, inclusive,

Defendants

CASE NO. 30-2020-01154383-CU-PL-CJC

COMPLAINT AND DEMAND FOR JURY TRIAL

1. Strict Product Liability-Failure to Warn
2. Strict Product Liability-Manufacturing Defect
3. Negligence
4. Intentional Misrepresentation/ Concealment
5. Negligent Misrepresentation/ Concealment

Plaintiff SUSAN MROWIEC ("Plaintiff") brings this action against Defendants ALLERGAN, INC., ALLERGAN HOLDCO U.S., INC., ALLERGAN HOLDINGS, INC., ALLERGAN SALES, LLC, ALLERGAN USA, INC., ALLERGAN PLC (all corporations headquartered in California with their principal place of business and key executives

located in California; collectively referred to as "Defendants" or "ALLERGAN"), and DOES 1-100 seeking damages arising out of ALLERGAN's negligence, deceit, concealment, and misrepresentations concerning the deadly and defective condition of its BIOCELL Textured Breast Implants.

INTRODUCTION

1. ALLERGAN is a global company that has long pushed a portfolio of consumer products in the medical aesthetics, eye care, central nervous system, and gastroenterology fields. Among its portfolio of products is a specific type of breast implant and tissue expander for cosmetic and reconstructive surgery, referred to broadly herein as the BIOCELL Textured Breast Implant suite of products. ALLERGAN developed, sought regulatory approval for, marketed, advertised, manufactured, distributed, and sold those BIOCELL Textured Breast Implants through its primary office in the United States, located in Irvine, California.

2. Across multiple generations of the product, ALLERGAN has sold hundreds of thousands of textured breast implants and developed and marketed dozens of additional styles incorporating their BIOCELL technology. Those products have been sold worldwide, and have been implanted into tens, if not hundreds, of thousands of California and United States consumers. This was highly profitable for ALLERGAN, which received tens, if not hundreds, of *millions* of dollars' worth of revenue through its sale and distribution of the BIOCELL Textured Breast Implants to consumers across the world.

3. ALLERGAN has longed claimed that these products are safe for consumer use and based on those promises they have been widely used by women for both reconstructive surgery—particularly after a breast cancer diagnosis, genetic testing, or other concern—as well as for cosmetic uses.

4. But those products pose a significant risk—a risk that was *long* hidden and buried by ALLERGAN in advertisements, flyers, reports, and other communications to both the marketplace and the FDA. ALLERGAN's BIOCELL Textured Breast Implants

have a surface roughness significantly *higher* than the industry standard and are capable of embedding silicone surface particles in the fibrous scar tissue that naturally forms around the implant, known as the "capsule."

5. In part because of that flaw, the medical and scientific consensus has determined that the extreme texturing of the implants, when combined with a bacterial accumulation or a genetic predisposition, form a perfect storm for the development of Breast Implant Associated–Anaplastic Large Cell Lymphoma (BIA-ALCL).[1] BIA-ALCL is an uncommon but emerging subtype of non-Hodgkin's lymphoma—a cancer that originates from lymphatic cells, which are part of the immune system. BIA-ALCL is thus a cancer of the immune system, and *not* a type of breast cancer.

6. Because of the processes used in their manufacture, ALLERGAN's BIOCELL Textured Breast Implants increase the likelihood of a woman developing BIA-ALCL dramatically from other textured breast implants on the market, with one study finding that the nexus jumps approximately *10 times* from other products on the US marketplace.

7. Despite the grave risks posed by its BIOCELL Textured Breast Implants, and the ready possibility of a safer product, ALLERGAN has for decades orchestrated a disinformation campaign aimed at discrediting and concealing the clearly established link between the occurrence of BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implant. This was done in the interest of placing ALLERGAN's pecuniary interest and profits over public safety, so that ALLERGAN could continue to sell and distribute a dangerous product into the marketplace at great financial gain to the company.

8. For example, Plaintiff is informed and believes and thereon alleges that between 2007 and 2010—following premarket approval for its first generation of

[1]Allergan's Vice President of Clinical Development, Stephanie Manson Brown, acknowledged—while still downplaying—that "[h]igher implant surface area may be a risk factor" because "[s]urface area contributes to bacterial accumulation" in her presentation at the FDA Medical Devices Advisory Committee General and Plastic Surgery Devices Panel on March 25, 2019.

silicone-filled breast implants—ALLERGAN received worldwide 22 complaints of BIA-ALCL in women implanted with the silicone brand of the BIOCELL Textured Breast Implants. Despite the public health crisis implicated by such statistics, ALLERGAN unlawfully failed to report these events of BIA-ALCL to the FDA ***at all***.

9. Thereafter, as events of BIA-ALCL continued to surface, ALLERGAN doubled-down on its unlawful concealment efforts by abusing its unique adverse health event summary reporting privilege for its breast implants, known as Alternative Summary Reporting. ***This privilege was available only for specific adverse event types associated with breast implants where compliance with some of the reporting requirements was not necessary to protect the public health because such events were known and well-documented.*** Despite its ineligibility for summary reporting, from at least 2009 until 2019 when the Alternative Summary Reporting was discontinued due to misuse, ALLERGAN buried complaints of BIA-ALCL, and symptoms associated therewith, transmitted to the company from health care professionals, user facilities, and patients in the unscrutinized summary reporting spreadsheets which only recently became publicly available.

10. Because ALLERGAN failed to perform its duties under federal law to warn the FDA about BIA-ALCL, and because ALLERGAN failed to comply with its reporting duties under federal law with respect to BIA-ALCL, Plaintiff's claims set forth below are not subject to preemption.

11. Plaintiff is informed and believes and thereon alleges that at all times ALLERGAN allowed their BIOCELL Textured Breast Implants to remain in the market knowing they suffered from a serious safety defect/risk and failed to disclose, concealed, and misrepresented the important safety risks associated with textured breast implants in representations made to Plaintiff and the FDA, specifically the clear links between ALLERGAN's BIOCELL Textured Breast Implants and BIA-ALCL. ALLERGAN misrepresented the scope of the risk, failed to publicly report the cases of BIA-ALCL that *had* been caused by its products as it was obligated to do under federal law and

regulations, and failed to remedy the danger to consumers around the world and across the country.

12. Had Plaintiff known the truth about ALLERGAN's BIOCELL Textured Breast Implants, she would not have had them implanted into her body. Instead, she would have, among other things, forwent implantation, or chosen smooth or microtextured implants, thereby avoiding the heightened risk of developing BIA-ALCL.

13. Finally, after decades of misrepresenting and hiding the scope of the problem—and the danger posed to women with these implanted products—the cancerous propensities of ALLERGAN's product finally started coming to light. On December 18, 2018, ALLERGAN was banned from selling its BIOCELL textured implants in the European Union based on health and safety concerns. Five months later, Health Canada suspended ALLERGAN's license to sell BIOCELL Textured Breast Implants in Canada following a safety review that brought to light the increased risk of BIA-ALCL amongst those implanted with BIOCELL Textured Breast Implants sold by the Defendants. Yet ALLERGAN continued to sell its textured implants in the United States.

14. On July 24, 2019, the FDA announced the world-wide recall of ALLERGAN's BIOCELL Textured Breast Implants in order to "protect individuals from the increased risk of BIA-ALCL, associated with BIOCELL textured breast implants."[2]

15. Following that recall, and with knowledge of the danger *finally* being provided to the public, numerous consumers across the country are left with fear, concern, and worry that their ALLERGAN BIOCELL Textured Breast Implants have now exposed them to the dangers of BIA-ALCL. As is only reasonable, people, like Plaintiff SUSAN MROWIEC, want these dangerous products *out* of their bodies—yet

[2] The FDA's analysis was attributed to a new worldwide reported total of 573 unique BIA-ALCL cases including 33 patient deaths. Of the 573 cases of BIA-ALCL, 481 are reported to have Allergan breast implants at the time of diagnosis. In addition, 12 of 13 deaths occurring in patients with BIA-ALCL where the manufacturer was known occurred in patients implanted with an Allergan breast implant at the time of their BIA-ALCL diagnosis.

ALLERGAN has refused to assist in providing for the surgical, medical, hospital, facility, and many other expenses that will be incurred by thousands upon thousands of women across the country, not to mention the stress, fear, anxiety, and worry caused by the company's dangerous products. This action is brought to remedy the dangerous, deceptive conduct of ALLERGAN resulting in the implantation of these dangerous, defective products in Plaintiff SUSAN MROWIEC.

VENUE AND JURISDICTION

16. Venue is proper in this county in accordance with Section 395 of the California Code of Civil Procedure because the injuries alleged herein arose from conduct that occurred in this county.

17. This Court has personal jurisdiction over Defendants. Defendants are and were at all relevant times residents of and/or authorized to conduct business in the State of California and Defendants conducted such business within the State including the performance of acts that caused or contributed to the harm giving rise to this action.

18. Specifically, the applicant addresses for each of the PMAs, *infra*, affected by the recall of BIOCELL Textured Breast Implants lists ALLERGAN's business office in California.[3-4] Thus, the recalled product that caused damage to the Plaintiff was, upon information and belief, researched, distributed, manufactured, managed, sold through, or represented through the PMA process that the products were initiated and approved from and through the Defendants' offices in California.

19. Moreover, ALLERGAN's medical aesthetics division responsible for design/development, clinical operation, data analysis and regulatory affairs for its breast

[3] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P990074; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040046; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K143354; https://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K102806.

[4] Per the California Secretary of State's website, Allergan, Inc.'s "Entity Address"—i.e. its primary worldwide business office, or the "nerve center" of the corporation—is located at 2525 Dupont Drive, Irvine, CA 92612. At minimum, general personal jurisdiction is appropriate over this defendant as it is "at home" in this forum.

implant products, including the BIOCELL Textured Breast Implants Class 1 Device Recall, is based in its Irvine, California headquarters. In fact, the FDA identifies the "Recalling Firm/Manufacturer" for the BIOCELL Textured Breast Implants Class 1 Device Recall as Defendant ALLERGAN PLC with a corresponding address of 2525 Dupont Dr., Irvine, CA 92612.[5]

20. Additionally, the most recent Establishment Inspection Report performed by FDA Supervisory Consumer Safety Officers on October 19, 2016 for the recalled BIOCELL Textured Breast Implants occurred at the Irvine, California headquarters. The name and address of the appropriate ALLERGAN employee for all FDA official correspondence regarding BIOCELL Textured Breast Implants was Defendant ALLERGAN PLC's CEO/President Mr. Brent Saunders with a corresponding address of 2525 Dupont Dr., Irvine, CA 92612.

21. Finally, ALLERGAN's predecessor corporation, INAMED CORPORATION, *infra*, conducted product development, executive functioning, and legal compliance for all of the recalled BIOCELL Textured Breast Implants in its California headquarters in Santa Barbara County.

22. At all times material hereto, Defendants maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district. Defendants received substantial financial benefit and profits as a result of the designing, formulating, testing, packaging, labeling, producing, creating, constructing, making, assembling, advertising, clinical testing, marketing, promoting, distributing, manufacturing, and selling BIOCELL Textured Breast Implants in this state and county, and throughout the United States. Defendants promoted, sold, distributed, made, assembled, marketed, advertised, and

[5] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=175502.

promoted the BIOCELL Textured Breast Implants in California—including to consumers in this judicial district—with those products ultimately causing harm in California.

23. At all times material hereto, the action arises from obligations that arise out of, or are connected with, Defendants' activities within the State of California.

24. Plaintiff is informed and believes and, on that basis alleges that Defendants have purposefully directed their activities at this forum State and the exercise of jurisdiction is reasonable and would not offend the traditional notions of fair play and substantial justice.

25. Plaintiff is informed and believes and, on that basis, alleges that Defendants have purposefully availed themselves of the privileges and benefits of conducting activities and business within the forum State, and have invoked the benefits and protections of its laws.

26. A substantial part of the events giving rise to Plaintiff's claims occurred in California, including federal and state regulatory compliance, the preparation and submission of the relevant product PMAs, and communication regarding the product, the design, formulation, testing, packaging, labeling, production, creation, construction, making, assembly, advertising, clinical testing, marketing, promotion, distribution, manufacturing, and selling of the BIOCELL Textured Breast Implants, as well as the implantation of the BIOCELL Textured Breast Implants into Plaintiff in this forum.

PARTIES

A. Plaintiff

27. Plaintiff SUSAN MROWIEC is a resident of the state of Michigan, County of Montcalm and city of Sheridan.

28. In or around 2002, SUSAN MROWIEC was implanted with McGhan style 468 breast implants, serial numbers 578468 (left) and 5814686 (right), by Dr. Carlos M. Villafane at DMC Huron Valley General Surgery in Commerce Charter Township, Michigan.

29. Thereafter, in 2015, SUSAN MROWIEC experienced severe swelling of her breast and the swelling extended into her neck and shoulder. After seeking assistance from a plastic surgeon, Plaintiff was referred to a cancer specialist and was ultimately referred to Dr. Marguerite Aitken for removal of the McGhan implants.

30. In or around August of 2015 Plaintiff underwent a removal of her McGhan textured breast implants and placement of Allergan smooth style 68 implants. During the procedure Dr. Aitken noted the left implant was ruptured and Plaintiff had a "periprosthetic late presenting sermoa, yellowish-green viscous fluid in nature." Out of an abundance of caution, Dr. Aitken sent the fluid to cytology to rule out ALCL. Plaintiff had a total capsulectomy performed on the left side, however it is unclear to Plaintiff whether a total capsulectomy was performed on the right side. During the procedure, Plaintiff had two Allergan style 68 smooth implants placed.

31. On or about August 26, 2015 Plaintiff met with Dr. Aitken and confirmed that she was diagnosed with malignant lymphoma, specifically ALCL. Plaintiff proceeded to consult with several doctors over the next five months and the doctors at the University of Michigan suggested Plaintiff undergo a complete removal of her implants as part of her ALCL treatment. Dr. Aitken advised against this on January 15, 2016.

32. In or around June of 2016 Plaintiff again discussed a removal of her implants in accordance with recommendations from her cancer specialists. Again, Dr. Aitken advised her of her options other than complete implant removal and total capsulectomy, as well as quotes for the costs of these out of pocket procedures.

33. On June 29, 2016 Plaintiff returned to Dr. Aitken after receiving a second opinion for her ALCL treatment from Cleveland Clinic. Physicians at that facility advised against implant removal and advocated for continued monitoring. Plaintiff elected this route of treatment. However on October 26, 2016, Plaintiff returned to Dr. Aitken requesting a complete removal of her implants and capsulectomy. This was

recommended to Plaintiff my multiple cancer doctors. A surgery was scheduled for November of 2016.

34. On November 26, 2016 Plaintiff underwent a bilateral capsulectomy with implant removal with Dr. Aitken at Zeeland Community Hospital in Zeeland, Michigan. Pathology of the removed capsules and implants was negative for malignancy.

35. SUSAN MROWIEC did not receive any update or warning from ALLERGAN any time before or after her surgeries in 2002 or 2015 about the clearly established link between ALLERGAN's BIOCELL Textured Breast Implants and BIA-ALCL.

36. Following the worldwide recall and revelations about the dangers of ALLERGAN's products, SUSAN MROWIEC fully understood that her diagnosis of ALCL was directly attributable to her McGhan textured breast implants. Before the recall, Plaintiff had no idea that the breast implants themselves could have caused her cancer as no doctor ever told her of the established link. Plaintiff's ALCL was never referred to as BIA-ALCL, just a rare, malignant lymphoma.

37. Plaintiff had to pay out-of-pocket for the removal of her breast implants because ALLERGAN has *refused* to do so.[6]

38. Plaintiff has worried about the risks she faces, has also been subject to out-of-pocket expenses in relation to seeking medical advice, evaluating the flawed product implanted into her body, and seeking recommendations for future care and treatment. Plaintiff also continue to suffer from mental stress, anxiety, worry, humiliation, fear, concern and other personal and financial hardship due to the continuous fear of her BIA-ALCL returning and aftermath from the suffering of BIA-ALCL.

[6] On July 30, 2019, following the worldwide recall, Carrie Strom, Senior Vice President, U.S. Medical Aesthetics, Allergan plc, announced to customer that "Allergan will not provide surgical fee assistance to revision patients."

39. Plaintiff has had to take time away from work in order to seek medical treatment, advice, and consultation, and due to the stress and anxiety related to her flawed ALLERGAN implants.

40. Plaintiff would not have had BIOCELL Textured Breast Implants implanted in her had the Defendants honestly, fully, and completely disclosed the risks.

B. Defendants

41. ALLERGAN does not adhere to the formalities of corporate structure, but rather employs an extremely fluid corporate hierarchy through a series of largely employee-less holding companies whereby the various entities within the corporate structure serve as alter-egos of each other.

42. Defendant ALLERGAN PLC (formerly known as Actavis plc) is the principal entity for the ALLERGAN business and was incorporated in Ireland on May 16, 2013.

43. Defendant ALLERGAN PLC ordinary shares are traded on the NYSE under the ticker symbol "AGN."

44. Defendant ALLERGAN PLC represents itself to the public as a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name pharmaceutical products, medical aesthetics, biosimilar, and over-the-counter pharmaceutical products. Conversely, when convenient, Defendant ALLERGAN PLC represents that it is simply a holding company that exists for the purpose of holding shares of other companies that manufacture and distribute such products rather than producing or selling its own goods or services.

45. Although Defendant ALLERGAN PLC claims its only principal office is located at Clonshaugh Business and Technology Park Coolock, Dublin, D17 E400, Ireland, it maintains headquarters located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 and 2525 Dupont Drive, Irvine, California 92612.

46. As a result of its acquisition of Defendant ALLERGAN, INC. on March 17, 2015, Defendant ALLERGAN PLC expanded its franchises to include medical aesthetics/ dermatology/plastic surgery, which included the BIOCELL Textured Breast Implants.

47. Defendant ALLERGAN, INC. represents itself to the public as a multi-specialty health care company focused on developing and commercializing innovative pharmaceuticals, biologics, medical devices and over-the-counter products "that enable people to live life to its full potential – to see more clearly, move more freely and express themselves more fully." Conversely, when convenient, Defendant ALLERGAN, INC. represents that it is a holding company with no employees.

48. Defendant ALLERGAN, INC. was established pursuant to the laws of Delaware with its principal executive office located at 2525 Dupont Drive, Irvine, California 92612. Defendant ALLERGAN, INC. is headquartered in California, with both its principal place of business as well as its executive team located primarily, if not entirely, in California.

49. Defendant ALLERGAN PLC utilized Defendant ALLERGAN, INC. in California as its primary agent, appointed subsidiary, and designated entity for the marketing, development, sales, research, distribution, approval, processing, and regulatory approval of products in the medical aesthetics, dermatology, and plastic surgery fields, including the BIOCELL Textured Breast Implants. Defendant ALLERGAN PLC was thus operating through Defendant ALLERGAN, INC. with respect to the BIOCELL Textured Breast Implants, and was doing so through Defendant ALLERGAN, INC.'s primary corporate offices in Irvine, California.

50. In fact, while Defendant ALLERGAN, INC. is a wholly owned subsidiary of Defendant ALLERGAN PLC, a Management Service Agreement between Defendant ALLERGAN PLC, on the one hand, and Defendants ALLERGAN, INC. and ALLERGAN SALES, LLC, on the other, puts these California entities in charge of Defendant ALLERGAN PLC's executive management; its strategic direction in terms of business operations, financial goals and long-term growth; and its general and

administrative services. Thus, Defendant ALLERGAN PLC is the shareholder of the very entities that manage it from California.

51. On March 23, 2006, Defendant ALLERGAN, INC. completed the acquisition of INAMED CORPORATION, then a global healthcare company that developed, manufactured, and marketed breast implants, a range of facial aesthetics, and obesity intervention products.

52. INAMED CORPORATION was the corporate successor to MCGHAN MEDICAL CORPORATION—the original manufacturer of breast implants for plastic and reconstructive surgery—which was incorporated in 1974.

53. INAMED CORPORATION and MCGHAN MEDICAL CORPORATION were the entities that sought and received PMAs for a majority of the recalled BIOCELL Textured Breast Implants, principally from their California headquarters located in Santa Barbara, California.

54. Defendant ALLERGAN SALES, LLC, a Delaware limited liability company formed on February 25, 2002, was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, BIOCELL Textured Breast Implants, and did so in part by extensively targeting, marketing to, packaging, distributing, manufacturing, advertising in, and selling to consumers in California.

55. Along with Defendant ALLERGAN, INC., Defendant ALLERGAN SALES, LLC manages Defendant ALLERGAN PLC's business operations.

56. Defendant ALLERGAN SALES, LLC maintains its principle executive office at 2525 Dupont Drive, Irvine, California. Defendant ALLERGAN SALES, LLC's members are Defendant ALLERGAN HOLDCO U.S., INC. and Defendant ALLERGAN HOLDINGS, INC., both of which are domiciled in California.

57. Defendant ALLERGAN HOLDCO U.S., INC., is engaged in developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic

products for consumers around the world, including ALLERGAN's BIOCELL Textured Breast Implants. Defendant ALLERGAN HOLDCO U.S., INC. is principally engaged in being an intermediate holding company between Defendant ALLERGAN, INC. and Defendant ALLERGAN SALES, LLC. As recently as August 20, 2019, Defendant ALLERGAN HOLDCO U.S., INC. represented in its periodic SI-550 form to the California Secretary of State that its principle executive office is in Irvine, California.

58. Defendant ALLERGAN HOLDINGS, INC., is engaged in developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for consumers around the world, including ALLERGAN's BIOCELL Textured Breast Implants. Defendant ALLERGAN HOLDINGS, INC. is principally engaged in being an intermediate holding company of between Defendant ALLERGAN, INC. and Defendant ALLERGAN SALES, LLC. Defendant ALLERGAN HOLDINGS, INC. maintains its principle executive office in Irvine, California.

59. Additionally, Defendant ALLERGAN HOLDINGS, INC. is the direct parent company of Allergan Pharmaceuticals Holdings Unlimited Company, which is the direct parent company of Allergan Costa Rica, S.R.L.—the entity responsible for actually manufacturing ALLERGAN's BIOCELL Textured Breast Implants at ALLERGAN's plant in Heredia, Costa Rica.

60. Defendant ALLERGAN USA, INC. was and is a wholly owned subsidiary of Defendant ALLERGAN SALES, LLC and is a corporation established pursuant to the laws of Delaware. Defendant ALLERGAN USA, INC. maintains its principle offices at 5 Giralda Farms, Madison, New Jersey and at 2525 Dupont Drive, Irvine, California.

61. At all relevant times, Defendant ALLERGAN USA INC. was engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, BIOCELL Textured Breast Implants, and did so in part by extensively targeting,

marketing to, packaging, distributing, manufacturing, advertising in, and selling to consumers in California.

62. At all material times, ALLERGAN or its parents and subsidiaries were engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor, or subsidiary, recalled BIOCELL Textured Breast Implants to patients for breast augmentation and reconstruction, in the United States including California, including the following recalled products:

Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) approved under PMA No. P990074. The following are the textured styles:

- Style 163 – BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants
- Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
- Style 363 – BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
- Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants

Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) approved under PMA No. P020056. The following are the textured styles:

- Style 110 – BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants
- Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants
- Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast Implants
- Style TRL - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRLP - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants

- Style TRM - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TCL – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCLP – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCM – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCF – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCX – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TSL – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSLP – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSM – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSF – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSX – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under PMA No. P040046. The following are the textured styles:

- Style 410FM
- Style 410FF
- Style 410MM
- Style 410MF
- Style 410FL
- Style 410ML
- Style 410LL
- Style 410LM
- Style 410LF

- Style 410FX
- Style 410MX
- Style 410LX

Allergan Tissue Expanders for the breast that have BioCell texturing originally cleared for commercial distribution under Section 510(k):

- Natrelle 133 Plus Tissue Expander (K143354)
- Natrelle 133 Tissue Expander with Suture Tabs (K102806)

(Collectively, "BIOCELL Textured Breast Implants")

63. Plaintiff is unaware of the true names and capacities of the remaining defendants sued in this action by the fictitious names DOES 1 through 100. Plaintiff will amend this complaint when those names and/or capacities become known to Plaintiff. Plaintiff is informed and believe that each of the fictitiously named defendants is in some manner responsible for the events and allegations set forth in this complaint.

64. At all relevant times, defendants, and each of them, were the agents and employees of each of the remaining defendants and were at all times acting within the purpose and scope of said agency and employment, and each defendant has ratified and approved the acts of its agents.

GENERAL ALLEGATIONS

A. Federal law and requirements

65. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq*., to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq*., impose a regime of detailed federal oversight administered by the FDA for medical devices. Depending on the nature of the device and the risks it presents, that oversight ranges from general federal regulations governing the labeling and manufacture of all medical devices, to a rigorous regime of premarket approval for certain devices.

66. FDA may grant premarket approval ("PMA") for a device only if it finds, among other things, that (a) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (b) the

proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). After premarket approval, a manufacturer generally must receive FDA's approval of a supplemental application before making any change to the device itself that would affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a).

67. PMA is specific to individual devices, but such devices are thereafter also subject to the more general provisions of the MDA and FDA's regulations. Of particular importance are the requirements that a medical device manufacturer:

(a) Collect and report to the FDA within certain timeframes information on certain adverse events associated with its device. See 21 U.S.C. 360i(a); 21 C.F.R. Part 803.

(b) Implement quality systems and current good manufacturing practices with respect to the device. See 21 U.S.C. 351(h); 21 C.F.R. Part 820.

68. Additionally, within the MDA exists an express preemption provision applicable to PMA devices which states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> (1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]. 21 U.S.C. 360k(a).

1. No express preemption of state-law claims paralleling MDA and federal regulatory requirements

69. As set forth in the MDA's express preemption provision, a state requirement is preempted only if it is "different from, or in addition to," federal requirements. 21 U.S.C. 360k(a)(1). Through that qualification, Section 360k(a) permits a

State to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. [7]

70. For example, where both the FDCA (as implemented by FDA) and State law require a manufacture to deliver warnings regarding its device through an appropriate channel—such as the FDA—those duties are parallel such that preemption is inapplicable. That parallelism is reinforced by the FDCA's command that either inadequate warnings (21 U.S.C. 352(f)(2)) or a failure to submit required adverse event reports to FDA (21 U.S.C. 352(r)(2), 360i(a)) will render a device misbranded, and therefore "prohibited [from] introduction or delivery for introduction into interstate commerce." 21 U.S.C. 331(a).

71. As the Ninth Circuit reasoned in *Stengel v. Medtronic Inc.*, such a "claim rests on a state-law duty that parallels a federal-law duty under the MDA ...." 704 F.3d 1224, 1233 (2013) (en banc). Specifically, the plaintiff alleged that the manufacturer's failure to warn the FDA of adverse health consequences constituted a violation of both the MDR requirements and the general duty of reasonable care under State law, which includes a duty to warn. *Ibid*.

72. This is because the MDR regulations are related to the manufacturer's duty to provide the FDA with information regarding a device's safety and effectiveness, and this information is disseminated to the public. Manufacturers provide these reports to the FDA, the FDA then disseminates the reports to the public, and the reports are then relied upon by physicians and authors of medical journals in comparing the relative safety of medical devices.

73. Likewise, California imposes a duty on manufacturers to warn of potential risks or dangers of their products, which sounds in both negligence and strict liability. See *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1110-1112. This is a continuing duty

[7] As the Supreme Court stated in *Riegel v. Medtronic, Inc.*, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (2008) 553 U.S. 312, 330 (citing *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 495).

that lasts as long as the product is in use. *Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1482; see also CACI Nos. 1205, 1222. The state-law duty to warn may in some circumstances be satisfied by giving the information to a third party who can reasonably be relied on to convey the danger. *Persons v. Salomon North America, Inc.* (1990) 217 Cal.App.3d 168, 175-178. California follows the Restatement Second of Torts standard for a manufacturer's reasonable reliance on an intermediary to convey warnings. *Id*. at 175 (adopting Restatement Second of Torts, § 388, com. n). The focus of this standard is whether, in light of all the circumstances, a manufacturer or supplier acted reasonably in relying on a third party to pass warnings on to the ultimate user. *Id*. at 175-178.

74. Thus, a factfinder could infer that a manufacturer's failure to provide information regarding a device's safety and effectiveness as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks.

75. This parallelism is reinforced under California's doctrine of negligence per se where the failure to exercise due care is presumed from a violation of a "statute, ordinance, or regulation of a public entity." Cal. Evid. Code, § 669(a)(1). By its terms, this doctrine applies to the law of any public entity, not just California public entities. See, e.g., *DiRosa v. Showa Denko K.K.* (1996) 44 Cal.App.4th 799, 808. Thus, under California law, a money damages remedy exists for negligent violation of the FDCA and regulations promulgated thereunder which proximately cause injuries, and there is no need for California's Legislature to act in order to create such a remedy.

76. The foregoing principles refute any anticipated contention by ALLERGAN that Section 360k(a) expressly preempts Plaintiff's state law claims set forth below. Under *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, the U.S. Supreme Court held the premarket approval of the plaintiff's device established preemptive requirements with respect to the design and labeling of the device. Those would preempt any claim alleging in substance that FDA should have conditioned its approval on adopting some

other design or labeling. Such were the nature of the claims at issue in *Riegel*, and those claims were therefore preempted.

77. But where, as here, a plaintiff's claims are based on conduct ***after*** a device received premarket approval, that conduct is governed not by the terms of the device's premarket approval, but rather by FDA's general regulations governing medical devices generally. Accordingly, state law claims—whether styled as arising from a failure to make adverse event reports to FDA or from a failure to maintain appropriate quality control systems—are not expressly preempted.

2. No implied preemption of state-law claims premised on violations of the MDA and federal regulatory requirements

78. Where a plaintiff alleges that a defendant had made fraudulent misrepresentations to the FDA in the course of obtaining premarket approval for a medical device, such "fraud on-the-FDA claims" are impliedly preempted because they conflict with the FDA's responsibility to police fraud on the agency and they seek to enforce an exclusively federal requirement not grounded in traditional tort law. *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 348-353.

79. Central to the doctrine of implied preemption is that a state law claim cannot exist solely by virtue of the federal enactments—State law has no role to play in policing the relationship between a federal agency and the entity it regulates. Conversely, claims relying on traditional State tort law which had predated the federal enactments in question are unaffected. Therefore, a claim against a device manufacturer is viable if the plaintiff is suing for conduct that violates the FDCA (or else her claim is expressly preempted by Section 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

80. Thus, as recognized in *Stengel*, a manufacturer's failure to report, for example, is more than a mere misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom the manufacturer owed an

independent duty under state law. Thus, such claims are grounded in a traditional category of state law failure-to-warn claims that predate the federal enactments in question, and the claims therefore do not exist solely by virtue of those enactments. As a result, such claims are not impliedly preempted by the MDA.

B. Statement of Facts Relating to Preemption Applicable to Plaintiff's Failure to Warn and Negligence Claims

81. All three generations of the recalled BIOCELL Textured Breast Implants received premarket approval under PMA Order Nos. P990074 (2000), P020056 (2006), and P040046 (2013).

82. In 2011 and in 2015, the recalled Natrelle 133 Plus Tissue Expander (K143354) and Natrelle 133 Tissue Expander with Suture Tabs (K102806) were approved for sale under section 510(k), respectively.[8]

83. Under federal law and regulation, Allergan was under a continuing duty to monitor its BIOCELL Textured Breast Implants after premarket approval and to discover and report to the FDA any complaints about the device's performance and any adverse health consequences of which it became aware and that are or may be attributable to its BIOCELL Textured Breast Implants. See 21 C.F.R. § 803.50 *et seq*; 21 C.F.R. § 820.198(a)(3); 21 U.S.C. 360i.

84. Pursuant to these regulations, ALLERGAN was obligated to file within a mandatory timeframe detailed medical device reports (MDRs) for ***all*** BIA-ALCL events related to its BIOCELL Textured Breast Implants that it had knowledge of, foreign or

[8] A medical device marketed after the MDA's effective date may bypass the PMA process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States. ***The MDA does not require an FDA determination that the device is, in fact, substantially equivalent to a grandfathered device.***

domestic, and this includes any event that could reasonably be interpreted as possible BIA-ALCL given the nature of the facility, doctor or patient complaint.

85. Notwithstanding this obligation, ALLERGAN failed to investigate complaints of adverse events and submit such adverse events concerning the BIOCELL Textured Breast Implants as MDRs in violation of general medical device regulations designed to ensure patient safety.

86. As a result, Allergan failed to properly perform its duties and failed to inform the FDA of the increased risk of BIA-ALCL associated with its BIOCELL Textured Breast Implants using medical device reports; even though it should have been aware of the many adverse events that did occur and was actually aware of these adverse events—but failed to file medical device reports pursuant to 21 C.F.R. Part 803; 21 C.F.R. § 820.198; and 21 U.S.C. 360i.

1. ALLERGAN violated 21 C.F.R. § 803.50 *et seq* by failing to file MDRs following receipt of both foreign and domestic complaints of BIA-ALCL

87. A manufacturer must report adverse events no later than 30 calendar days after the day that it received or otherwise become aware of information, ***from any source***, that reasonably suggests that a device may have caused or contributed to a death or serious injury, or malfunctioned. 21 C.F.R. § 803.50 (emphasis added).

88. This reporting duty is triggered not just for events occurring within the United State and its territories, but also adverse events occurring in a foreign country concerning the device. Under the FDA's Medical Device Reporting for Manufacturers Guidance for Industry, the FDA considers an event that occurs in a foreign country reportable under the MDR regulations if it involves a device that has been cleared or approved in the United States– or a device similar to a device marketed by the manufacturer that has been cleared or approved in the United States – and is also lawfully marketed in a foreign country.

89. Thus, even when a device is manufactured to modified specifications to meet standards in different countries, if these changes do not substantially alter the

performance of the device, then any device events that are MDR reportable events relating to such modified devices should be reported under the MDR regulations.

90. Notwithstanding this reporting obligation for events worldwide, between 2007 and 2010—following premarket approval for its first generation of silicone-filled breast implants in 2006—internal ALLERGAN documents show ALLERGAN received 22 worldwide complaints of BIA-ALCL in women implanted with the silicone brand of the breast implants:

Year	Description	Worldwide by Surface Type			
		Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total
2004	Count of ALCL Complaints by Received Year	0	0	0	0
	Sales Volume by Distribution Year			NA	
2005	Count of ALCL Complaints by Received Year	0	0	0	0
	Sales Volume by Distribution Year			NA	
2006	Count of ALCL Complaints by Received Year	0	0	0	0
	Sales Volume by Distribution Year			NA	
2007	Count of ALCL Complaints by Received Year	1	2	0	3
	Sales Volume by Distribution Year			NA	
2008	Count of ALCL Complaints by Received Year	0	5	4	9
	Sales Volume by Distribution Year			NA	
2009	Count of ALCL Complaints by Received Year	0	3	3	6
	Sales Volume by Distribution Year			NA	
2010	Count of ALCL Complaints by Received Year	1	0	3	4
	Sales Volume by Distribution Year			NA	
2011	Count of ALCL Complaints by Received Year	0	9	0	9
	Sales Volume by Distribution Year			NA	
2012	Count of ALCL Complaints by Received Year	1	14	2	17
	Sales Volume by Distribution Year			NA	
2013	Count of ALCL Complaints by Received Year	1	21	0	22
	Sales Volume by Distribution Year			NA	
2014	Count of ALCL Complaints by Received Year	0	18	8	26
	Sales Volume by Distribution Year			NA	
2015	Count of ALCL Complaints by Received Year	0	32	4	36
	Sales Volume by Distribution Year			NA	
Total (2004-2015)	Count of ALCL Complaints by Received Year	4	104	24	132
	Sales Volume by Distribution Year			NA	

91. Despite the public health crisis implicated by such statistics, ALLERGAN unlawfully failed to report these events of BIA-ALCL to the FDA ***at all***.[9][10] Moreover, the internal ALLERGAN data set forth above does not account for the untold number of

[9] The FDA's Manufacturer and User Facility Device Experience (MAUDE database) is available online and can be searched to locate MDRs. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

[10] The first instance of ALLERGAN filing an adverse event report for a complaint of BIA-ALCL in connection with its silicone filled breast implants was received by the FDA on May 4, 2011. See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2097844.

complaints of BIA-ALCL in women implanted with their saline filled brand of BIOCELL Textured Breast Implants.[11]

92. Such information, had it been disclosed by ALLERGAN, would have enabled physicians and patients to take proper precautions to determine whether the increased risk of BIA-ALCL should be avoided by electing not to use Allergan's BIOCELL textured implants. Or, the FDA would have recalled the BIOCELL textured implants before Plaintiff ever had them implanted.

93. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

94. As a result of ALLERGAN's post-market failure to appropriately report adverse events as required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise never would have been implanted in the Plaintiff at all.

2. ALLERGAN violated 21 C.F.R. §§ 803.50 and 803.52 by concealing pertinent adverse event reports by burying them in unscrutinized spreadsheets

95. As complaints of BIA-ALCL continued to rise in frequency as outlined in the chart above, rather than complying with the federal statute and regulations on medical device reporting, ALLERGAN began using Alternative Summary Reports

[11] Due to safety concerns, from April 1992 until November 2006 silicone gel-filled breast implants were only available in the U.S. to women enrolled in clinical studies, whereas saline-filled breast implants remained in the market during this time via 510(k) approval and, after 2001, premarket approval.

(ASRs) to report of BIA-ALCL events associated with its BIOCELL Textured Breast Implants.[12]

96. ASRs differ from MDRs in that eligible events are aggregated into a single periodic report where only rudimentary information about a particular adverse event is set forth in a line item format within a dense spreadsheet containing thousands of other adverse events.

97. Whereas 21 C.F.R. § 803.52 mandates that a traditional medical device report must contain dozens of categories and subcategories of information, including unique product identification, a detailed event description with a discussion of how the device was involved, and a manufacturer's narrative, an ASR merely contains generic device and problem coding that was never made available to the public or physicians before late 2019.[13]

98. While the FDA allowed manufacturers to use the ASR reporting system to report ***specific*** adverse events in lieu of MDR reporting, this was only allowed where compliance with some of the reporting requirements ***"is not necessary to protect the public health"*** because such events were ***"known and well-documented."*** 60 Fed. Reg. 63,592 (December 11, 1995) (emphasis added). In the case of breast implants, manufacturers like ALLERGAN could ***only*** summarize reports of "rupture, leaks, deflation/inflation, wrinkling, capsular contracture, and non-specific complaints."[14]

99. Moreover, under the FDA's October 19, 2000 ASR Guidance for Industry, the FDA requested that any medical device manufacturer seeking to use the ASR reporting system affirmatively apply for an exemption, in writing, for specific device events, as required by 21 C.F.R. § 803.19(b), with the following information: a statement notifying the FDA of the request to participate in the ASR program; an explanation why the request is justified; identification of the device manufacturer; the product

[12] Note: The ASR program is also referred to by the FDA as Postmarket Spreadsheet Reporting (PSR).
[13] Compare **Exhibit A**, a single MDR, with **Exhibit B**, 105 ASRs.
[14] See https://www.accessdata.fda.gov/cdrh_docs/pdf/P990074B.pdf.

classification codes for the device that will be included in the ASR report; and the reporting site registration number, contact person, and address of the firm who will be submitting the ASR reports to the FDA.

100. ALLERGAN failed to comply with 21 C.F.R. § 803.19(b) and the corresponding ASR Guidance and used the ASR reporting system to report BIA-ALCL events associated with its BIOCELL Textured Breast Implants despite never being granted an exemption to do so by the FDA.

101. The FDA's October 19, 2000 ASR Guidance was clear, device manufacturers could not lawfully use the ASR reporting system under any circumstances for unusual, unique, or even uncommon events. BIA-ALCL, and the symptoms associated therewith, are unequivocally an unusual, unique, or uncommon events—but an event type ALLERGAN was aware of since at least 1997 when the first known event appeared in the medical literature with a description of its characteristics.

102. Likewise, the FDA was unambiguous in its May 2, 2019 statement regarding the agency's efforts to protect women's health and help to ensure the safety of breast implants: "[The ASR] program was established in 1997 to more efficiently review adverse events for well-established risks but was not allowed for patient deaths and ***unusual, unique or uncommon adverse events, which, in the case of breast implants, included BIA-ALCL***."

103. On information and belief, hundreds of complaints related to BIA-ALCL and symptoms associated therewith surfaced from 1997 to 2019. ALLERGAN was aware of these events, and that they were unusual, unique, or uncommon events relating to BIA-ALCL. ALLERGAN—rather than reporting these events in compliance with the MDR reporting requirements—misused the ASR reporting system in violation of 21 C.F.R. § 803.19(b); 21 C.F.R. § 803.50; 21 C.F.R. § 820.198(a)(3); 21 U.S.C. 360i; and its duty to report to the FDA.

104. The first identified misuse of the ASR system to report an event of BIA-ALCL occurred in 2009 when a healthcare professional reported to an ALLERGAN

employee the events of BIA-ALCL and seroma.[15] However, following the FDA's decision to end the ASR program due to manufacturer abuse, the FDA in late 2017 also began to require manufacturers to also submit companion MDRs so that some information collected through the ASR program would be visible publicly. As a result, it became known that ALLERGAN has been misusing the ASR program to report ineligible events since as early as March 1997.[16]

105. In fact, ALLERGAN started late filing hundreds of MDRs related to BIA-ALCL events it had known about for many years but had buried in the ASR spreadsheets to belatedly comply with 21 C.F.R. § 803.50; 21 C.F.R. § 820.198(a)(3); and 21 U.S.C. 360i—and also in violation of these statute and regulations—after the FDA ended the ASR program in late 2017. Two such examples of the now thousands of MDRs recently filed and available only after 2017 in the FDA's Adverse Event Database clearly demonstrate Allergan's years/decades-long delay in filing these MDRs:

ALLERGAN (COSTA RICA) STYLE 410 COHESIVE SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED Back to Search Results

Catalog Number N-27-MM135-400
Device Problem Adverse Event Without Identified Device or Use Problem
Event Type Injury
Manufacturer Narrative

Information in this medwatch was previously reported via 410 psr on 17/jul/2014. The event of lymphoma is a physiological complication and analysis of the device generally does not assist allergan in determining a probable cause for this event. Further information from the reporter regarding event, product, or

Report Date 01/23/2019

ALLERGAN (COSTA RICA) STYLE 120 SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED Back to Search Results

Catalog Number 120-500
Device Problem Adverse Event Without Identified Device or Use Problem
Event Date 03/22/2010
Event Type Injury
Manufacturer Narrative

Information contained in this report was previously submitted through responsive psr on (b)(6) 2010. A review of the device history record has been initiated. If any new, changed or corrected information is noted, a supplemental medwatch will be submitted. The events of lymphoma, and "melanoma" are physiological

Report Date 07/15/2019

106. The FDA was not aware, did not consent, and did not grant any exemption to ALLERGAN to use ASR reporting for BIA-ALCL events.

[15] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2842518.
[16] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7326850.

107. Medical device reporting serves a critical public safety function and failing to follow the federal statutes and regulations on such reporting can cause patients serious injuries. This is precisely why MDR reporting was required for events or risks, like BIA-ALCL, that were not well-known or established. As the FDA plainly stated in their June 21, 2019 statement: "The ASR Program allowed the FDA to more efficiently review reports of *well-known, well-understood* adverse events, so we [can] focus on identifying and taking action on new safety signals and less understood risks."

108. The FDA did not review or investigate reports for ASR-reported events; and reserved its resources for events requiring a medical device report. ASR reported events were not even available to FDA Supervisory Consumer Safety Officers for review in advance of conducting periodic site visits to ALLERGAN's California headquarters.

109. Because this information about BIA-ALCL was routinely transmitted by ALLERGAN to the FDA in the unscrutinzied spreadsheets, the recall for ALLERGAN's BIOCELL Textured Breast Implants took approximately 20 years to be initiated by the FDA and only because ALLERGAN failed to lawfully report BIA-ALCL events to the FDA.

110. Use of the ASR reporting system buried patient injury events and they were not investigated by the FDA, and could not be discovered by physicians either. Had ALLERGAN lawfully reported BIA-ALCL events from 1997 until the time of Plaintiff's implantation or symptoms, she would not have suffered her injuries because either: (a) a recall would have been initiated before Plaintiff's implantation date of the subject devices; or (b) the risks would have been well-understood and Plaintiff or her physician would have been informed of the risk of BIA-ALCL. Instead, the Plaintiff and her physician were both unware of the extent of the risk of BIA-ALCL when the subject devices were implanted causing her serious injuries.

111. Accordingly, Plaintiff SUSAN MROWIEC was injured as a result of Defendants' post-market failure to properly submit MDRs as required (by statute and that FDA's regulations), and as a result of Defendants' post-market negligence,

ALLERGAN's BIOCELL Textured Breast Implants belatedly became known to be defective and unreasonably dangerous only *after* having been implanted in Plaintiff.

112. As a result of its failure to establish and maintain effective post-market surveillance and reporting to ensure defect-free products, Plaintiff suffered severe injuries.

113. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

114. As a result of ALLERGAN's post-market failure to appropriately report adverse events as required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise never would have been implanted in the Plaintiff at all.

3. ALLERGAN failed to investigate and evaluate complaints of BIA-ALCL per 21 C.F.R. 820.198 and 803.18(e) and prepare corresponding medical device reports

115. Pursuant to 21 C.F.R. § 820.198(a), ALLERGAN was required to have a formally designated unit for the purposes of receiving, reviewing and evaluating complaints of adverse events. 21 C.F.R. §§ 803.17, 803.18, and 820.198.

116. The FDA's definition of "complaint" is all encompassing and includes "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution." 21 C.F.R. § 820.3(b).

117. Typically, complaints are prepared and transmitted to the company by physicians, nurse, hospitals, attorneys, and even the patients themselves on the

comprehensive FDA Form 3500B for voluntary reporters—designed with the intent of streamlining the manufacturer's reporting by mirroring the information contained in FDA's Form 3500A for mandatory reporters, like ALLERGAN.

118. Upon receipt of a complaint by ***any*** employee, ALLERGAN was required to evaluate all available information related to the complaint to determine whether it represents an MDR reportable event. 21 C.F.R. §§ 820.198(a) and 803.18. Said evaluation must include information in the manufacturer's possession or that is reasonably available to ALLERGAN, such as information can be obtained by contacting a user facility (e.g. hospital, surgical center), importer or other initial reporter related to the adverse event. 21 C.F.R. § 803.50.

119. If the adverse event complaint qualifies for reporting to FDA under 21 C.F.R. Part 803—i.e., the device may have caused or contributed to a death or serious injury, or malfunctioned—then ALLERGAN was required to conduct an investigation of the event. 21 C.F.R. §§ 803.3 and 803.50.[17] Said investigation must include a determination (1) whether the device failed to meet specifications; (2) whether the device was being used for treatment or diagnosis; and (3) the relationship, if any, of the device to the reported incident or adverse event. 21 C.F.R. § 820.198(d).

120. Accordingly, under these general complaint handling requirements, ALLERGAN was under the continuing duty to receive, evaluate, and investigate such events related to BIA-ALCL and make a determination as to the relationship between the BIOCELL Textured Breast Implants and BIA-ALCL.

121. Notwithstanding ALLERGAN's complaint handling obligations for adverse events of BIA-ALCL and symptoms associated therewith, on numerous occasions ALLERGAN ignored complaints of such events.

[17] Death or serious injury includes events occurring from: 1) Failure; 2) Malfunction; 3) Improper or inadequate design; 4) Manufacture; 5) Labeling; or 6) User error. 21 C.F.R. § 803.3.

122. Two such examples of these ignored complaints further demonstrate ALLERGAN's cavalier and unlawful attitude towards the risks of BIA-ALCL:[18]

MCGHAN MCGHAN 363 LF SALINE FILLED BREAST IMPLANTS Back to Search Results

Model Number 363LF-300
Event Date 12/07/2016
Event Type Injury
Event Description

Pt had mcghan 363lf saline filled implants placed on (b)(6) 2016. Presented with large right breast seroma on (b)(6) 2016. Ultrasound guided aspiration of seroma performed on (b)(6) 2016 after ultrasound and mri showed large loculated right breast fluid collection. Aspirated fluid showed cd30+ and alk1 - cells, leading to the diagnosis of alcl. She had bilateral capsulectomies and removal of implants on (b)(6) 2017. Pathology did not reveal any extension of the alcl into the capsular. She is currently being worked up by our oncologists were as well as our geneticists.

INAMED INAMED SALINE BREAST IMPLANT Back to Search Results

Event Type No Answer Provided
Event Description

Alcl case report: this pt had bilateral breast augmentation performed in 2005. She recently developed a seroma that was aspirated and found to have atypical t cells. I performed bilateral implant removal and total capsulectomy. Her final pathology revealed alcl of the left breast.

123. Rather than conducting the required investigations into complaints transmitted by concerned physicians and/or patients, ALLERGAN, in violation of their general complaint handling requirements, allowed the complaints to fall on deaf ears.

124. As a result, ALLERGAN never conducted the required evaluation to determine whether the complaint qualified for public medical device reporting (instances of BIA-ALCL most assuredly qualify), never conducted the required investigation to determine the relationship between the event and the device, and therefore deprived the FDA or public of vital knowledge necessary to make informed decisions about the BIOCELL Textured Breast Implants.

125. Such information, had it been disclosed by ALLERGAN, would have enabled physicians and patients to take proper precautions to determine whether the increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL Textured Breast Implants before Plaintiff ever had them implanted.

[18] The FDA makes publicly available complaints submitted on the FDA's Form 3500B for voluntary reporters, even when, as here, there is no corresponding medical device report submitted by the manufacturer.

126. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

127. As a result of ALLERGAN's post-market failure to appropriately report adverse events as required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise never would have been implanted in the Plaintiff at all.

4. ALLERGAN failed to timely submit reports of BIA-ALCL per 21 C.F.R. § 803.50(a) and attempted to transmit such reports years after first receiving notice of the event

128. As aforementioned, after ALLERGAN's misuse of the ASR program came to light in late 2017, ALLERGAN belatedly started late filing thousands of MDRs for a variety adverse event types that were not eligible for ASR reporting dating back to 1997. Amongst these late reports were hundreds of adverse events related to BIA-ALCL and symptoms associated therewith that ALLERGAN had known about for many years, but the existence of which the FDA and the public had no knowledge of.

129. It was, in part, because of these late MDRs establishing the true extent of the nexus between BIA-ALCL and the presence of an ALLERGAN's BIOCELL Textured Breast Implant, that the FDA was equipped with sufficient knowledge to initiate the July 2019 worldwide recall.

130. Two particularly egregious examples are as follows, revealing ALLERGAN failed to submit the mandatory MDRs until ***twelve years*** and ***twenty-nine years*** after the underlying adverse event, with latter only being reported to the FDA, and therefore disclosed to the public, as recent as December 11, 2019:

ALLERGAN (COSTA RICA) STYLE 163 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE Back to Search Results

Catalog Number 163-440
Device Problem No Apparent Adverse Event
Event Date 01/01/2007
Event Type Injury
Event Description

Health professional reported patient "developed rapid late seroma. Diagnosed with bia-alcl right breast, stage ie, underwent bilateral capsulectomies and implant removal. Received chop, ice, chemotherapy and radiation therapy followed by stem cell transplant postoperatively. Follow up imaging with pet, no recurrence of disease. Remains healthy. ".

Manufacturer Narrative

Unique identifier (udi) #: not applicable. Device labeling addresses: there were no reported events of lymphoma/alcl, for patients in the core study, in the labeling for silicone implants. Potential adverse events that may occur with silicone gel-filled breast implant surgery include: implant rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. After breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: hematoma/seroma, implant extrusion, necrosis, delayed wound healing, and breast tissue atrophy/chest wall deformity. Calcium deposits can form in the tissue capsule surrounding the implant with symptoms that may include pain and firmness. Lymphadenopathy has also been reported in some women with implants.

Report Date 08/28/2019

ALLERGAN (COSTA RICA) STYLE 120 SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED Back to Search Results

Catalog Number 120-260
Device Problem Patient-Device Incompatibility
Event Date 10/08/1990
Event Type Injury
Manufacturer Narrative

The events of capsular contracture and lymphoma-alcl are physiological complications and analysis of the device generally does not assist allergan in determining a probable cause for these events. The reason for reoperation: capsular contracture, baker grade iii and "being treated for alcl. " further information from the reporter regarding event, product, or patient details has been requested. No additional information is available at this time. These are known potential adverse events addressed in the product labeling.

Event Description

Healthcare professional reported capsular contracture, baker grade iii and "being treated for alcl. " patient reported "joint pain, muscle pain and stiffness," and a bilateral exchange from textured to smooth breast implants due to the patient¿s concern with the product. Patient also reported "inability to walk, numbness in extremities, tingling in extremities, flu like symptoms, losing vision, seeing spots, memory loss, anxiety, suicidal thoughts, depression, sties in eyes, reoccurring staph in nose, chills, dizziness," these events are not related to the device. Device remains implanted. This record is for the left side.

Report Date 12/11/2019

131. Contrary to ALLERGAN's unlawful reporting practices, MDR reportable events must be submitted to the FDA within ***30 calendar days*** after the day the manufacturer becomes aware of the event. 21 C.F.R. §§ 803.10 and 803.50. The only exception is when a medical device report is required to be submitted within ***5 workdays*** after the day the manufacturer becomes aware of the need to submit such a report. 21 C.F.R. §§ 803.10(c)(2) and 803.53.

132. A manufacturer is considered to have "become aware" of an event whenever any of its employees becomes aware of information that reasonably suggests that an event is required to be reported in a 30-day report or in a 5-day report. 21 C.F.R. § 803.3.

133. Notwithstanding these strict and mandatory reporting deadlines, as demonstrated above, ALLERGAN has been submitting late adverse event reports to the FDA related to BIA-ALCL, often times many years, sometimes decades, after first receiving knowledge of the event.

134. Such information, had it been timely disclosed by ALLERGAN, would have enabled physicians and patients to take proper precautions to determine whether the increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL Textured Breast Implants before Plaintiff ever had them implanted.

135. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

136. As a result of ALLERGAN's post-market failure to appropriately report adverse events as required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise never would have been implanted in the Plaintiff at all.

5. ALLERGAN failed to provide all information reasonably known to it per 21 C.F.R. § 803.50(b) in its reports of BIA-ALCL but rather simply regurgitated its misleading and deficient labeling

137. A medical device report must contain all the information required by 21 C.F.R. § 803.52 that is known, or reasonably known to the manufacturer.

138. Information considered reasonably known includes any information: 1) that can be obtained by contacting a user facility, importer, or other initial reporter; 2)

that is in the manufacturer's possession; or 3) that can be obtained by analysis, testing or other evaluation of the device. 21 C.F.R. § 803.50(b).

139. Far from providing all information reasonably known it, as part of its manufacturing narrative in medical device reports concerning BIA-ALCL, ALLERGAN, more often than not, simply recited its device labeling with the unsubstantiated and misleading claim that "device labeling addresses" the issue already, thereby indicating that no further investigatory or remedial action was needed.

140. Notwithstanding the fact that ALLERGAN has had to update its device labeling on multiple occasions due to inaccurate information regarding BIA-ALCL, as reflected in the following medical device report dated November 12, 2019 for a BIA-ALCL event occurring in 2010, ALLERGAN has pointed to completely inapplicable parts of its labeling to attempt to explain away and disregard events of BIA-ALCL:

ALLERGAN (COSTA RICA) STYLE 168 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE Back to Search Results

Catalog Number 168-800
Device Problem Fluid Leak
Event Date 10/20/2010
Event Type Death
Event Description

Initially, pt reported right side lymphoma, deflation, infection, irritation/inflammation with right breast implant. F/u with the implanting surgeon's office noted the pt was seen in the emergency room for what was thought to be a right breast abscess or an infection. The pt was then sent to see the implanting surgeon, who performed an antibiotic wash and had the pt have an ultrasound as well. Operative notes were requested and state, "on the right side, once incised, we encountered a large volume of purulent fluid. This was sent for culture. We found a completely deflated saline implant. The capsule was angry and inflamed. The pathology final diagnosis: alcl; cd30+ alk- including cd45+. The pt was to see an oncologist at a later date. Additional info provided by the surgeons' offices notes that the pt was seen by the oncologist and breast implant that was removed was discarded.

Manufacturer Narrative

Medwatch submitted to the fda on 02/14/2011. Explanted devices were requested to be returned to allergan, but were discarded by the facility and not available for analysis. Device labeling: "pts should be advised that implants are not considered lifetime devices and they will likely undergo implant removal, with or without replacement, over the course of their life. " "if any unusual symptoms occur after surgery, such as fever or noticeable swelling or redness in one breast, you should contact your surgeon immediately. " "published studies indicate that breast cancer is no more common in women with implants than those without. ".

Report Date 11/12/2019

141. As shown in the November 12, 2019 example—which is just one of many with this deficiency—ALLERGAN has claimed that its representations in the device labeling that "implants are not considered lifetime devices" or "if any unusual symptoms occur after surgery . . . you should contact your surgeon immediately" constitute a sufficient warning of the risks of BIA-ALCL.

142. Worse yet, the notion that "published studies indicate that breast cancer is no more common in women with implants than those without" has any relevancy on an

event of BIA-ALCL is as ridiculous as it is insulting to those affected. Again, BIA-ALCL is a cancer of the immune system, and *not* a type of breast cancer—a fact ALLERGAN has been well aware of since 1997.

143. By failing to provide all information reasonably known to it, and instead misleadingly regurgitating irrelevant and inapplicable parts of its device labeling, ALLERGAN violated 21 C.F.R. §§ 803.50(b) and 803.52.

144. Such information, had it been disclosed by ALLERGAN, would have enabled physicians and patients to take proper precautions to determine whether the increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL Textured Breast Implants before Plaintiff ever had them implanted.

145. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

146. As a result of ALLERGAN's post-market failure to appropriately report adverse events as required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise never would have been implanted in the Plaintiff at all.

6. ALLERGAN failed to use the appropriate device problem code for reports of BIA-ALCL instead representing that there was "no apparent adverse event"

147. The FDA receives a significant number of MDRs in any given month or year. Accordingly, it has implemented and relied upon a problem coding system to

enable FDA officials to conduct trend and risk analysis for a device without the immediate need to read and review every MDR.

148. There exist four categories of problem codes: 1) Device Problem Code; 2) Patient Problem Code; 3) Evaluation Results Code; and 4) Evaluation Conclusion Code. However, only the Device Problem Code on MDRs is made publicly available on the FDA's MAUDE interface.

149. These codes must be provided to the FDA in an adverse event report pursuant to 21 C.F.R. § 803.52. The codes must represent the manufacturers best knowledge of the adverse event and a manufacturer is not limited to more than one code per category for an event. When entering the device problem code, manufacturers are expected to select the lowest-level (i.e. most detailed) code or codes that most accurately describe the device failures or problems observed during the event.

150. To the extent the FDA's coding manual does not provide a matching or similar code(s) that would best describe the patient or device problem or the evaluation result and conclusion, a manufacturer has the ability to contact the FDA to assign a new code(s) as applicable.

151. However, in violation of 21 C.F.R. § 803.52, rather than providing an accurate device problem code for events of BIA-ALCL, ALLERGAN had a pattern and practice of providing the Device Problem Code No. 3189, meaning "No Apparent Adverse Event."

152. As the title suggests, Device Problem Code No. 3189: No Apparent Adverse Event has a unique meaning to the FDA that "[a] report has been received but the description provided ***does not appear to relate to an adverse event***. This code allows a report to be recorded for ***administration purposes***, even if it ***doesn't meet the requirements for adverse event reporting***."[19]

[19] See https://www.fda.gov/media/109148/download.

153. ALLERGAN knew this code was "for FDA use only" because "an event that is not an adverse event is, by definition, not a reportable adverse event."[20]

154. ALLERGAN nevertheless utilized this code in their medical device reporting for events of BIA-ALCL, which had the intended consequence of excluding these reports from the FDA's trend analysis.

155. As a result of ALLERGAN's deceitful coding practices in violation of 21 C.F.R. § 803.52, for years the FDA was deprived of the necessary information to expeditiously determine the need for regulatory action, such as a recall, without having to first review and analysis each MDR for the device.

156. If the FDA's trend analysis had not been undermined by ALLERGAN's reporting practices, the recall would have been initiated before Plaintiff's implantation date of the subject devices; or the risks would have been well-understood and Plaintiff or her physician would have been informed of the risk of BIA-ALCL.

157. Worse yet, this practice of representing events of BIA-ALCL as "no apparent adverse event" was not limited to its domestic reporting practices, but also was ALLERGAN's standard operating procedure internationally. On multiple occasion in its Incident Report Forms to European regulatory authorities, ALLERGAN ranked cases of BIA-ALCL in the fields of "All Other Reportable Incident" and "No Threat of Public Health." As a result, ALLERGAN was reprimanded by French regulatory authorities in May 2015. Nonetheless, ALLERGAN continued to use the "No Apparent Adverse Event" code domestically for events of BIA-ALCL.

158. Such information, had it been disclosed by ALLERGAN, would have enabled physicians and patients to take proper precautions to determine whether the increased risk of BIA-ALCL should be avoided by electing not to use Allergan's BIOCELL textured implants. Or, the FDA would have recalled the BIOCELL textured implants before Plaintiff ever had them implanted.

[20] See https://www.fda.gov/medical-devices/mdr-adverse-event-codes/coding-faqs.

159. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

160. As a result of Allergan's post-market failure to appropriately report adverse events as required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise never would have been implanted in the Plaintiff at all.

C. Statement of Facts Relating to Preemption Applicable to Plaintiff's Manufacturing Defect and Negligence Claims

161. As noted above, ALLERGAN has received pre-market approval from the FDA for all three generations of BIOCELL Textured Breast Implants. As such, ALLERGAN was under a continuing duty to follow the general requirements set forth current good manufacturing practices ("CGMPs") provisions of the MDA governing the safety and effectiveness of a PMA medical device. See 21 U.S.C. 351; 21 C.F.R. Part 820.

162. Pursuant to these regulations, ALLERGAN was obligated to implement and maintain quality control systems to validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants, specifically those with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. 351; 21 C.F.R. §§ 820.70 and 820.75.

163. Notwithstanding this obligation, ALLERGAN produced, at times, adulterated BIOCELL Textured Breast Implants that had numerous unwanted particles and solid fragments of silicone on the implant surface in violation of CGMP regulations designed to ensure device quality and patient safety.

164. As a result, ALLERGAN failed to properly perform its duties and failed to implement and maintain quality control systems with respect to the texturization process for manufacturing its BIOCELL Textured Breast Implants, even though it was aware that its textured implants regularly contained contaminants, fragments, particles, and impurities in violation of 21 C.F.R. Part 820 and 21 U.S.C. 351.

165. On information and belief, BIOCELL Textured Breast Implants were adulterated within the meaning of 21 U.S.C. 351(h) when they were placed in the stream of commerce by ALLERGAN, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the CGMP design controls enumerated in 21 C.F.R. Part 820 designed to prevent exposing patients to risks of serious injury or death when the device is used as intended by the surgeon.

166. ALLERGAN violated these regulations, in part, by failing to establish norms and guidelines for biocompatibility, mechanical properties of the shell, modes of sterilization, packaging, and most importantly, surface texturing. As a result, ALLERGAN's BIOCELL textured surface—produced through its unique lost-salt technique—leaves many irregular depressions on the surface of the shell. These pores are—in both diameter and height—significantly larger and much more aggressive than the manufacturing and design specifications mandated by the FDA as part of the PMAs, as well as industry standards where nodules are typically a fraction of the size.

167. Moreover, this extreme texturing process routinely leads to the shedding of debris from the implant surface, resulting in significantly greater quantities of silicone particles in the surrounding capsules than the industry standard and the product specifications. These shredded particles, over time, give rise to chronic inflammation which in turn leads to BIA-ALCL.

168. It was the duty of ALLERGAN to comply with the FDA's Quality System Regulations and Current Good Manufacturing Practices. Yet notwithstanding this duty, ALLERGAN violated the FDCA and the regulations promulgated pursuant to it.

169. As a consequence, ALLERGAN violated 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820 by introducing or delivering for introduction into interstate commerce a device that was adulterated.

170. ALLERGAN violated 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820 by receiving in interstate commerce a device that was adulterated and delivering the device for pay or otherwise.

171. ALLERGAN violated 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820 by manufacturing a device that was adulterated.

172. ALLERGAN violated 21 C.F.R. § 820.30 by failing to establish and maintain procedures for validating the device design of BIOCELL Textured Breast Implants to ensure that the implants conformed to patients' needs and intended uses, including failing to test production units under actual or simulated use conditions.

173. ALLERGAN violated 21 C.F.R. § 820.50 by failing to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, including evaluating and selecting potential suppliers, contractors, and consultants on the basis of their ability to meet quality requirements; defining the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results; and establishing and maintaining records of acceptable suppliers, contractors, and consultants.

174. ALLERGAN violated 21 C.F.R. § 820.70(a) by failing to develop, conduct, control, and monitor production processes to ensure that the BIOCELL Textured Breast Implants conformed to their specifications, as well as maintaining process controls to ensure conformance to specifications. This includes, but is not limited to, ensuring that the any BIOCELL Textured Breast Implants did not exceed the maximum allowable roughness.

175. ALLERGAN violated 21 C.F.R. § 820.70(h) with respect to its lost-salt process of texturizing by failing to establish and maintain procedures for the use and

removal of such manufacturing materials to ensure that the amount of silicone particles embedded on the implant due to this texturizing process is limited to an amount that does not adversely affect the device's quality.

176. ALLERGAN violated 21 C.F.R. § 820.90(a) by failing to establish and maintain procedures to control texturized implants that do not conform to specification, including failing to adequately identify, document, evaluate, segregate, and dispose of nonconforming implants.

177. ALLERGAN, in violation of 21 C.F.R. § 820.100(a), failed to establish and maintain procedures for implementing corrective and preventive action in order to properly detect recurring quality problems related to the lost-salt process, investigate causes of nonconformities, identifying necessary action to correct and prevent recurrence of nonconforming implants, implementing changes in methods to correct such quality problems, and validating the corrective and preventive action.

178. ALLERGAN violated 21 C.F.R. § 820.22 by failing to establish procedures for quality audits to determine the effectiveness of the quality system and to ensure corrective action related to BIOCELL Textured Breast Implants be taken as necessary.

179. ALLERGAN failed to adequately inspect, test, and validate BIOCELL Textured Breast Implants after completion of assembly and immediately before delivery for implantation into consumers, like Plaintiff SUSAN MROWIEC, to mitigate the development of bacterial accumulation and other risks which cause BIA-ALCL, as mandated by 21 C.F.R. § 820.160.

180. Upon information and belief, when BIOCELL Textured Breast Implants were manufactured, ALLERGAN had the technological capability to manufacture BIOCELL Textured Breast Implants in a reasonably safe manner and ALLERGAN is held to the level of knowledge of an expert in the field. ALLERGAN itself had alternative measures to make a safer product but chose not to do so in the interests of further its profits.

181. Plaintiff SUSAN MROWIEC was injured as a result of Defendants' post-market failure to properly implement Good Manufacturing Practices, and as a result of Defendants' post-market negligence, ALLERGAN's BIOCELL Textured Breast Implants belatedly became known to be defective and unreasonably dangerous only after having been implanted in Plaintiff.

182. As a result of its failure to establish and maintain effective post-market quality control standards and good manufacturing practices to ensure defect-free products, Plaintiff suffered severe injuries.

183. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must adequately inspect, test, and validate its product and its components, and monitor its manufacturing and quality control processes to ensure there are no deviations from product specifications or regulations that could affect the safety of its products, such as the BIOCELL Textured Breast Implants.

184. As a result of ALLERGAN's post-market failure to properly implement quality control procedures required by federal statute and FDA regulations, as a as a result of ALLERGAN's post-market negligence, the products were defective and unreasonably dangerous when implanted in Plaintiff.

D. Statement of Facts Applicable to Plaintiff's Intentional and Negligent Misrepresentation Claims

1. ALLERGAN spent *years* downplaying or dismissing the growing link between BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implant

185. The first line of BIOCELL Textured Breast Implants was submitted for PMA in November 1999 and approved by the FDA in May 2000 under PMA No. P990074. These previously unregulated implants were then known as McGhan Medical RTV Saline-Filled Breast Implants and utilized ALLERGAN's BIOCELL lost-salt technology.

186. But approximately three years prior to that approval, in 1997, the first reported case of ALCL in a patient with a McGhan Medical RTV Saline-Filled Breast Implant (Style 168—one of the recalled implant styles) was published in the journal of Plastic and Reconstructive Surgery. Notably, the location for the lymphoma was encased in the right breast area, evidencing it was related to the implant itself.

187. Since then, there have been dozens of medical studies and regulatory alerts examining the progression of BIA-ALCL related knowledge, with one of the earliest studies being commissioned by ALLERGAN.

188. In 2003, a team of ALLERGAN consultants, advisors, and research coordinators initiated a 14-year prospective clinical study concerning 42,035 BIOCELL Textured Breast Implants and their link to BIA-ALCL.

189. Importantly, the ALLERGAN Study was not designed to determine whether there exists a link between BIOCELL Textured Breast Implants to BIA-ALCL—***that fact was already presumed by the ALLERGAN Study***. Instead, the ALLERGAN Study was seeking to determine if employing certain sterilization techniques at the time of implantation of a BIOCELL Textured Breast Implants would mitigate the risk of developing BIA-ALCL in light of the disease's nexus to bacterial accumulation.[21]

190. Also in 2003, a case report and review of the literature in The Archives of Pathology and Laboratory Medicine, *Anaplastic Large Cell Lymphoma Arising in a Silicone Breast Implant Capsule: A Case Report and Review of the Literature,* that a silicone gel-filled implant placed in the left breast in 1991 resulted in BIA-ALCL in the left breast diagnosed in March 2000. Notably, pathology of the left breast capsule showed refractile material consistent with silicone particles in close proximity to the tumor cells.

191. In 2007, ALLERGAN received at least three complaints of BIA-ALCL in women implanted with silicone filled breast implants, two of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of

[21] *Macrotextured Breast Implants with Defined Steps to Minimize Bacterial Contamination around the Device: Experience in 42,000 Implants*. Plastic and Reconstructive Surgery. 140. 427-431.

complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

192. BIA-ALCL first garnered attention after 2008, when a study described four patients with a CD30-positive T-cell lymphoproliferative disorder surrounding breast implants.

193. In November 2008, the Journal of the American Medical Association published a study by a group of Dutch researchers that had identified 11 patients with breast implants and reported BIA-ALCL of the breast diagnosed between 1990 and 2006. The study found a positive association between breast implants and the development of ALCL, with an odds ratio of 18:1—meaning that patients with implants were 18 times more likely to develop BIA-ALCL than patients without breast implants.

194. In 2008, ALLERGAN received at least nine complaints of BIA-ALCL in women implanted with silicone filled breast implants, five of which were confirmed to have been implanted ALLERGAN textured breast implants. The number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

195. On November 24, 2008, a healthcare professional reports to an ALLERGAN employee the events of BIA-ALCL and seroma. Rather than reporting the event to the FDA in an MDR, ALLERGAN buries the complaint in the 2009 Alternative Summary Reporting spreadsheet.

196. In 2009, ALLERGAN received at least six complaints of BIA-ALCL in women implanted with silicone filled breast implants, three of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

197. In 2010, ALLERGAN received at least four complaints of BIA-ALCL in women implanted with silicone filled breast implants. The number of complaints of BIA-

ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

198. On May 25, 2010, ALLERGAN files an MDR for the first time following an event of BIA-ALCL associated with one of their saline-filled breast implants which resulted in the death of the patient. The entirety of ALLERGAN's manufacturer narrative for this death was redacted by ALLERGAN as "(b)(4)" meaning the information constitutes "trade secrets and commercial or financial information."

199. In January 2011, the FDA issued a report titled "Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants." The report stated that "in a thorough review of scientific literature published from January 1997 through May 2010, the FDA identified 34 unique cases of ALCL." The FDA concluded, ***"The FDA believes that there is a possible association between breast implants and ALCL."*** The FDA further noted that, "ALCL has been found ***more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."***

200. Despite the FDA's January 2011 Report, a spokeswoman for ALLERGAN, whose products were linked to the cases, downplayed the concerns in an emailed statement: "***A woman is more likely to be struck by lightning than get this condition***," said Caroline Van Hove. "Patients' safety is Allergan's absolute first priority and ***we continue all efforts to collect and analyze further information about the very rare occurrence of ALCL in patients with breast implants***."

201. In 2011, ALLERGAN received at least nine complaints of BIA-ALCL in women implanted with silicone filled breast implants, all nine of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

202. On March 16, 2011, the FDA received the first MDR from ALLERGAN for an event of BIA-ALCL associated with one of their silicone filled breast implants where the operative notes described a "moderate brown liquid" in the implant capsule.

203. In 2012, the first cases of BIA-ALCL in women with breast implants began to be reported in Australia. This prompted ALLERGAN to publish a second study, in May 2012, estimating the incidence of developing BIA-ALCL at 1.46 for every 100,000 breast implants.

204. The ALLERGAN-sponsored study was described as using "crude figures," but nevertheless was used by the company to downplay the risk to patients and effectively served to silence debate among academics and regulators on the emerging issue.

205. In 2012, ALLERGAN received at least seventeen complaints of BIA-ALCL in women implanted with silicone filled breast implants, fourteen of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

206. In 2013, ALLERGAN received at least twenty-two complaints of BIA-ALCL in women implanted with silicone filled breast implants, twenty-one of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

207. On December 8, 2014, a major analysis of the breast implant and BIA-ALCL connection was published, which identified 173 cases of BIA-ALCL. The authors reviewed 37 articles in the world literature reporting on 79 patients and collected another 94 unreported cases. The study confirmed that there are no known pure smooth implant cases. ***Additionally, the study determined that out of 170 breast implants, in 61 cases the manufacturer was unknown yet in 97 cases (or 56%) the implants were BIOCELL Textured Breast Implants.***

208. In 2014, ALLERGAN received at least twenty-six complaints of BIA-ALCL in women implanted with silicone filled breast implants, eighteen of which were confirmed to have been implanted with ALLERGAN textured breast implants. The

number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

209. Also, in March 2015, the French National Cancer Institute (Agence Nationale de Sécurité du Médicament, "ANSM") announced, "There is a ***clearly established link*** between the occurrence of this disease and the presence of a breast implant."

210. In 2015, ALLERGAN received at least thirty-six complaints of BIA-ALCL in women implanted with silicone filled breast implants, thirty-two of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of complaints received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast implants for the same time period is still unknown.

211. In 2016, more information continued to come out addressing the link between breast implants and BIA-ALCL as regulatory agencies around the world began making more definitive and stronger statements alerting of the link. For example, in May 19, 2016, the World Health Organization ("WHO") issued a guidance definitively linking breast implants to ALCL and officially named the disease "breast implant associated ALCL."

212. In July 2016, the ANSM released an update stating that, based upon 29 cases of ALCL reported, and due to the predominance of textured cases, it was calling for all implant manufacturers selling in France to submit clear data for textured implants within the year or their respective devices would be restricted from sale.

213. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to discuss the association between breast implants and BIA-ALCL and to provide ongoing advice. In December 2016, the TGA issued a report about BIA-ALCL which indicated a substantially higher risk associated with textured versus smooth implants. Furthermore, the TGA-reported incidence rate was in the range of 1:1,000-10,000 for patients with textured implants.

214. On December 28, 2016, ALLERGAN sponsored a third study purported to examine the incidence of capsular contracture, malposition and late seroma in patients that received the ALLERGAN's Style 410 breast implant. The study found that out of the 17,656 patients, four developed ALCL. This would in fact suggest an incidence rate, at the time of the study, of close to 1:4,000 for the now recalled Style 410 implants. Nevertheless, the study found that the incidence of capsular contracture, implant malposition and late seroma were low enough to conclude that, "[t]hese data reaffirm the safety of the Natrelle 410 breast implant."

215. In April 2017, researchers from the M.D. Anderson Cancer Center in Houston performed a literature review on the etiology of ALCL and confirmed that "textured implants are commonly implicated in the development" of BIA-ALCL. Additionally, the study pulled information from the adverse events reports from the FDA's MAUDE database to determine the distribution of BIA-ALCL by manufacturer. **The data showed that out of the US cases reported to the FDA MAUDE database, 184 (or 80.3%) of the ALCL cases reported were ALLERGAN's BIOCELL Textured Breast Implants.**

216. In March 2018, the FDA issued an update which reported a total of 414 received reports of BIA-ALCL– up from 359 a year earlier. The report stated that the lifetime risk for BIA-ALCL is between 1 in 3,817 and 1 in 30,000 women with textured breast implants.

217. In August 2018, the FDA reported that of the 272 cases of BIA-ALCL for which the implant surface was known, approximately 89% were textured. The FDA further noted that the real number of cases and size of the risk was not known, because there was a lack of information about how many women in the United States and worldwide had received implants.

218. On August 3, 2018, researchers from the M.D. Anderson Cancer Center reported that the risk of BIA-ALCL for patients implanted with ALLERGAN's BIOCELL Textured Breast Implants after a decade of could be as great as 1 in 2,200. This estimate

was extrapolated from ALLERGAN's own two studies of its Style 410 BIOCELL Textured Breast Implants, published on December 28, 2016, as discussed above. At the time the study was published, four women out of 17,656 had developed BIA-ALCL. By August 2018, eight women of the 17,656 had developed BIA-ALCL.

219. As discussed further below, and despite these mounting issues, ALLERGAN continued to downplay and dismiss the prevalence of BIA-ALCL in connection with its Textured Breast Implants, and continued to market, sell, distribute, and push those implants onto consumers, including Plaintiff, around the world.

2. As early as 2010, when ALLERGAN would publicly address BIA-ALCL in its adverse event reports, they were riddled with half-truths and misrepresentations

220. Despite actually possessing exclusive knowledge about the risks of BIA-ALCL particular to the BIOCELL Textured Breast Implants, for decades ALLERGAN failed to publish, disseminate, or otherwise communicate, in any form, and by any means, the true risk of BIA-ALCL. ALLERGAN omitted material information about the disease not just to the FDA, but also to the medical and scientific community, device user facilities, and consumers like Plaintiff as part of a deliberate and intentional effort to induce such persons and entities to rely on the omissions and to allow the BIOCELL Textured Breast Implants to be in and remain in the marketplace for purchase. Through its omissions alone, ALLERGAN actively conspired to and did conceal the risks of BIA-ALCL associated with the BIOCELL Textured Breast Implants.

221. Moreover, despite the growing number of complaints, studies and concerns regarding the link between textured implants and BIA-ALCL, ALLERGAN continued to make false and misleading statements regarding BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implant.

222. In particular, ALLERGAN's false and incomplete statements surfaced in its hundreds of adverse event reports prepared following events of BIA-ALCL.

223. ALLERGAN had a duty on all matters related to events of BIA-ALCL associated with their BIOCELL Textured Breast Implants to report in a manner that avoided making any written or oral communication containing an untrue statement or omitting any material fact necessary to make statements made, in light of the circumstances under which they were made, not misleading.

224. However, as part of a scheme designed to downplay the risks of BIOCELL Textured Breast Implants in the MDRs and to induce the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff into believing that there was no unique risks of BIA-ALCL associated with their BIOCELL Textured Breast Implants in order to sell more implants, ALLERGAN willfully concealed and failed to disclose all information reasonably known to it in the adverse event reports.

225. In hundreds of adverse event reports following complaints from health care facilities, hospitals, physicians, nurse, and the patients themselves pertaining to events related to BIA-ALCL, rather than providing an honest account of the relationship between the device and the occurrence of BIA-ALCL in the report based on the knowledge in its possession as required by the applicable regulations, ALLERGAN for years provided incomplete information and/or simply quoted its device labeling.

226. For example, in an MDR dated November 1, 2010, ALLERGAN stated in its narrative for an event of BIA-ALCL:

> Device labeling addresses [. . .] ***There were no reported events of cancer including lymphoma for patients in the a95/r95 study included in the labeling for saline breast implants*** [. . .] "If unusual symptoms occur after surgery, such as fever or noticeable swelling or redness in one breast, you should contact your surgeon immediately. ".

227. Again, in a medical device report regarding BIA-ALCL dated March 25, 2011, ALLERGAN stated:

> Device labeling addresses: there were no reported event of lymphoma/alcl for pts in the (b)(4) study included in the labeling for saline breast implants. "if unusual symptoms occur after surgery, such as fever or

noticeable swelling or redness in one breast, you should contact your surgeon immediately. ".

228. On March 12, 2012:

Device labeling reviewed: there were no reported events of lymphoma/alcl, for pts in the core study, in the labeling for silicone implants.

229. On December 27, 2012:

Allergan product labeling for saline implants: there were no reported events of lymphoma/alcl, for patients in the (b)(4) study, as well as the (b)(4) study ((b)(4) study) included in the labeling for saline breast implants.

230. On May 2, 2014:

Device labeling reviewed: there were no reported events of lymphoma/alcl observed in the care study, in the labeling for silicone implants. There were no reported events of lymphoma/alcl observed in the (b)(4) study included in the labeling for saline breast implants.

231. On March 3, 2015:

Potential adverse events that may occur with saline-filled breast implant surgery include: [. . .] Published studies indicate that breast cancer is no more common in women with implants than those without implants. ***A large, long-term follow-up found no significant increases in the risk rates for a wide variety of cancers, including stomach cancer, leukemia, and lymphoma***.

232. On June 25, 2015:

Based on the info reported to fda and found in medical literature, ***a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl)***, a type of non-hodgkins' lymphoma. Women with breast implants may have a very small but increased risk of developing alcl in the fluid or scar capsule adjacent to the implant. ***Alcl has been reported globally in pts with an implant history that includes allergan's and other mfrs' breast implants***.

233. On March 21, 2016:

Device labeling addresses: "lymphoma, including anaplastic large t-cell lymphoma (alcl) - information from medical literature has suggested a possible association, ***without evidence of causation***, between breast implants and the very rare occurrence of alcl in the breast. ***The disease is***

> ***exceptionally rare***, may present as a late occurring peri-prosthetic seroma, and ***occurs in women with and without breast implants***.

234. On July 26, 2017:

> Device labeling: alcl has been reported globally in patients with an ***implant history that includes allergan's and other manufacturers' breast implants***. You should consider the possibility of alcl when you have a patient with late onset, persistent peri-implant seroma.

235. Finally, after a decade of disinformation but nonetheless still inadequately, on February 24, 2018, ALLERGAN begins to state:

> Based on information reported to global regulatory agencies and found in medical literature, ***an association*** has been identified ***between breast implants and the development of anaplastic large cell lymphoma (alcl)***, a type of non-hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing breast implant associated alcl (bia-alcl) in the fluid or scar capsule adjacent to the implant, with documented potential for local, regional, and distant spread of the cancer with mortality reported in rare cases. ***Bia-alcl has been reported globally in patients with an implant history that includes allergan's and other manufacturers' breast implants with various surface properties, styles, and shapes***. Most of the cases in the literature reports describe a history of the use of ***textured implants***.

236. In light of ALLERGAN's sophisticated knowledge of the nature of the BIA-ALCL and its relationship to its BIOCELL Textured Breast Implant—which was exclusively known internally within ALLERGAN as early as 2003—each of the above-representations by ALLERGAN, and the hundreds more like them, were false, incomplete, and misleading in the context in which they were made, and were known to be so when made.

237. The principle fraudulent omission in these adverse events was the failure to acknowledge that BIA-ALCL is exclusively found in textured implants and that ALLERGAN's BIOCELL Textured Breast Implants are, *by far*, associated with more cases than any other type of textured implant.

238. These representations created the false impression that the full extent of BIA-ALCL's relationship with the textured breast implants was already a known and disclosed risk, and further that ALLERGAN's breast implants were no more likely to be found in individuals suffering from BIA-ALCL than other companies' products.

239. Plaintiff, by and through the FDA, medical and scientific community, and her device user facility, justifiably relied upon ALLERGAN's misleading and incomplete representations concerning BIA-ALCL and its nexus to the BIOCELL Textured Breast Implants. Unaware of the true risks of BIA-ALCL, Plaintiff succumbed to the misrepresentations of ALLERGAN, and on or about April 2017, was implanted with BIOCELL Textured Breast Implants.

240. Had Plaintiff known the true facts relating to BIA-ALCL and its nexus to the BIOCELL Textured Breast Implants, Plaintiff would not have elected to be implanted with BIOCELL Textured Breast Implants, but rather would have chosen a different style of implant or forwent implantation altogether.

E. Statement of Facts Relating to Causation Applicable to All Counts

1. The connection between ALLERGAN's failure to report and Plaintiff's injuries

241. As a result of Allergan's failure to appropriately file MDRs to the FDA as required by 21 U.S.C. 360i and 21 C.F.R. § 803.50—its BIOCELL textured implants were misbranded post-market.

242. Plaintiff further alleges that Defendants failed to take reasonable post-market corrective action to warn, either directly or through an appropriate channel, physicians who had implanted its devices, and patients in whom they had been implanted, of the risks of BIA-ALCL.

243. Such warnings, had they been given, would have caused physicians and patients, like Plaintiff, to take proper precautions to determine whether the substantially increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's

BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL Textured Breast Implants before Plaintiff ever had them implanted.

244. Allergan was or should have been aware as early as 1997 that its BIOCELL Textured Breast Implants carried a much greater risk of BIA-ALCL than other textured implant products, or compared to smooth implant products—yet Allergan failed to give effective post-market notice to the FDA, physicians, and patients to put them on adequate notice of the problem, and failed to inform them of how to avoid that risk.

245. Also, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must timely and appropriately report adverse events concerning the safety of its products. ALLERGAN was under a continuing duty under state law to adequately report injuries and problems with its devices, including the BIOCELL Textured Breast Implants, to the FDA.

246. As a result of Allergan's post-market failure to properly implement procedures required by federal statute and FDA regulations, and as a result of ALLERGAN's post-market negligence, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise would have never would have been implanted in the Plaintiff at all.

2. The connection between ALLERGAN's failure to implement quality control systems and Plaintiff's injuries

247. As a result of ALLERGAN's failure to establish such quality systems as required by 21 C.F.R. Part 820—its BIOCELL Textured Implants were adulterated within the meaning of 21 U.S.C. 351(h) when they were placed in the stream of commerce by ALLERGAN.

248. Plaintiff further alleges that Defendants failed to take reasonable post-market corrective and preventive action in order to properly detect recurring quality problems related to the lost-salt process and implement changes in methods to correct such quality problems.

249. Such corrective and preventive action, had they been implemented, would have prevented Plaintiff from being exposed to an aggressive, potentially fatal form of lymphoma. Or, the FDA would have recalled the BIOCELL Textured Breast Implants before Plaintiff ever had them implanted.

250. Also under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must adequately inspect, test, and validate its product and its components, and monitor its manufacturing and quality control processes to ensure there are no deviations from product specifications or regulations that could affect the safety of its products, such as the BIOCELL Textured Breast Implants.

251. As a result of ALLERGAN's post-market failure to properly implement quality control procedures required by federal statute and FDA regulations, as a as a result of ALLERGAN's post-market negligence, the products were defective and unreasonably dangerous when implanted in Plaintiff.

252. ALLERGAN was or should have been aware as early as 1997 that its BIOCELL Textured Breast Implants carried a much risk of BIA-ALCL than other textured implant products, or compared to smooth implant products—yet ALLERGAN failed to implement effective post-market action to mitigate or eliminate the risk of BIA-ALCL, and failed to inform physicians and patients of how that risk could be avoided.

3. The connection between ALLERGAN's misrepresentations and Plaintiff's injuries

253. As discussed above, adverse event reports published in the FDA's MAUDE database represent a public communication by a manufacturer about a device's performance and its relationship to a particular adverse health event.

254. These adverse event reports are routinely reviewed by the FDA to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

255. Moreover, such reports are relied upon by the medical and scientific community, including cancer researchers as described above, as a valuable source of information in learning about the genesis of an adverse health event and any adverse health trends associated with a medical device.

256. Device user facilities, including hospitals, outpatient facilities, nursing homes and surgical facilities, routinely analyze the medical device reports when determining the risks of selling one particular medical device over another, or one brand over another. For example, with respect to breast implants, a device user facility relies upon the information contained in the medical device reports when deciding whether to sell smooth or textured implants, or ALLERGAN's brand over a competitor.

257. To the extent the medical device reports contain false, inaccurate, or incomplete information, the FDA is deprived of vital information needed to detect potential device-related safety issues and disseminate public alerts about particular device problem and/or its association to a particular disease.

258. Likewise, the medical and scientific community is deprived of the information needed to educate their patients and obtain informed consent about the risks in choosing a particular device.

259. Further, device user facilities are unable to make informed decisions about the risks of offering for purchase a particular medical device over others on the market.

260. ALLERGAN fraudulently omitted in its adverse event reports associated with the BIOCELL Textured Breast Implants that BIA-ALCL is exclusively found in textured implants and that ALLERGAN's BIOCELL Textured Breast Implants are associated with more cases than any other type of textured implant.

261. These incomplete representations created the false impression that the full extent of BIA-ALCL's relationship with the textured breast implants was already a known and disclosed, and further that ALLERGAN's breast implants were no more likely to be found in individuals suffering from BIA-ALCL than other companies' products.

262. Moreover, ALLERGAN had actual knowledge of the material facts as alleged herein regarding the risks of BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implant. However, for decades, ALLERGAN outright failed or refused disclose such facts in any form, whether it by through their adverse event reports or any other communication, although such facts were readily available.

263. Plaintiff, by and through the FDA, medical and scientific community, and her device user facility, justifiably relied upon ALLERGAN's omissions, and misleading and incomplete representations concerning BIA-ALCL and its nexus to the BIOCELL Textured Breast Implants. Unaware of the true risks of BIA-ALCL, Plaintiff succumbed to the omissions and misrepresentations of ALLERGAN, and in or about 2014 and 2016, was implanted with BIOCELL Textured Breast Implants.

264. As a result of Allergan's failure to disclose all of the known risks associated with BIOCELL Textured Breast Implants and BIA-ALCL, including in the adverse event reports, and as a result of ALLERGAN's fraudulent misrepresentations and omissions, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise would have never would have been implanted in the Plaintiff at all.

FIRST CAUSE OF ACTION

(Strict Product Liability-Failure to Warn)

Against All Defendants

265. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

266. At all times pertinent hereto, Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed its BIOCELL Textured Breast Implants to clinics, hospitals and plastic surgeons, who ultimately operated and implanted them in consumers' bodies.

267. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed the BIOCELL Textured Breast Implants implanted into Plaintiff's body.

268. The BIOCELL Textured Breast Implants that were implanted into Plaintiff were defective and unreasonably dangerous when they left the possession of the Defendants as a result of inadequate warnings, including:

(a) failing to provide adequate warnings, information, or both, to alert consumers and their prescribing physicians that the BIOCELL Textured Breast Implants posed an unreasonably high risk of causing BIA-ALCL once implanted;

(b) failing to properly market the BIOCELL Textured Breast Implants in light of the BIOCELL Textured Breast Implants' cancerous propensities;

(c) failing to ensure the performance of the BIOCELL Textured Breast Implants conformed to the representations made by Defendants concerning the risk of BIA-ALCL; and

(d) representing that the BIOCELL Textured Breast Implants were suitable for their intended use; and

(e) failing to handle the BIOCELL Textured Breast Implants in a manner that conformed to applicable federal laws and regulations.

269. Such warnings, if given, would have caused such physicians and patients to be informed when selecting the appropriate breast implant and would have enabled patients, including Plaintiff, to avoid the risks of developing BIA-ALCL.

270. Rather, Defendants continued to disseminate product labeling that was inadequate and defective despite having received post-market information regarding BIA-ALCL after the FDA approved such labeling—information Defendants failed to report to FDA in violation of the MDA and the regulations promulgated thereunder.

271. At all relevant times, under federal law and regulation, Defendants were under a continuing duty to monitor the product after premarket approval, and to

discover and report to the FDA any complaints about the product's performance and any adverse health consequences or AERs of which it became aware and that are, or may be, attributable to the product.

272. Defendants failed to submit appropriate medical device reports to inform the FDA of the danger of developing BIA-ALCL in connection with the BIOCELL Textured Breast Implants, as required by 21 C.F.R. § 803.50, even though they should have been aware of such adverse incidents and were actually aware of such incidents, including at least 22 events of BIA-ALCL Defendants had received between 2007-2010.

273. Instead, ALLERGAN exploited the FDA's non-public ASR program to bury evidence of its BIOCELL Textured Breast Implants causing BIA-ALCL. As a result, Defendants failed to fulfill its duty to report to the FDA per 21 C.F.R. § 803.50 and warn physicians or patients—including Plaintiff—implanted with ALLERGAN's BIOCELL Textured Breast Implants of the dangers of BIA-ALCL.

274. In addition to its unlawful use of the ASR program, ALLERGAN failed to:

(a) Investigate and evaluate complaints of BIA-ALCL per 21 C.F.R. §§ 820.198 and 803.18(e) and prepare corresponding medical device reports;

(b) Timely submit reports of BIA-ALCL per 21 C.F.R. § 803.50(a) and instead attempted to transmit such reports years after first receiving notice of the event;

(c) Provide all information reasonably known to it per 21 C.F.R. § 803.50(b) in its reports of BIA-ALCL but rather simply regurgitated its misleading and deficient labeling; and

(d) Use the appropriate device problem code for reports of BIA-ALCL per 21 C.F.R. § 803.52 but instead represented there was "no apparent adverse event."

275. Defendants, as developers and manufacturers of the BIOCELL Textured Breast Implants, are held to the level of knowledge of experts in the field of that type of

breast implant and had a duty to warn its consumers and prescribing physicians of the dangers associated with the implants and failed to do so.

276. At the time Plaintiff's physician implanted the BIOCELL Textured Breast Implants, her physician did not have substantially the same knowledge as the Defendants about the unreasonably high risks of causing BIA-ALCL because the Defendants failed to provide adequate warnings of those risks.

277. As the direct and proximate result of Defendants' failure to warn of the defective condition of the BIOCELL Textured Breast Implants, the Plaintiff was implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment, therapy, recovery, and expense associated with the removal of the BIOCELL Textured Breast Implants, the potential for the development of BIA-ALCL, and any condition or symptoms associated with BIA-ALCL or the prevention of that issue.

278. As a further proximate result of Defendants' failure to warn of the defective condition of the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating physical pain and mental suffering, was/will be required to undergo additional surgeries and other procedures, incurred substantial hospital, medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of these injuries are permanent and continuing.

279. The FDCA contains an express preemption provision, 21 U.S.C. 360k(a), which as relevant, states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."

280. This cause of action is based on the Defendants' post-market violations of federal safety statutes and regulations.

281. Moreover, Plaintiff does not bring the underlying action as an implied statutory cause of action but rather she is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal statutes and regulations.

282. Plaintiff's strict product liability for failing to warn claim is, thus, not preempted by Section 360k(a), because the violations alleged are all based on federal statutory and regulatory standards which includes no "requirement which is different from, or in addition to, any requirement applicable under" the FDCA and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the FDCA and regulations promulgated thereunder.

SECOND CAUSE OF ACTION

(Strict Product Liability-Manufacturing Defect)

Against All Defendants

283. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

284. At all times material hereto, Defendants, directly or indirectly, created, manufactured, assembled, designed, sterilized, tested, packaged, labeled, marketed, promoted, advertised, sold and/or distributed into the stream of commerce BIOCELL Textured Breast Implants, including the BIOCELL Textured Breast Implants implanted into Plaintiff.

285. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed the BIOCELL Textured Breast Implants implanted into Plaintiff's body.

286. The BIOCELL Textured Breast Implants that were implanted into Plaintiff were defective and unreasonably dangerous when they left the possession of the Defendants in one or more of the following ways:

(a) manufacturing and selling BIOCELL Textured Breast Implants that differ from the specifications set forth in the PMA, its Supplements, the Conditions of Approval, and/or other federal regulations;

(b) manufacturing and selling BIOCELL Textured Breast Implants with nonconforming materials and uncertified components, inconsistent with the specifications set forth in the PMA, its Supplements, the Conditions of Approval, or other federal regulations;

(c) manufacturing, distributing, and selling BIOCELL Textured Breast Implants knowing, or while capable of knowing, that they created an unreasonably high risk of causing BIA-ALCL when implanted into patients, including the Plaintiff;

(d) incorporating components into BIOCELL Textured Breast Implants that could not stand up to normal usage;

(e) failing or refusing to properly meet the applicable standard of care by not complying with applicable federal laws and regulations in manufacturing, marketing, selling, and distributing the BIOCELL Textured Breast Implants;

(f) failing or refusing to include adequate warnings with the device that would alert Plaintiff and her prescribing physician to the potential risks and serious side effects of the BIOCELL Textured Breast Implants;

(g) failing or refusing to exercise reasonable care in its inspecting and testing of the BIOCELL Textured Breast Implants both before and after they were placed on the market which, if properly performed, would have shown that the device caused serious side effects, including BIA-ALCL;

(h) failing or refusing to warn, or adequately warn, the Plaintiff or her prescribing physicians that the BIOCELL Textured Breast Implants created a higher risk of causing BIA-ALCL than other similar textured implants currently on the market;

(i) failing or refusing to provide adequate post marketing warnings or instructions to the Plaintiff and her prescribing physicians of the significant risk of causing BIA-ALCL;

(j) failing or refusing to exercise reasonable care in its manufacturing and quality control processes;

(k) placing an unsafe and defective breast implant into the stream of commerce; and

(l) underplaying the significant risks posed by the BIOCELL Textured Breast Implants to the public, including the Plaintiff and her prescribing physicians in order to make a profit from sale of the device.

287. Such measures, if implemented, would have mitigated or eliminated the risk posed by silicone particles shredding from the BIOCELL Textured Breast Implants and would have enabled patients, including Plaintiff, to avoid the risks of developing BIA-ALCL.

288. At all relevant times, under federal law and regulation, Defendants were also required to comply with the FDA's Quality System Regulations and Current Good Manufacturing Practices under 21 C.F.R. Part 820, which, among other things, requires that each manufacturer put procedures in place to test products for compliance with product specifications, document and check compliance with product specifications before products are accepted for sale and use, and identify and control all products that fail to conform with product specifications.

289. It was the duty of the Defendants to comply with the FDCA, and the regulations promulgated pursuant to it. Yet, notwithstanding this duty, Defendants violated the FDCA and regulations in one or more of the following ways:

(a) introducing or delivering for introduction into interstate commerce a device that was adulterated (21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820);

(b) receiving in interstate commerce a device that was adulterated and delivering the device for pay or otherwise (21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820);

(c) manufacturing a device that was adulterated (21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820);

(d) failing to establish and maintain procedures for validating the device design of BIOCELL Textured Breast Implants to ensure that the implants conformed to patients' needs and intended uses, including failing to test production units under actual or simulated use conditions (21 C.F.R. §820.30);

(e) failing to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, including evaluating and selecting potential suppliers, contractors, and consultants on the basis of their ability to meet quality requirements; defining the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results; and establishing and maintaining records of acceptable suppliers, contractors, and consultants (21 C.F.R. §820.50);

(f) failing to develop, conduct, control, and monitor production processes to ensure that the BIOCELL Textured Breast Implants conformed to their specifications, as well as maintaining process controls to ensure conformance to specifications. This includes, but is not limited to, ensuring that the any BIOCELL Textured Breast Implants did not exceed the maximum allowable roughness (21 C.F.R. §820.70(a));

(g) failing to establish and maintain procedures with respect to its lost-salt process of texturizing for the use and removal of such manufacturing materials to ensure that the amount of silicone particles embedded on the

implant due to this texturizing process is limited to an amount that does not adversely affect the device's quality (21 C.F.R. §820.70(h));

(h) failing to establish and maintain procedures to control texturized implants that do not conform to specification, including failing to adequately identify, document, evaluate, segregate, and dispose of nonconforming implants (21 C.F.R. §820.90(a));

(i) failing to establish and maintain procedures for implementing corrective and preventive action in order to properly detect recurring quality problems related to the lost-salt process, investigate causes of nonconformities, identifying necessary action to correct and prevent recurrence of nonconforming implants, implementing changes in methods to correct such quality problems, and validating the corrective and preventive action (21 C.F.R. §820.100(a));

(j) failing to establish procedures for quality audits to determine the effectiveness of the quality system and to ensure corrective action related to BIOCELL Textured Breast Implants be taken as necessary (21 C.F.R. §820.22);

(k) failing to adequately inspect, test, and validate BIOCELL Textured Breast Implants after completion of assembly and immediately before delivery for implantation into consumers, like Plaintiff, to mitigate the development of bacterial accumulation and other risks which cause BIA-ALCL (21 C.F.R. §820.160); and

(l) failing to monitor, receive, review, and evaluate and/or investigate complaints received from breast implant patients and their physicians, failing to timely identifying any problems with one of its devices and, failing to take appropriate corrective actions to ensure consumer safety (21 C.F.R. § 820.198).

290. Because Defendants failed to follow specifications, regulations, and required good manufacturing practices, Plaintiff's BIOCELL Textured Breast Implants were at a heightened risk of causing the development of BIA-ALCL.

291. Upon information and belief, Defendants had the technological capability to manufacture BIOCELL Textured Breast Implants in a reasonably safe manner and is held to the level of knowledge of an expert in the field.

292. As the direct and proximate result of Defendant's acts and omissions concerning the BIOCELL Textured Breast Implants, the Plaintiff was implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment, therapy, recovery, and expense associated with the removal of the BIOCELL Textured Breast Implants, the potential for the development of BIA-ALCL, and any condition or symptoms associated with BIA-ALCL or the prevention of that issue.

293. As a further proximate result of Defendant's acts and omissions concerning the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating physical pain and mental suffering, was/will be required to undergo additional surgeries and other procedures, incurred substantial hospital, medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of these injuries are permanent and continuing.

294. The FDCA contains an express preemption provision, 21 U.S.C. 360k(a), which as relevant, states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."

295. This cause of action is based on the Defendants' post-market violations of federal safety statutes and regulations.

296. Moreover, Plaintiff does not bring the underlying action as an implied statutory cause of action but rather she is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal statutes and regulations.

297. Plaintiff's manufacturing defect claim is, thus, not preempted by Section 360k(a), because the violations alleged are all based on federal statutory and regulatory standards which includes no "requirement, which is different from, or in addition to, any requirement applicable under" the FDCA and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the FDCA and regulations promulgated thereunder.

THIRD CAUSE OF ACTION

(Negligence)

Against All Defendants

298. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

299. At all times pertinent hereto, Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed their BIOCELL Textured Breast Implants to clinics, hospitals and plastic surgeons, who ultimately operated and implanted them in consumers' bodies.

300. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed the BIOCELL Textured Breast Implants implanted into Plaintiff's body.

301. Defendants owed Plaintiff, and the public, a duty to use reasonable care in testing and inspecting their BIOCELL Textured Breast Implants, in designing the BIOCELL Textured Breast Implants placed into Plaintiff and in manufacturing and marketing those BIOCELL Textured Breast Implants.

302. The BIOCELL Textured Breast Implants that were implanted into Plaintiff were defective and unreasonably dangerous when they left the possession of the Defendants in that the BIOCELL Textured Breast Implants did not conform to applicable federal laws and regulations.

303. At all relevant times, Defendants violated the FDA's Quality System Regulations and Current Good Manufacturing Practices under 21 C.F.R. Part 820, because ALLERGAN produced adulterated BIOCELL Textured Breast Implants that had numerous unwanted particles and solid fragments of silicone on the implant surface in violation of CGMP regulations designed to ensure device quality and patient safety.

304. Such measures, if implemented, would have caused mitigated or eliminated the risk posed by silicone particles shredding from the BIOCELL Textured Breast Implants and would have enabled patients, including Plaintiff, to avoid the risks of developing BIA-ALCL.

305. Defendants also violated the above described post-market reporting requirements under 21 C.F.R. Part 803 for the BIOCELL Textured Breast Implants, by virtue of their abuses of the FDA's ASR Program and other reporting violations. As a result, Defendants negligently failed to adequately warn of the dangers of BIA-ALCL and test its product before Plaintiff was implanted with ALLERGAN's BIOCELL Textured Breast Implants.

306. Such warnings, if given, would have enabled the FDA, as well as the medical and scientific community, to ensure physicians and patients were adequately informed when selecting the appropriate breast implant and would have enabled patients, including Plaintiff, to avoid being exposed to BIA-ALCL.

307. Plaintiff was implanted with BIOCELL Textured Breast Implants without adequate warning and with manufacturing defects, in violation of the general regulatory requirements, resulting in serious injury to Plaintiff. The injuries Plaintiff suffered are expected to have resulted from such defects. Plaintiff and her physician were unaware

that the BIOCELL Textured Breast Implants were defective at the time of implant and thereafter.

308. As the direct and proximate result of Defendant's negligent acts and omissions concerning the BIOCELL Textured Breast Implants, the Plaintiff was implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment, therapy, recovery, and expense associated with the removal of the BIOCELL Textured Breast Implants, the potential for the development of BIA-ALCL, and any condition or symptoms associated with BIA-ALCL or the prevention of that issue.

309. As a further proximate result of Defendant's negligent acts and omissions concerning the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating physical pain and mental suffering, was/will be required to undergo additional surgeries and other procedures, incurred substantial hospital, medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of these injuries are permanent and continuing.

310. The FDCA contains an express preemption provision, 21 U.S.C. § 360k(a), which as relevant, states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."

311. This cause of action is based on the Defendants' post-market violations of federal safety statutes and regulations.

312. Moreover, Plaintiff does not bring the underlying action as an implied statutory cause of action but rather she is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal statutes and regulations.

313. Under California's doctrine of negligence per se, failure to exercise due care is presumed from a violation of a "statute, ordinance, or regulation of a public entity." Cal. Evid. Code, § 669(a)(1). By its terms, this doctrine applies to the law of any public entity, not just California public entities. See, e.g., *DiRosa v. Showa Denko K.K.* (1996) 44 Cal.App.4th 799, 808. Thus, under California law, a money damages remedy exists for negligent violation of the FDCA and regulations promulgated thereunder which proximately cause injuries, and there is no need for California's Legislature to act in order to create such a remedy.

314. Plaintiff's negligence claim is, thus, not preempted by Section 360k(a), because the violations alleged are all based on federal statutory and regulatory standards which includes no "requirement, which is different from, or in addition to, any requirement applicable under" the FDCA and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the FDCA and regulations promulgated thereunder.

FOURTH CAUSE OF ACTION

(Fraud – Intentional Misrepresentation and Concealment)

Against All Defendants

315. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

316. Each Defendant actively participated in, agreed to, aided and abetted, conspired in, and/or furthered a fraudulent scheme, as set forth herein, which conduct constitutes fraud and deceit.

317. Defendants superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of BIA-ALCL and their international dissemination of promotional and marketing information about BIOCELL Textured Breast Implants for the purpose of maximizing its sale, each give rise to the affirmative duty to meaningfully disclose

important material facts concerning the safety of the BIOCELL Textured Breast Implants, specifically regarding the risks of developing BIA-ALCL.

318. Defendants omitted material information to the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff as part of a deliberate and intentional effort to induce such persons and entities to rely on the omissions and to allow the BIOCELL Textured Breast Implants to be in and remain in the marketplace for purchase. Through their omissions, Defendants actively conspired to and did conceal the risks of BIA-ALCL associated with the BIOCELL Textured Breast Implants.

319. Defendants omitted material information regarding the risks of BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implants with intent to defraud the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff.

320. Defendants intentionally failed to disclose material facts to the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff that they had a duty to disclose, including the risks of BIA-ALCL associated with the BIOCELL Textured Breast Implants. Each Defendant was aware of and/or approved the material omissions by or on behalf of Defendants.

321. Moreover, Defendants made representations about BIA-ALCL but did not disclose facts which materially qualified the facts disclosed, which rendered their disclosure likely to mislead. The true facts about BIA-ALCL and the correlation with ALLERGAN BIOCELL Textured Breast Implants were known to Defendants, and Defendants knew they were not known to or reasonably discoverable by Plaintiff.

322. Defendants knew that their half-truths, concealment and failure to disclose to Plaintiff, by and through the FDA, medical and scientific community, and her device user facility, all information reasonably available to them related to the nexus between BIA-ALCL and their BIOCELL Textured Breast Implants, would mislead Plaintiff by creating the false impression that the full extent of BIA-ALCL's relationship with the

BIOCELL Textured Breast Implants was already a known and disclosed by ALLERGAN, and further that ALLERGAN's breast implants were no more likely to be found in individuals suffering from BIA-ALCL than other companies' products. Defendants also knew that if Plaintiff became aware of the cancerous propensities associated the BIOCELL Textured Breast Implants, Plaintiff would not agree to purchase said implants.

323. Nevertheless, in willful disregard of Plaintiff's rights and the duties owed to Plaintiff by Defendants, and each of them, concealed and failed to disclose to Plaintiff all information reasonably available to them related to the nexus between BIA-ALCL and their BIOCELL Textured Breast Implants with the express purpose of inducing Plaintiff against her own interest to purchase their cancer-inducing breast implants.

324. Likewise, Defendants had a statutory and regulatory duty on all matters related to adverse events of BIA-ALCL associated with their BIOCELL Textured Breast Implants to report in a manner that avoided making any written or oral communication containing an untrue statement or omitting any material fact necessary to make statements made, in light of the circumstances under which they were made, not misleading.

325. However, as part of their scheme designed to downplay the risks of BIOCELL Textured Breast Implants in the medical device reports and to induce the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff into believing that there was no unique risks of BIA-ALCL associated with their BIOCELL Textured Breast Implants in order to sell more implants, Defendants willfully concealed and failed to disclose all information reasonably known to it in the MDRs.

326. The principle fraudulent omission in these MDRs was the failure to acknowledge that BIA-ALCL is exclusively found in textured implants and that ALLERGAN's BIOCELL Textured Breast Implants are associated with more cases than any other type of textured implant–by far.

327. Moreover, Defendants omitted, suppressed, and concealed material facts concerning the dangers and risks of injuries associated with BIOCELL Textured Breast

Implants and BIA-ALCL, including by exploiting the FDA's non-public ASR program to hide evidence of it BIOCELL Textured Breast Implants causing BIA-ALCL. Specifically, Defendants deliberately failed to file medical device reports associated with BIA-ALCL events despite its obligations under 21 U.S.C. 360 and 21 C.F.R. § 803.50—and deliberately and willfully concealed the increased risk of BIA-ALCL associated with its BIOCELL Textured Breast Implants when it either did not reports these events in any form to the FDA, or unlawfully used the ASR reporting system to report these complaints.

328. Defendants intended the FDA, the medical and scientific community, and device user facilities, and patients to rely on the Defendants' important material representations and concealment regarding the safety of the BIOCELL Textured Breast Implants and their link to BIA-ALCL.

329. Plaintiff, by and through the FDA, medical and scientific community, and her device user facility, did in fact rely on and were induced by Defendants' misrepresentations, omissions, or active concealment of the dangers of BIOCELL Textured Breast Implants and the link to BIA-ALCL.

330. Plaintiff, her physician, her device user facility, and the medical and scientific community did not know that the representations made by the Defendants were false and were justified in relying upon Defendants' representations.

331. As the direct and proximate result of Defendant's fraudulent misrepresentations and intentional concealment of facts concerning the BIOCELL Textured Breast Implants, upon which Plaintiff reasonably relied, she was implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment, therapy, recovery, and expense associated with the removal of the BIOCELL Textured Breast Implants, the potential for the development of BIA-ALCL, and any condition or symptoms associated with BIA-ALCL or the prevention of that issue.

332. As a further proximate result of Defendant's fraudulent misrepresentations and intentional concealment of facts concerning the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating physical pain and mental suffering, was/will be required to undergo additional surgeries and other procedures, incurred substantial hospital, medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of these injuries are permanent and continuing.

333. Defendants' fraudulent misrepresentations evidenced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff, as well as their goal to place company profits over the safety of hundreds of thousands of consumers, subjecting Defendants to punitive and exemplary damages according to the reprehensibility of their conduct and based on the wealth of said Defendants.

FIFTH CAUSE OF ACTION

(Negligent Misrepresentation and Concealment)

Against All Defendants

334. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

335. Each Defendant negligently participated in, agreed to, aided and abetted, conspired in, and/or furthered a fraudulent scheme, as set forth herein, which conduct constitutes negligent misrepresentation and concealment.

336. Defendants superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of BIA-ALCL and their international dissemination of promotional and marketing information about BIOCELL Textured Breast Implants for the purpose of maximizing its sale, each give rise to the affirmative duty to meaningfully disclose

important material facts concerning the safety of the BIOCELL Textured Breast Implants, specifically regarding the risks of developing BIA-ALCL.

337. Defendants negligently omitted material information to the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff which induced such persons and entities to rely on the omissions and to allow the BIOCELL Textured Breast Implants to be in and remain in the marketplace for purchase. Through their negligent omissions, Defendants concealed the risks of BIA-ALCL associated with the BIOCELL Textured Breast Implants.

338. Defendants negligently omitted material information regarding the risks of BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implants to the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff.

339. Defendants negligently failed to disclose material facts to the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff that they had a duty to disclose, including the risks of BIA-ALCL associated with the BIOCELL Textured Breast Implants. Each Defendant was aware of and/or approved the material omissions by or on behalf of Defendants.

340. Moreover, Defendants made representations about BIA-ALCL but did not disclose facts which materially qualified the facts disclosed, which rendered their disclosure likely to mislead. The true facts about BIA-ALCL and the correlation with ALLERGAN BIOCELL Textured Breast Implants were known to Defendants, and Defendants knew they were not known to or reasonably discoverable by Plaintiff.

341. Defendants knew that their half-truths, concealment and negligent failure to disclose to Plaintiff, by and through the FDA, medical and scientific community, and her device user facility, all information reasonably available to them related to the nexus between BIA-ALCL and their BIOCELL Textured Breast Implants, would mislead Plaintiff by creating the false impression that the full extent of BIA-ALCL's relationship with the BIOCELL Textured Breast Implants was already a known and disclosed by

ALLERGAN, and further that ALLERGAN's breast implants were no more likely to be found in individuals suffering from BIA-ALCL than other companies' products. Defendants also knew that if Plaintiff became aware of the cancerous propensities associated the BIOCELL Textured Breast Implants, Plaintiff would not agree to purchase said implants.

342. Nevertheless, in a negligent disregard of Plaintiff's rights and the duties owed to Plaintiff by Defendants, and each of them, concealed and negligently failed to disclose to Plaintiff all information reasonably available to them related to the nexus between BIA-ALCL and their BIOCELL Textured Breast Implants, thereby inducing Plaintiff against her own interest to purchase their cancer-inducing breast implants.

343. Likewise, Defendants had a statutory and regulatory duty on all matters related to adverse events of BIA-ALCL associated with their BIOCELL Textured Breast Implants to report in a manner that avoided making any written or oral communication containing an untrue statement or omitting any material fact necessary to make statements made, in light of the circumstances under which they were made, not misleading.

344. However, Defendants negligently downplayed the risks of BIOCELL Textured Breast Implants in the medical device reports, thereby inducing the FDA, the medical and scientific community, device user facilities, and consumers like Plaintiff into believing that there were no unique risks of BIA-ALCL associated with their BIOCELL Textured Breast Implants. As a result, ALLERGAN negligently concealed and failed to disclose all information reasonably known to it in the MDRs.

345. The principle fraudulent omission in these MDRs was the failure to acknowledge that BIA-ALCL is exclusively found in textured implants and that ALLERGAN's BIOCELL Textured Breast Implants are associated with more cases than any other type of textured implant–by far.

346. Moreover, Defendants negligently omitted, suppressed, and concealed material facts concerning the dangers and risks of injuries associated with BIOCELL

Textured Breast Implants and BIA-ALCL, including by exploiting the FDA's non-public ASR program to hide evidence of it BIOCELL Textured Breast Implants causing BIA-ALCL. Specifically, Defendants negligently failed to file medical device reports associated with BIA-ALCL events despite its obligations under 21 U.S.C. 360 and 21 C.F.R. § 803.50—and negligently concealed the increased risk of BIA-ALCL associated with its BIOCELL Textured Breast Implants when it either did not reports these events in any form to the FDA, or unlawfully used the ASR reporting system.

347. Defendants intended the FDA, the medical and scientific community, and device user facilities, and patients to rely on the Defendants' important material representations regarding the safety of the BIOCELL Textured Breast Implants and its link to BIA-ALCL.

348. Plaintiff, by and through the FDA, the medical and scientific community, and her device user facility, did in fact rely on and were induced by Defendants' negligent misrepresentations, omissions, or concealment of the dangers of BIOCELL Textured Breast Implants and the link to BIA-ALCL.

349. Plaintiff, her physician, her device user facility, and the medical and scientific community did not know that the representations made by the Defendants were false and were justified in relying upon Defendants' representations.

350. As the direct and proximate result of Defendant's negligent misrepresentations and concealment of facts concerning the BIOCELL Textured Breast Implants, upon which Plaintiff reasonably relied, she was implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment, therapy, recovery, and expense associated with the removal of the BIOCELL Textured Breast Implants, the potential for the development of BIA-ALCL, and any condition or symptoms associated with BIA-ALCL or the prevention of that issue.

351. As a further proximate result of Defendant's negligent misrepresentations and concealment of facts concerning the BIOCELL Textured Breast Implants, Plaintiff

suffered debilitating physical pain and mental suffering, was/will be required to undergo additional surgeries and other procedures, incurred substantial hospital, medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of these injuries are permanent and continuing.

PUNITIVE DAMAGE ALLEGATIONS

(Brought by Plaintiff Against Defendants)

352. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

353. The acts, conduct, and omissions of Defendants, and each of them, as alleged throughout this Complaint were willful and malicious and were done with a conscious disregard for the rights of Plaintiff as a user of Defendants' BIOCELL Textured Breast Implants and for the primary purpose of increasing Defendants' profits from the sale and distribution of BIOCELL Textured Breast Implants. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against each Defendant in an amount appropriate to punish and make an example of each Defendant.

354. Prior to the manufacturing, sale, and distribution of BIOCELL Textured Breast Implants, Defendants and each of them knew that said implants were in a defective condition as previously described herein and knew that those who were implanted with BIOCELL Textured Breast Implants would be at a heightened risk of developing BIA-ALCL, and would therefore experience and did experience severe physical, mental and emotional injuries. Further, Defendants and each of them through their officers, directors, managers, and agents, had knowledge that the BIOCELL Textured Breast Implants presented a substantial and unreasonable risk of harm due to BIA-ALCL to the public, including Plaintiff, and as such, was unreasonably subjected to the risk of injury or death from the implantation of BIOCELL Textured Breast Implants.

355. Despite such knowledge, Defendants, and each of them, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in said BIOCELL Textured Breast Implants and failed to warn the public, including Plaintiff, of the risk of developing BIA-ALCL occasioned by said defects inherent in said BIOCELL Textured Breast Implants. Said Defendants and their individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of said BIOCELL Textured Breast Implants knowing persons would be exposed to serious danger in order to advance Defendants' own pecuniary interests and monetary profits.

356. Defendants conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary decent people and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

THEREFORE, Plaintiff demands judgment for the following:

1. Past and future medical and incidental expenses, according to proof;
2. Past and future loss of earnings and/or earning capacity, according to proof;
3. Past and future general damages, according to proof;
4. Punitive and exemplary damages in an amount to be determined at trial;
5. Prejudgment and post judgment interest;
6. Costs to bring this action; and
7. Such other and further relief as the court may deem just and proper.

Dated: August 9, 2020

COWPER LAW LLP

By: */s/ C. Moze Cowper*
C. Moze Cowper
Noel E. Garcia
Counsel for the Plaintiff

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: August 9, 2020

COWPER LAW LLP

By: */s/ C. Moze Cowper*
C. Moze Cowper
Noel E. Garcia
Counsel for the Plaintiff