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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	Case No. 2:19-md-02921 (BRM) (JAD) MDL NO. 2921
	HON. JUDGE BRIAN R. MARTINOTTI HON. JUDGE JOSEPH A. DICKSON
TANYA CODY, Plaintiff v.	DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER 6
ALLERGAN PLC, now known as ABBVIE, INC.; ALLERGAN, INC., ALLERGAN USA, INC., and DOEs 1-100; Defendants	Civil Action No.:

Plaintiff files this Complaint pursuant to CMO No. 6, and is to be bound by the rights, protections, privileges, and obligations of that CMO. In accordance with CMO No. 6, Plaintiff hereby designates the United States District Court for the Northern District of Florida, as the place of remand as this case may have originally been filed there.

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Plaintiff, by and through undersigned counsel, files this Complaint against Defendants, Allergan plc, n/k/a AbbVie, Inc., Allergan, Inc., Allergan USA, Inc. and DOEs 1-100 (collectively "Allergan"), and alleges as follows:

INTRODUCTION

1. Plaintiff is a patient who had Allergan's BIOCELL breast implants implanted into her body. Evidence has emerged over time that these implants cause a form of cancer known as Breast-Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Plaintiff is bringing claims for Allergan's violations of state law in the design, manufacture, labeling, and marketing of BIOCELL products and for breaching warranties and its failure to adequately warn regarding the risk of BIA-ALCL, all of which parallel requirements of federal law.

2. On July 24, 2019, Allergan announced a worldwide recall of BIOCELL textured breast implants and tissue expanders (collectively referenced herein as "BIOCELL,""BIOCELL line," or the "BIOCELL product line")[1]. This followed the U.S. Food and Drug Administration's ("FDA") request to Allergan to recall the BIOCELL product line due to the risk of BIA-ALCL, a cancer of the immune system.

3. Allergan, through its predecessor, McGhan Medical Corporation, first introduced a textured breast implant in or about 1987. A textured implant is characterized by its textured surface, as contrasted with smooth implants, which have a smooth surface. Allergan's textured implants were implanted in patients for reconstruction following mastectomy or for

[1] BIOCELL is the tradename of Allergan's texturing process and refers to the textured silicone elastomer shell on both saline and silicone filled implants, as well as tissue expanders.

augmentation. They were available with silicone and saline-filled models and were placed under or over the pectoral muscle of the patient.

4. Allergan also manufactured, marketed and sold textured tissue expanders. These devices were used following mastectomy when a reconstructive surgery was undertaken to try to restore a more normal breast appearance. This sometimes involved the placement of tissue expanders to stretch the breast to make room for breast implants. A tissue expander is an empty breast implant that is gradually filled with normal saline over a period of weeks to months, causing the progressive expansion of the breast tissue until it reaches the desired breast size. In this type of reconstruction, a pocket is made under or above a large muscle in the chest, and the tissue expanders are placed in that space. After the tissue expansion is completed, a second surgery is done to remove the expanders and insert permanent breast implants.[2]

5. Specific manufacturing processes were used by Allergan for "texturing" of the implants, including a process known as the "salt loss technique." "BIOCELL" is the trade name of the salt loss texturing process. Allergan began marketing the BIOCELL textured breast implant in 1988 (including both saline and silicone filled implants). BIOCELL implants have been sold in the United States pursuant to Investigational Device Exemptions ("IDE"), Premarket Approval ("PMA"), as well as pursuant to pre-PMA and non-IDE non-clinical trial. BIOCELL tissue expanders have been sold through 510(k) clearance (including Allergan's Natrelle 133 tissue expanders).[3]

[2] Plaintiffs in the above captioned Multi-District Litigation include women who have had a BIOCELL implant, a BIOCELL implant as well as a BIOCELL tissue expander, or a BIOCELL tissue expander without a BIOCELL implant thereafter.

[3] On information and belief, Allergan's saline-filled breast implant BIOCELL line of products were non-PMA devices from 1988 to 2000; Allergan's silicone-filled breast implant BIOCELL line of products received an IDE exemption from 1998-2006; Allergan received PMAs for its BIOCELL line of products in 2000, 2006 and 2013.

6. This action arises from Allergan's wrongful conduct, including its: (a) failure to manufacture the BIOCELL line in accordance with intended and approved design specifications and processes, thereby rendering the product defective, (b) failure to warn physicians, and as a result patients, about serious health risks, (c) deliberate concealment, misrepresentation and obstruction of public and regulatory awareness of serious health risks, (d) failure to complete mandatory studies necessary to determine the safety, reliability and effectiveness of its products and to otherwise comply with current good manufacturing practices and qualify system regulation; and (f) failure to utilize reasonable care, all in violation of state law, which imposed no requirements different from or in addition to the parallel federal requirements which were similarly violated.

7. Plaintiff's claims against Allergan are not based upon an implied or private cause of action pursuant to an implied statutory or private cause of action under the applicable federal safety statutes and regulations; rather, Plaintiff's claims are brought pursuant to state law and based upon Allergan's violations of parallel federal requirements, as applicable.

THE PARTIES

8. Plaintiff is a breast cancer survivor who was implanted with Allergan BIOCELL textured breast implants as part of reconstructive surgery following mastectomy. As a result of having the BIOCELL products implanted, Plaintiff has endured evaluation and explant of the recalled BIOCELL textured implant due to the risk of BIA-ALCL, as well as reconstruction and re-implantation of an alternative implant.

9. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions,

scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity and other economic and non-economic damages. The losses are permanent and continuing in nature.

10. At all times relevant herein Plaintiff was a resident of Tallahassee, Florida.

11. Allergan consists of a number of corporate entities, each intertwined and sharing certain governance, officers, employees, agents, resources, planning, facilities, aspects of finances and financial planning, and other common interests and activities, upon information and belief. Allergan does not adhere to strict segregation of corporate entities and corporate resources and, as a result, each operates with dependence on the other rather than as separate and independent entities. Certain Allergan Defendants have held themselves out and have, upon information and belief, acted in concert with one another with regard to certain of the issues involved in this litigation. Through a series of mergers, acquisitions, schemes and other corporate arrangements, Allergan Defendants each continued the prior business of the other for the marketing, manufacturing, sale and distribution of BIOCELL products up until July 24, 2019 when Allergan plc announced a world-wide recall of the products. Allergan Defendants were and are alter egos and agents of one another and were complicit with one another in committing tortious and wrongful conduct in the United States at the time of sale of its textured BIOCELL products, at implantation of BIOCELL products, at explantation of BIOCELL products, and at diagnosis of ALCL, all of which resulted in Plaintiff's severe and ongoing personal injuries. Therefore, the Allergan Defendants have shared responsibility for the damages sustained, share successor liability, or otherwise expressly or impliedly assumed liability for injuries caused to Plaintiff by BIOCELL.

12. AbbVie, Inc. ("AbbVie") is a Delaware corporation, with its principal executive offices in Illinois. It acquired Allergan plc, which includes Allergan, Inc. and Allergan USA, Inc., upon the approval of a Scheme deal in the High Court of Ireland on May 6, 2020 and regulatory approval in the United States on May 8, 2020. Upon information and belief, AbbVie assumed the liabilities of Allergan plc (and thereby the liabilities of Allergan, Inc. and Allergan, USA, Inc.).

13. At times material to this action, Allergan plc was an Irish-domiciled company with headquarters in New Jersey. As a publicly traded company, it operated as a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, studying, and distribution of brand name pharmaceutical products, medical aesthetics, biosimilar, and over-the-counter pharmaceutical products, including BIOCELL. Allergan plc was formerly known as Actavis plc. In 2015, Actavis, a pharmaceutical company headquartered in Dublin, Ireland with a principal place of business in New Jersey, purchased Allergan, Inc. and adopted the Allergan plc name.

14. Allergan plc announced the world-wide recall of its BIOCELL product line on July 24, 2019. Allergan plc's Senior Vice President, Carrie Strom, coordinated the recall of BIOCELL products with the FDA. Allergan plc, through Ms. Strom, sent correspondence to patients with BIOCELL products ("Allergan Plastic Surgery Customer") less than one week after the recall advising patients to speak with the Allergan Plastic Surgery Sales representative or contact the Allergan Product Surveillance team prior to undergoing breast revision surgery. Such representatives and team members are agents of Allergan USA, Inc., upon information and belief.

15. Allergan USA, Inc., is a Delaware corporation with its principal place of business in New Jersey. It was formerly a wholly-owned subsidiary of Allergan plc . Allergan USA, Inc. was acquired by AbbVie pursuant to the May 8, 2020 acquisition described above. Allergan USA, Inc., in addition to Allergan, Inc. and Allergan plc, was involved in the business of designing, manufacturing, developing, studying, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and selling for profit, either directly or indirectly, through an agent, affiliate, predecessor or subsidiary, BIOCELL Textured Breast Implants and tissue expanders, to consumers in the United States, including Plaintiff. Allergan USA, Inc., in addition to Allergan, Inc. and Allergan plc, was also charged with complying with all conditions of the PMA approvals, 510(k) clearances, IDEs and pre-PMAs with respect to BIOCELL products, including an obligation to adhere to all PMA requirements, for example completing mandatory studies, applicable regulations, QSRs, CGMPS and parallel state laws.

16. Allergan, Inc. is a Delaware corporation with its principal place of business in California. It was formerly a wholly-owned subsidiary of Allergan plc after being acquired by Allergan plc's predecessor in name Actavis in 2015. Also in 2015, Allergan, Inc. was the identified and responsible party, via its UK agent, in the French report of deficiencies regarding BIOCELL, more fully described below. Thereafter, Allergan, Inc. was acquired by AbbVie pursuant to the May 8, 2020 acquisition, described above. Allergan, Inc. is the registered holder of the BIOCELL trademark. Allergan, Inc. also announced the recall of BIOCELL products.

17. Allergan, Inc. acquired Inamed Corporation on March 27, 2006 and took over the manufacturing, marketing, studying, selling and distributing of BIOCELL products. At that time, Inamed was one of the largest manufacturers of breast implants.

18. Inamed, while operating under the name First American Corporation, entered the breast implant market when it acquired McGhan Medical Corporation, in 1985. First American Corporation changed its name to Inamed in 1986.

19. McGhan began the production of BIOCELL products in the 1980's and obtained the patent for the BIOCELL texturing process. As a wholly owned subsidiary of Inamed, McGhan obtained the first PMA for BIOCELL products, on May 10, 2000. In 2001, Inamed renamed its McGhan Medical Corporation subsidiary "Inamed Medical Products Corporation." It was thereafter acquired by Allergan, Inc.

20. BIOCELL products were manufactured by McGhan in Arklow Ireland and continued to be manufactured in Ireland by Inamed and then Allergan, until Allergan transferred manufacturing operations to Costa Rica in approximately 2008.

21. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other. The Allergan Defendants carried out a joint venture, scheme, business plan, or policy in all respects, carried on the business of the other upon joinder, acquisition or merger, have successor liability, or expressly or impliedly assumed the liability for injuries from the BIOCELL products which are the subject of this Complaint, and each is legally liable for such injuries.

22. DOEs 1-100 are individuals and entities who are liable and responsible for Plaintiff's damages, but who have not yet been identified.

23. All references to "Allergan," refers to each and every Defendant individually and collectively.

JURISDICTION AND VENUE

24. Plaintiff files this Complaint directly into these Multidistrict Litigation (MDL)

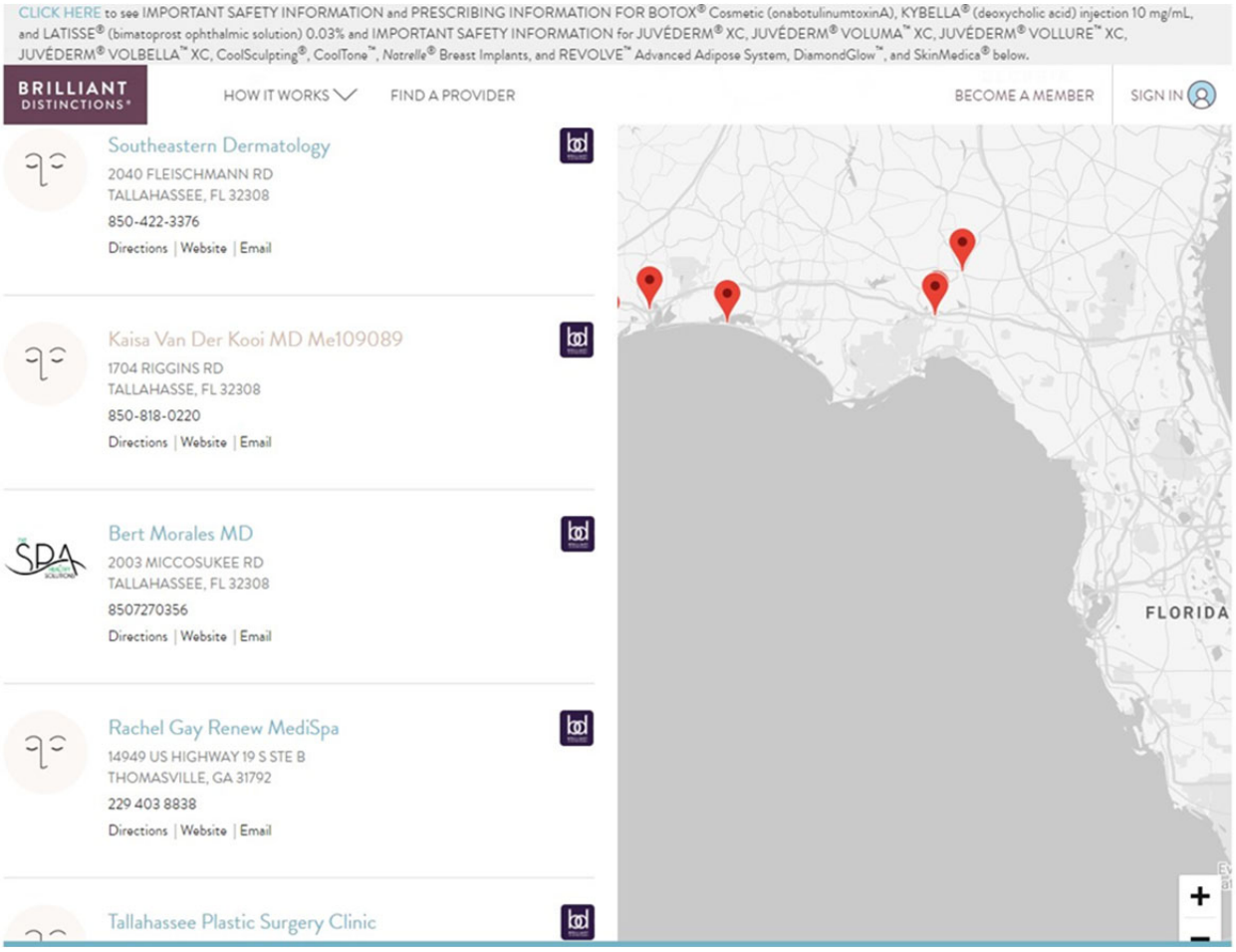
proceedings. In accordance with Case Management Order No.6. (MDL Doc. 83), Plaintiff's designated forum is the United States District Court for the Northern District of Florida. Pursuant to 28 U.S.C. § 1391, the United States District Court for the Northern District of Florida is proper because, as detailed below, a substantial part of the events or omissions giving rise to the claims occurred in Florida and because Defendants conduct substantial business in Florida.

25. This Court has jurisdiction over the consolidated MDL and pre-trial proceedings pursuant to 28 U.S.C. § 1407.

26. This Court and the United States District Court for the Northern District of Florida have jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and Defendants.

27. The United States District Court for the Northern District of Florida has specific personal jurisdiction over Defendants because this action arises out of and relates to Defendants' contacts with that forum.

28. As depicted below, Defendants have ongoing contacts with the Northern District of Florida by directing their products, including BIOCELL products to physicians within the Northern District of Florida. *Brilliant Distinctions by Allergan*, Defendants' patient-rewards program, has a web-based search platform that allows patients to locate physicians who use Allergan products. A query of the search platform indicated that at least 20 providers use Allergan products in the Northern District of Florida:



29. Defendants are registered to do business in the State of Florida and within the Northern District of Florida. Defendants directed the BIOCELL products through the stream of commerce into this District. Defendants have advertised and marketed within this District through sales representatives, through the wires and mails, and via e-commerce websites.

30. Defendants sold BIOCELL products to healthcare providers in the District for the purpose of making them available for purchase and use by patients, including Plaintiff, in that District.

31. Defendants also maintain corporate and sales offices in Weston and Sunrise, Florida.

32. Defendants have done substantial business, have committed a tort in whole or in

part, have substantial and continuing contact with, and derive substantial revenue from goods sold and used within the State of Florida. The Defendants actively sold, marketed and promoted their BIOCELL products to healthcare providers throughout the State of Florida.

33. Venue is proper in the Northern District of Florida, because a substantial part of the events or omissions giving rise to the claim occurred in Florida, and because Defendants conduct substantial business in Florida.

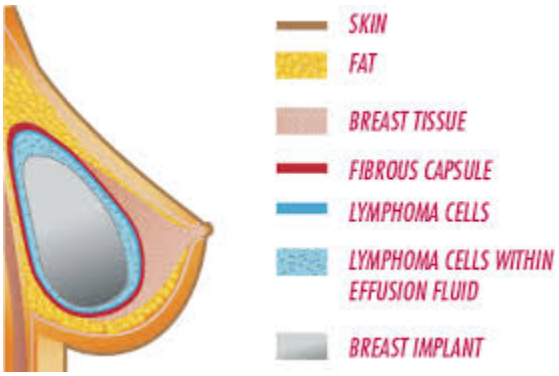
FACTUAL BACKGROUND

I. BREAST IMPLANT ASSOCIATED-ANAPLASTIC LARGE CELL LYMPHOMA "BIA-ALCL"

33. BIA-ALCL is a subtype of non-Hodgkin's lymphoma, a cancer of the immune system. It most often presents as a late-onset seroma, a non-resolving fluid collection around a breast implant, or as a solid mass in the scar tissue surrounding the implant, or in an adjacent axillary lymph node.[4] A patient with BIA-ALCL may have swelling from seroma accumulation, asymmetry, pain, heat sensations, rashes, capsular contracture, a painful or palpable mass under the arm, or no symptoms at all. In approximately two-thirds of the cases documented to date, BIA-ALCL is found in the fluid between the "capsule" (meaning the scar tissue the body forms around the implant) and the implant itself. In some cases, it can spread to the lymph nodes or throughout the body. If found in an advanced state, BIA-ALCL has a dismal prognosis and a high mortality rate.[5]

[4] Although seromas are not an uncommon complication in the *immediate* postoperative period, in the absence of a BIA-ALCL diagnosis (which has made it a more common complication), seromas are an extremely rare late complication of breast implantation.

[5] Thompson, P.A., Prince HM, Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis, *Curr. Hematol Malig Rep*. 2013 Sep 8(3): 196-210. Doi 10.1007/s11899-013-0164-3.



Implant Diagram Reflecting Seroma (Effusion Fluid)

34. Allergan's concealment and manipulation of information about BIA-ALCL caused physicians and patients to be uninformed and misinformed about the risk of BIA-ALCL, caused delays in patients being properly evaluated, diagnosed and treated for BIA-ALCL, and caused significant underreporting of BIA-ALCL cases.[6]

35. The recommended diagnostic testing for BIA-ALCL is invasive and includes, but is not limited to, imaging studies, guided needle aspirations and core tissue biopsies. BIA-ALCL may manifest years after implant or expander placement, with symptoms presenting from six months to 26 years post-implant.[7] BIA-ALCL is treated with extensive, disfiguring surgery to remove the implant and the surrounding capsule and tissue, and the treatment may include additional reconstructive surgery, chemotherapy, radiation and other extreme medical interventions. This cancer causes permanent harm and sometimes death.

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[6] Florian, F, Turner, S.D., Kenner, L Is Breast Implant-Associated Anaplastic Large Cell Lymphoma a Hazard of Breast Implant Surgery? *Open Biol.* 2019 Apr; 9(4): 190006. Published online 2019 Apr 3. doi: 10.1098/rsob.190006; Collett, D.J., et al. Current Risk Estimate of Breast-Implant-Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants, *Plast Reconst Surg*. 2019 Mar. The occurrence of late-onset seromas in patients with BIOCELL textured implants is recognized in the medical literature. *See also,* Spear SL, Rottman SJ, Glicksman C, Brown M, Al-Attar A. Late seromas after breast implants: theory and practice. *Plast Reconstr Surg*. 2012;130(2):423-435. doi:10.1097/PRS.0b013e3182589ea9. Three of the five authors were Allergan's paid consultants. They suggested the cause of late-onset seroma remained idiopathic, suggesting that the condition arises without any identifiable cause. Allergan had reason well before this date to suspect an association between ALCL and its textured implants.

[7] Allergan.com

36. On May 19, 2016, the World Health Organization ("WHO") designated BIA-ALCL as a distinct clinical entity, separate from other categories of ALCL.[8]

37. The first breast implant associated report of ALCL was published in August 1997 in the Journal of Plastic and Reconstructive Surgery in an article titled *Anaplastic T-Cell Lymphoma in Proximity to a Saline Filled Breast Implant*. In the article, Doctors John Keech and Brevator Creech described a patient who developed anaplastic T-cell lymphoma in proximity to her Style 168 BIOCELL breast implant manufactured by McGhan Medical Corporation, Allergan's predecessor. The patient described in Dr. Keech's article had to undergo chemotherapy and radiation to treat the cancer. Additional cases in the literature were seen throughout the early 2000s.[9] As reports of BIA-ALCL increased in the world medical literature, cases were also discussed at various conferences and gatherings in which Allergan representatives were in attendance. Respected surgeons and pioneers of BIA-ALCL research reported concerns about ALCL to Allergan representatives years before Allergan provided any warning regarding its BIOCELL products and the risk of ALCL associated with them.

38. State law required Allergan to exercise reasonable care in monitoring safety issues, such as keeping informed of reports of BIA-ALCL in the medical literature and through other pathways, so that Allergan could provide adequate and strengthened warnings. Further, Allergan was required by state law to warn physicians, and as a result patients, and the FDA and other regulatory bodies about the risk of BIA-ALCL.

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[8] Prior to the WHO classification of BIA-ALCL, a *non*-breast implant associated type of ALCL was long recognized in the medical literature. It occurred in the skin (cutaneous) or in a more aggressive type in lymph nodes and other organs (systemic). *See*, Lymphoma.org.

[9] *See*, Sunati, S., et al, Anaplastic Large Cell Lymphoma Arising in a Silicone Breast Implant Capsule: A Case Report and Review of the Literature *Arch of Path & Lab Med* 2003 127:3, e115-e118; Newman, M. Primary Breast Lymphoma in a Patient With Silicone Breast Implants: a Case Report and Review of the Literature *Plast Reconst & Aest Surg* 61:7 (822-825) (July 2008). DOI: https://doi.org/10.1016/j.bjps.2007.03.027.

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39. Allergan had a continuing, parallel federal post-market duty to learn of published and unpublished reports involving BIOCELL implants and timely report the information to the FDA. By way of example, 21 C.F.R. § 814.84(b)(2) required Allergan to provide the FDA with a periodic report containing any published or unpublished reports about BIOCELL implants.

40. Allergan also had a parallel duty to find, investigate, and report adverse events to the FDA. For example, 21 C.F.R. part 803 required Allergan to conduct a thorough investigation of each event, including seeking additional information about the event from user facilities (such as hospitals or doctors' offices). This duty is triggered when Allergan becomes aware of information from *any* source that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned, and, this device or a similar device it markets, is likely to cause or contribute to a death or serious injury, if the malfunction were to recur. 21 C.F.R. § 803.50 (emphasis added).

41. Allergan received complaints and reports from physicians and patients which raised the potential connection between the BIOCELL line and BIA-ALCL, yet it failed to reasonably investigate those complaints and reports, failed to adequately report them to the FDA and other regulatory bodies, and failed to warn physicians, and as a result, patients about the risk of BIA-ALCL associated with its BIOCELL implants. Allergan had information showing that its BIOCELL implants were associated with BIA-ALCL for years prior to submitting its first MAUDE report to the FDA, described below.[10] Moreover, in its May 2016 response to the French Health Authority (ANSM) notice of deficiency findings, as more fully described below,

[10] The FDA Maude Database contains reports of adverse events (medical device reports, "MDRs") involving medical devices. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers). This is a passive surveillance system which the FDA acknowledges has limitations, however, MDRs comprise only one of the FDA's several important postmarket surveillance data sources. The MAUDE database includes records back to 12/24/1991. *See*, FDA.report/MAUDE/.

Allergan conceded that it had received 104 reports of confirmed, suspected, and pending confirmation ALCL cases associated with a textured breast implant between at least 2007 and 2015.[11]

42. Despite these reports and Allergan's obligations to find, investigate, and report adverse events to the FDA pursuant to federal law, Allergan failed to do so. Among its earliest reports, Allergan submitted a Medical Device Report ("MDR") involving a case of BIA-ALCL to the FDA on 6/23/2010. That report was from an event that occurred more than three years earlier, on or about 6/1/2007, and it involved a patient who was diagnosed with ALCL and died. When Allergan finally reported this event to the FDA, Allergan misleadingly described the patient's ALCL diagnosis and death by claiming that the report involved "No Apparent Adverse Event."[12] The FDA publishes adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. Therefore, the timely and accurate reporting of these events is an important part of product safety surveillance and plays a vital role in tracking products subject to a PMA to assess risk and benefit profiles.

ALLERGAN STYLE 168 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE Back to Search Results

Catalog Number UNK STYLE 168
Device Problem No Apparent Adverse Event
Event Date 06/01/2007
Event Type Death

[11] *See*, ANSM.SANTE.FR – website for French Agency.
[12] *See*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=1735706&pc=FWM.

Event Description

Healthcare professional reports a diagnosis of alcl and the death of this patient.

Manufacturer Narrative

(b) (4).

Manufacturer Narrative

The events of lymphadenopathy and abscess are physiological complications and analysis of the device generally does not assist allergan in determining a probable cause for this event.

Event Description

Healthcare professional additionally reported "diffuse lymphadenopathy" and "left breast abscess.".

Search Alerts/Recalls

Allergan reported a 2007 death of a patient with BIOCELL in 2010.

43. As a manufacturer, Allergan has unique knowledge concerning the frequency, severity and predictability of the complications and risks associated with its devices. Accordingly, there is a post-market responsibility under the FDA Regulations related to complaint handling, investigation and reporting to the FDA, including but not limited to:

a. 21 C.F.R. § 803.10 (for example, § 803.10(c) requires adverse events to be reported by a manufacturer in set time frames from 5 to 30 days when the event becomes known);

b. 21 C.F.R. § 803.17 ("Medical device manufacturers must develop and implement standardized medical device reporting procedures so that timely evaluation of events and communication of findings can occur.");

c. 21 C.F.R. § 803.18 (§ 803.18(1)(d) requires a device distributor to maintain complaint files and records, including any written, electronic or oral communication, either received or generated by the distributor, that

alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device.);

d. 21 C.F.R. § 803.20 ("Manufacturers must timely communicate a reportable event. Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.");

e. 21 C.F.R. § 803.3 ("If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.");

f. 21 C.F.R. § 803.50 ((a) "If you are a manufacturer, you must report to the FDA information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) Information reasonably known to a manufacturer to a manufacturer includes (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the

information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).");

g. 21 C.F.R. § 803.52 (detailed individual and device information must be submitted for each adverse event);

h. 21 C.F.R. § 803.53 (information regarding detailed individual and device information must be submitted in a timely manner when remedial action may be required);

i. 21 C.F.R. § 803.56 (supplemental reporting must be done if additional information is learned that became known after the initial report was submitted);

j. 21 C.F.R. § 814.82(a)(2) (manufacturer has a duty of "[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted.");

k. 21 C.F.R. § 814.84 (the periodic reports required by law must contain the reports in the scientific literature that pertain to the device which are known or should be known to the manufacturer);

l. 21 C.F.R. § 820.198 ("Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (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").

44. As discussed *infra*, the state law duties to monitor, investigate, evaluate and timely report injuries and other important safety information regarding a medical device are no

different from, and are not in addition to, these federal requirements, all of which Allergan violated when it failed to monitor, investigate and report regarding ALCL risk and incidence and to take the necessary steps to continually evaluate the safety, effectiveness and reliability of its BIOCELL products, and to take necessary steps to warn, strengthen its warnings, and take other measures to assure compliance with its obligations.

II. THE RECALL OF THE BIOCELL LINE OF IMPLANTS

45. On July 24, 2019, Allergan announced a global recall of BIOCELL textured breast implants and tissue expanders after the Food and Drug Administration requested the recall. The recall was requested by the FDA because of concerns that ALCL was occurring more frequently than previously appreciated and nearly always in conjunction with Allergan's BIOCELL textured products. At the time of the BIOCELL recall, the FDA indicated that there were 573 known cases of BIA-ALCL worldwide[13] and that 33 people had died as of that time, a "significant increase" since the FDA's last update a few months earlier, reflecting 116 new cases and 24 more deaths. The FDA announced: "Based on the currently available information, the FDA's analysis demonstrated that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. Continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL." The FDA noted that of the 573 cases of BIA-ALCL known to it, 481 were attributed to Allergan implants. Out of the 531 ALCL cases with a clearly identified

[13] As of April 24, 2020, the American Society of Plastic Surgeons reported that the worldwide total of suspected and confirmed cases of ALCL is 903. https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources.

manufacturer,[14] Allergan was the manufacturer for 91% of them. For the deaths from ALCL in which the manufacturer was confirmed, Allergan was the manufacturer for 92% of them. Dr. Amy Abernethy, FDA Principal Deputy Commissioner stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action." The FDA has identified this recall as a "Class I recall, the most serious type of recall," and warns that "use of these devices may cause serious injury or death."

46. Other regulatory bodies around the world were also alarmed about the risk to life and health caused by the BIOCELL products. Prior to Allergan's July 2019 recall in the US and world-wide, Allergan's CE mark was suspended[15], halting all sales in the European Union, and regulatory agencies in Brazil and Canada[16] also precluded Allergan from selling any BIOCELL products in those countries. Regulatory agencies attributed these extreme regulatory actions to concerns about BIA-ALCL being associated with Allergan's BIOCELL product line.

47. The recalled BIOCELL products are:

> **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:

[14] Allergan was not excluded as the manufacturer in the remaining 42 cases. There was simply not enough information to identify the manufacturer of the products involved.

[15] CE marking is a certification mark used in Europe to indicate that products conform with safety, health and environmental protection standards.

[16] Canadian regulators found, as did the French, that Allergan was neither timely nor appropriately responsive to requests for safety information. Health Canada, the regulatory agency of Canada, found information Allergan submitted to be inadequate to show that the benefits of BIOCELL exceeded its risks. In fact, Health Canada found the risks exceed the benefits. Health Canada indicated that 85% of its reported ALCL cases involved BIOCELL. It estimated that the risk for BIA-ALCL with BIOCELL is 1 in 3,565, while the risk for ALCL with Mentor, a competitor textured breast implant manufacturer, is 1 in 16,703. The agency also noted that there were no cases of BIA-ALCL reported with smooth implants.

- 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 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 P040046. The following are the textured styles:

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

Allergan Natrelle Dual-Gel styles LX, MX, and FX.

Allergan Natrelle Komuro breast implants styles KML, KMM, KLL, and KLM.

Allergan Natrelle Ritz Princess breast implants styles RML, RMM, RFL, and RFM.

Allergan Natrelle 150 Full Height and Short Height double lumen implants.

McGhan BioDimensional Silicone-Filled breast implants (style 153)

Allergan tissue expanders for the breast that have BIOCELL texturing originally cleared as:

- Natrelle 133 Plus Tissue Expander (K143354)
- Natrelle 133 Tissue Expander with Suture Tabs (K102806)[17]

[17] Allergan tissue expanders were cleared for marketing as 510(k) device and maintained the 510(k) clearance until the recall.

48. As to each of the BIOCELL products implanted in Plaintiff, the products:

a. Were defective and unreasonably dangerous when they left Allergan's possession;

b. Were defectively manufactured when they left Allergan's possession;

c. Were not merchantable and reasonably suited for the intended purpose;

d. Reached Plaintiff without substantial change in the condition in which the products were sold;

e. Failed to include sufficient instructions and warnings of potential safety hazards;

f. Had inherent risks which outweighed the product's benefits, beyond the expectations of an ordinary consumer;

g. Failed to perform in a manner reasonably expected;

h. Were distributed at a time in which a safer alternative design was available[18] which was practical and which would have reduced the risk of injury posed by Allergan's products;

i. Were of such defective and unreasonably dangerous quality as to make it foreseeable to Allergan that injuries would occur and such foreseeability was known or should have been known when the products left Allergan's control;

j. Were appropriately and reasonably used by Plaintiff and her physician, in a foreseeable manner, but Plaintiff suffered foreseeable injuries due to the defective and unreasonably dangerous nature of Allergan's products;

k. Were misbranded and adulterated.

III. REGULATORY HISTORY OF THE BIOCELL PRODUCT LINE AND PARALLEL FEDERAL REQUIREMENTS:

[18] "Smooth" breast implants were on the market at the times in which Allergan's textured implants were sold. No confirmed cases of BIA-ALCL have been associated solely with the use of smooth implants. These implants have a smooth texture and do not undergo a salt loss texturing process as the Allergan BIOCELL products undergo. Even among the textured implants sold in the U.S., Allergan's BIOCELL line is associated with the vast majority of ALCL cases.

49. In the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress instituted a process for product review and clearance, using different pathways and processes to permit drugs and medical devices to be sold to U.S. consumers. One process is the Premarket Approval Process (PMA). Three classes of medical devices are regulated by the act, Class I, Class II and Class III, with greater degrees of scrutiny and regulation imposed on the manufacturer as the levels go from I to III. Allergan's textured breast implants manufactured after its 2000 PMA are Class III devices, with exception of model 153. Allergan's textured breast implants manufactured before its 2000 PMA and all of its textured breast tissue expanders are not Class III devices and are not subject to the same requirements or express preemption defenses. Moreover, Allergan's conduct and representations that are outside a PMA ("non-PMA") are also excluded from express preemption defenses.

50. Under a Class III PMA, manufacturers have substantial and ongoing duties because of the degree of risk associated with products carrying the classification. Failing to fulfill the duties and comply with the associated requirements can result in the PMA being withdrawn. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Another process, used for Class II medical devices, which are viewed as carrying less risk to human life and health, is called a 510(k) clearance. A 510(k) device is subject to less scrutiny and does not go through the pre or post-marketing surveillance process. This type of clearance is based on cursory review and also does not carry the same strict guidelines on manufacturers that continue well after the product enters (and even exists) the market. When a device is submitted for a 510(k) premarket clearance, the premarket notification and submission need only demonstrate that the device is substantially equivalent to another

device within that type. 21 U.S.C. § 360e(b)(1)(B). State law, via common law and statutory enactments, provides financial remedies for personal injuries arising from violations of parallel federal regulations applicable to Class III devices. State law, via common law and statutory enactments, provides financial remedies for personal injuries caused by 510(k) clearance devices and other non-PMA devices, without such state law claims being subject to MDA preemption defenses. 21 U.S.C. § 360(k)(a). Likewise, Allergan's Model 153 textured breast implants are not subject to MDA preemption defenses, as it was removed from Allergan's PMA application.

51. The PMA application process includes but is not limited to the following:

> PART 814 -- PREMARKET APPROVAL OF MEDICAL DEVICES
> Subpart B--Premarket Approval Application (PMA)
>
> Sec. 814.20 Application…
>
> (b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include:
>
> …
>
> (3) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:
>
> (i) *Indications for use.* A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.
>
> (ii) *Device description.* An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included.
>
> …
>
> (iv) *Marketing history.* A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all

countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person.

(v) *Summary of studies.* An abstract of any information or report described in the PMA under paragraph (b)(8)(ii) of this section and a summary of the results of technical data submitted under paragraph (b)(6) of this section. Such summary shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:

(A) A summary of the nonclinical laboratory studies submitted in the application;

(B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such).

(vi) *Conclusions drawn from the studies.* A discussion demonstrating that the data and information in the application constitute valid scientific evidence within the meaning of 860.7 and provide reasonable assurance that the device is safe and effective for its intended use. A concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA.

(4) A complete description of:

(i) The device, including pictorial representations;

(ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or

ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(iv) The principles of operation of the device; and

(v) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

…

(6) The following technical sections which shall contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval of the application:

(i) A section containing results of the nonclinical laboratory studies with the device including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate. Information on nonclinical laboratory studies shall include a statement that each such study was conducted in compliance with part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(ii) A section containing results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE shall be identified as such. Information on clinical investigations involving human subjects shall include the following:

…

(7) For a PMA supported solely by data from one investigation, a

> justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results.
>
> (8)(i) A bibliography of all published reports not submitted under paragraph (b)(6) of this section, whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device.
>
> (ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.
>
> …
>
> (9) One or more samples of the device and its components, if requested by FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices.
>
> (10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under section 201(m) of the act.
>
> …
>
> (e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. These updates are considered to be amendments to the PMA.

52. Upon the 1976 enactment of the MDA, the FDA categorized saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process, rather than through the PMA process. The devices could be sold so long as manufacturers later provided "reasonable assurance" that their products were substantially equivalent to another device within that type. 21 U.S.C. § 360e(b)(1)(B).

53. McGhan Medical Corporation, Allergan's predecessor, began marketing BIOCELL textured breast implants in 1987-1988.

54. In 1988, the FDA reclassified breast implants from Class II medical devices to Class III. Following this reclassification, McGhan was required to file a PMA for all of its BIOCELL line of products.

55. In 1991, McGhan applied for PMA for various styles of implants but was denied. An exception was given for use of the products for treatment of breast cancer patients requiring reconstruction and revision surgeries. The FDA concluded that none of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support approval. Saline-filled implants, including those from the BIOCELL line of products, remained available for augmentation and reconstruction during this time period. These products were sold without PMA and are not subject to the same considerations as PMA devices, for example, 21 U.S.C. § 360(k)(a).

56. In 1998, McGhan applied and was approved for an IDE for use of the silicone gel-filled implants in ongoing clinical studies, referred to as the "core" study. McGhan also identified and was approved in 2002 for use of the subject devices in an adjunct study that was being conducted but not pursuant to an IDE. *See* 21 U.S.C. § 360j(g); 21 C.F.R. § 812.20; 21 C.F.R § 812.25; 21 C.F.R. § 812.27; 21 C.F.R. § 812.30.

57. In 1999, the FDA issued a final rule requiring PMAs to be completed within 90 days for saline-filled implants. The first PMA for BIOCELL textured implants was granted in 2000.

Allergan BIOCELL Textured Implant

58. Allergan was granted 510(k) clearance for Allergan textured tissue expanders in 2011 and 2015. Clearance for Natrelle 133 Plus Tissue Expander was granted in January 2011. Clearance for Natrelle 133 Tissue Expander With Suture Tabs (K143354) was granted in August 2015. The expanders were never submitted for PMA and thus not governed by the provisions of 21 U.S.C. § 360e.

A. Allergan's Duties as a Class III Device Manufacturer: PMA and Post-PMA.

59. Allergan received three PMAs for the BIOCELL line of textured breast implants: the first on May 20, 2000, the second on November 17, 2006, and the third on February 20, 2013. The textured BIOCELL product line was categorized as a Class III Medical Device. The duties of a Class III medical device manufacturer do not end with PMA approval. Rather, the MDA imposes a number of ongoing manufacturer responsibilities, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order pursuant to applicable federal regulations, including, but not limited to, 21 C.F.R. parts 803, 814 and 820. Such manufacturers are also required to conduct ongoing safety studies and to notify the FDA of any unexpected serious problems with the device.

60. A manufacturer is required by federal law (and parallel state law) to sell and distribute only non-adulterated products pursuant to its PMA. A medical device is deemed adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. This duty is ongoing. *See* 21 U.S.C. § 351.

61. A manufacturer is prohibited by federal law (and parallel state law) from selling and distributing misbranded products pursuant to its PMA. A medical device is deemed misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling. This duty is ongoing. *See* 21 U.S.C. § 352(a). Moreover, restricted devices are deemed misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. § 352(q). In the PMA orders for BIOCELL textured implants, the FDA indicated that the devices were restricted devices, subject to 21 U.S.C. § 352(q). Thus, Allergan had a federal duty not to advertise the BIOCELL textured implants in a way that was false or misleading.

62. Allergan, as a manufacturer of BIOCELL textured implants, a Class III medical device with PMA approval, was required to do the following, among other things:

a. Comply with the FDA's Quality Systems Regulations ("QSRs"). 21 C.F.R. part 820. The specific QSRs promulgated by the FDA are known as Current Good Manufacturing Practices ("CGMP"). 21 C.F.R. § 820.1(a). A manufacturer must satisfy these quality standards in the manufacture and production of medical devices. 21 C.F.R. § 820.1(a).

b. Adopt procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. §§ 820.1-.250.

c. "Establish and maintain procedures to identify and address any product that does not conform to specified requirements," such as a failure to conform to performance and design standards set forth in the

manufacturer's PMAs and supplements. 21 C.F.R. § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSRs also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21C.F.R. § 820.100.

d. Formulate and then effectively execute a Post-Marketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 C.F.R. § 822.8.

e. Review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 C.F.R. § 820.198(b).

f. Complete an investigation when a complaint involves the possible failure of a device, its labeling or its packaging to meet any of its specifications. 21 C.F.R. § 820.198(c).

g. Establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 C.F.R. § 820.250 and 21 C.F.R. § 820.1(a)(3).

h. Comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device. 21 C.F.R. § 820.1(c); 21 U.S.C. § 352 (f)(2); 21 U.S.C. § 321(m); 21 U.S.C. § 352(a); 21 U.S.C. § 352(q); 21 U.S.C. § 321(n).

i. Keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21. U.S.C. § 360i.

j. Report adverse events associated with a medical device within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction recurs. 21 C.F.R. § 803.50(a). This reporting is mandatory and is a condition of continued PMA approval. 21 C.F.R. § 814.82. Such reports must contain all information reasonably known to

a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 C.F.R. § 803.50(b)(1).

k. Conduct an investigation of each adverse event and evaluate the cause of the adverse event. 21 C.F.R. § 803.50(b)(3). A manufacturer must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 C.F.R. § 803.52(f)(9).

l. Report to the FDA in five (5) business days after becoming aware of any MDR event or events, including a trend analysis, which necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. 21 C.F.R. § 803.53. This reporting is mandatory and a condition for continued PMA approval.

m. Report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. 21 C.F.R. § 806.10(a). FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by a manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 C.F.R. § 806.10(b). The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. A manufacturer must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. 21 C.F.R. § 806.109(c).

n. Prevent adulterated devices from being implanted in patients. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packaging, storage, or installation are not in conformity with the federal requirements. 21 U.S.C. § 351(e) and (h). Devices subject to an FDA recall are, by definition, adulterated and prohibited for introduction into interstate commerce by the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 331(a).

o. Implement changes to its device, its manufacturing processes or its labeling to enhance the safety of the device prior to obtaining FDA approval. These changes may include, but are not limited to, labeling changes that add or strengthen a contraindication, warning precaution,

> information about an adverse reaction or information intended to enhance safe use, or changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provides additional assurance of purity, strength or reliability of the device. Conversely, a manufacturer is not permitted to change design specifications or manufacturing processes if such changes could adversely affect safety or effectiveness. 21 C.F.R. § 814.39(d)(1) and (2) and § 360e(d)(5)(A)(i).

63. Allergan failed to comply with these obligations, and but for Allergan's failure, Plaintiff's injuries would not have occurred. In addition, these violations of federal law also violated state law duties, described more fully *infra*, which give rise to state law claims that parallel the federal obligations outlined in the preceding paragraphs, and such state law requirements do not exceed or modify the requirements imposed by federal law. State law precludes the sale of adulterated and misbranded products as well as those that contain outdated inadequate warnings based upon the information currently known or reasonably knowable to the manufacturer. State law also requires manufacturers to adhere to design and manufacturing specifications. But for Allergan's violations of the parallel state law duties, Plaintiff's injuries would not have occurred.

B. <u>Allergan's Premarket Approval for the BIOCELL Line of Implants Included Conditions That Were Never Met.</u>

64. On May 20, 2000, Allergan was granted PMA approval to market the BIOCELL line of products, and in particular the McGhan Medical RTV Saline-Filled Breast Implants, including styles 163, 168, 363, and 468 (hereinafter the "RTV").

65. The FDA set forth in the PMA "Conditions of Approval." As one condition of approval, the FDA required McGhan to conduct multiple post-approval studies to characterize the long-term performance and safety of the devices. These included:

a. "10-year post-approval study to assess the long-term clinical performance of the device;

b. Retrieval study to collect visual examination, physical, and

histological data on explanted implants to determine the mode of failure of implants;

c. Focus-group study to obtain immediate feedback on the patient informed decision brochure for both augmentation and reconstruction patients. This will involve obtaining responses from patients on the patient labeling format and content, generating a report of the findings, and incorporating all appropriate revisions immediately; and

d. Mechanical testing (i.e., fatigue, rupture, and shelf-life)."

66. The PMA and PMA Conditions of Approval requirements included, but were not limited to, monitoring, evaluating, and reporting of adverse events and complications to doctors, patients, and the FDA, assuring that all advertisements and promotional labeling comply with the PMA, and submitting supplemental PMAs to modify and strengthen, and render accurate, the warnings and labeling information to reflect information obtained by or known to Allergan.

67. The PMA and PMA Conditions of Approval required Allergan to submit strengthened and more accurate labeling to the FDA for approval via supplemental PMA, and under some circumstances, including where necessary to protect the safety of patients, to disseminate the modified labels while awaiting FDA approval. In all instances, the FDA would have approved the strengthened labeling that Allergan was required to submit and disseminate. These requirements were consistent with applicable federal regulations. The Conditions of Approval included the following requirements:

a. "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 C.F.R. 814.39(d). . . These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement – Changes Being Effected."

b. A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

c. Continued approval of this PMA is contingent upon the submission of post-approval reports under 21 C.F.R. 814.84 at intervals of 1 year from the date of approval of the original PMA. Post-approval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified in the approval order for the PMA supplement. . . shall include. . . (1) Identification of changes described in 21 C.F.R. 814.39(a) and changes required to be reported to FDA under 21 C.F.R. 814.39(b). (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant: (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and (b) reports in the scientific literature concerning the device.

d. In order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" . . . within 10 days after the applicant receives or has knowledge of information concerning: . . . (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and (a) has not been addressed in the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

e. Pursuant to the Medical Device Reporting ("MDR") Regulation the manufacturer must] report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

68. The PMA provided that "Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act." *See also* 21 C.F.R. § 814.82(a) ("FDA may impose post-approval requirements in a PMA approval order . . . at the time of approval of the PMA"); § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or

advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.").

69. Under the FDA's Changes Being Effected ("CBE") regulation for medical devices, a device manufacturer is permitted to change a label, without prior FDA approval, "to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device," if the change "add[s] or strengthen[s] a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association." 21 C.F.R. § 814.39(d). The Conditions of Approval directed Allergan to disseminate strengthened labeling pending FDA approval, pursuant to the CBE regulations.

70. Pursuant to the PMA Conditions of Approval and the CBE regulations, Allergan was required to strengthen its warnings on its BIOCELL products, as there was "sufficient evidence of a causal association with the drug, biologic, or medical device," including the risk of ALCL, and failed to do so, in violation of the PMA, federal regulations and parallel state law. 21 C.F.R. part 814, § 814.39(d).

71. BIOCELL's regulatory history, particularly with regard to RTV, stated that a manufacturer "has an obligation to monitor post-marketing experiences and maintain its labeling under applicable Federal Regulations," and must strengthen the label where the disclosure of risks is inadequate[19]:

> a. "Indeed, it can maintain its labeling by using all existing tools, including through prior approval supplements, CBE-30 day supplements (Sec. § 314.70(c), § 601.12(c) and § 814.39(e)), and CBE supplements, along with other changes that may be reported in an annual report. Under both the rule of construction and this final rule, a sponsor still must update its labeling under Federal law…

[19] 21 C.F.R. 814.20(e).

b. Sponsors are still required to act promptly to add risk information to labeling . . . This rule describes the standard for one type of change to the labeling. It is intended to clarify the circumstances in which sponsors are required to update labeling, not to undermine or remove a sponsor's obligation to modify labeling to reflect appropriate new information. Under FDA's regulations and this final rule, sponsors are required to warn as soon as appropriate new information comes to light…

c. Under current regulations, sponsors must warn about risks of approved products if the requirements for updating labeling are triggered. This rule does not change those standards… 73 Fed. Reg. 49603."

72. In addition, the FDA's website recites its longstanding position on this point: A PMA supplement must be submitted when unanticipated adverse effects, device failures, or increases in the incidence of anticipated adverse effects necessitate a labeling, manufacturing, or device modification.[20]

73. In addition, under the FDCA, a device is misbranded "[i]f its labeling is false or misleading in any particular," and "[u]nless its labeling bears . . . adequate warnings." 21 U.S.C. § 352(a), (f)(2). The FDCA therefore placed upon device manufacturers the requirement to maintain adequate warnings.

74. On or about November 17, 2006, Allergan was granted PMA approval to market a segment of the BIOCELL line of products, and in particular the Inamed Silicone-Filled Breast Implants (later marketed under the trade name Natrelle Silicone-Filled Breast Implants, including styles 110, 115, and 120). On or about February 25, 2015, Allergan was approved for a "line extension" to include Natrelle Inspira Silicone-Filled Breast Implants (including those with textured shells). Collectively, the Allergan textured silicone-filled breast implants included styles 110, 115, 120 and Inspira (hereinafter referred to as "Natrelle Silicone Implants"). This approval included similar Conditions of Approval, but also included additional requirements:

[20] https://www.fda.gov/medical-devices/premarket-approval-pma/pma-conditions-approval.

a. Core Post-Approval Study, through 10-year follow up;

b. Large Post-Approval Study, a 10-year study to include 39,390 Allergan silicone gel patients and 19,605 saline-filled breast implant patients as the control group;

c. Device Failure Studies, including pre-clinical studies for the 10-year duration of the Large Post-Approval Study, and evaluation of various failure modes;

d. Focus Group Study, with regard to the patient labeling.

e. Distribution of the Informed Decision Process documentation, for use by physicians during the informed consent process.

f. Allergan Adjunct Study, completing follow up through 5-year evaluations.

75. Neither the Summary of Safety and Effectiveness Data ("SSED") nor Directions for Use ("DFU") for either of these PMAs contained any reference to BIA-ALCL or any information about a potential risk of lymphoma. The above federal requirements mandated the submission of strengthened labeling for approval, and dissemination of the strengthened labeling to physicians to patients. 21 C.F.R. part 814, § 814.39(d). State law also required timely submission of appropriately strengthened labeling be directed to physicians and patients to warn of the risk of ALCL.

76. On February 20, 2013, Allergan was granted the third and final PMA approval. It was for the purpose of marketing a segment of the BIOCELL line of breast implants known as the Natrelle 410 Highly cohesive Anatomically Shaped Silicone-Filled Breast Implants ("Natrelle 410"). The post-approval studies required for the Natrelle 410 implants included:

a. PMA Core Study, including submission of a 10-year follow-up final study report for the Premarket Core Study within 90 days of PMA.

b. Natrelle 410 Full and Moderate height/projection Breast Implant Continued Access Study, including 5 years post-implant follow-up of approximately 3,500 subjects who were enrolled before the date of approval in designated clinical studies and all safety and effectiveness endpoints evaluated premarket will continue to be studied through 5 years

of follow-up. This also required Device Explant Analyses.

c. Natrelle 410 Breast Implant vs. Post-Approval Study, to evaluate the long-term clinical performance of the Natrelle 410, involving 2,587 subjects, to be followed annually for 10 years, with multiple safety endpoints. This also required Device Explant Analyses.

d. Focus Group Studies – to improve the format and content of the patient labeling.

e. Non-PAS Device Explant Analyses.

77. Allergan was required to submit Annual Reports, providing the information required by 21 C.F.R. § 814.84. In addition, the PMA required the Annual Report to include, separately for each model number, the number of devices sold and distributed during the reporting period, including those distributed to distributors, to serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

78. The PMA provided that "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

73. Allergan failed to fulfill the requirements of the PMA, and the applicable federal regulations, which were parallel to applicable state laws, and such parallel state laws did not impose any new or different responsibilities or duties on manufacturers. Allergan's violations of federal law and parallel state law included the failure to disclose and warn of the risk of BIA-ALCL in a timely fashion. Allergan continually acquired new information regarding the association and causal connection between its BIOCELL products and the development of BIA-ALCL and knew or should have known that its products involved much greater frequency of ALCL than other textured breast implants made by other manufacturers. This information was

not adequately or accurately included in the warnings in the product labeling; nor was it adequately or accurately disclosed to the FDA.

74. The 2013 Directions for Use for the Natrelle 410 breast implants contained the first warning by Allergan for its US BIOCELL products and a possible link to BIA-ALCL, but the language was inadequate and misleading.

The 2013 DFU stated:

Anaplastic Large Cell Lymphoma

> Based on information 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-Hodgkin's 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 patients with an implant history that includes Allergan's and other manufacturers' breast implants.

75. The 2013 warning was inadequate and insufficient. It failed to adequately describe the nature, severity, frequency or causal connection of BIA-ALCL to the BIOCELL line of implants. It further failed to make clear that there was a much higher incidence in the frequency of BIA-ALCL in the BIOCELL implants than in other implants. If Allergan had complied with its state law duties, which are parallel to the applicable federal requirements, including those set forth in this Complaint, earlier and stronger warnings which adequately disclosed what Allergan knew or should have known would have been provided for the BIOCELL line. Subsequent and additional warnings and labeling promulgated for the BIOCELL line of products was similarly inadequate and failed to adequately warn of the risks, pursuant to state law and the parallel federal requirements

76. Allergan not only failed to promulgate more adequate and accurate warnings than it included in the 2013 and subsequent and additional warning, in violation of state law and

parallel federal requirements, it also continuously undermined the warning (and subsequent warnings) and misrepresented the risk of BIA-ALCL in its non-PMA communications. Physicians who were already familiar with the product line, including many who had used it for an extensive period of time, were unaware of and misled about the nature and context of the 2013 warning. Allergan continued to reassure physicians who became aware of the warning that the product line was safe. Allergan told physicians who had expressed concerns about possible risks that their concerns were unsupported. Allergan placed these concerns in a negative light and challenged them, through its agents, physician consultants and other representatives. The net effect of these tactics and misleading non-PMA communications was to obstruct knowledge of, and/or weaken the impact of the warning(s) and cause physicians to continue to recommend and utilize the BIOCELL implants. Consequently, physicians were either unaware of the risk, or unaware of the extent of the risk and the significantly increased risk for the BIOCELL textured products as contrasted to others, and they therefore failed to disclose the risk of ALCL when recommending BIOCELL implants to patients during informed consent discussions.

77. Plaintiff has not received, and Allergan has refused to provide, discovery related to this wrongful conduct, which includes but is not limited to, FDA correspondence, PMAs and PMA Supplements for the BIOCELL line, adverse event reporting, post marketing surveillance materials, manufacturing and quality control records, internal communications and presentations, manufacturing and related quality control documents, reports of BIA-ALCL received from third parties, reports made to regulatory agencies beyond the FDA, internal research regarding incidence or risk of BIA-ALCL, and inspection reports by any entity or agency, pertaining to the recalled products. Plaintiff anticipates, upon information and belief, that these documents, and other information obtained in discovery, will demonstrate more completely how Allergan failed

to comply with the PMA, and violated its obligations under federal law and parallel state law requirements. This additional information will be helpful and necessary to more fully describe Allergan's conduct and the issues and claims addressed in this Complaint.

C. The FDA Warned Allergan That it Failed to Comply with 21 C.F.R. § 814.82(a) Post Approval Study Requirements.

78. The FDA issued a Warning Letter to Allergan on May 14, 2020 and noted that it has failed to comply with the Post Approval Study (PAS) requirements established under 21 C.F.R. § 814.82(a).[21]

79. Under the provisions of 21 C.F.R. § 814.82(a)(2) and (9), the FDA may impose post approval study requirements as a condition of device approval when necessary to provide reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended or suggested in the labeling of the device. Specifically, the FDA may require as a condition to approval that the applicant continue to evaluate the safety, effectiveness and reliability of the device, including the number of patients to be evaluated.

80. In its May 14, 2020 Warning Letter to Allergan, the FDA concluded that Allergan had violated federal duties in the above sections in conjunction with the November 17, 2006 PMA P020056 for NATRELLE Round Responsive Silicone-Filled Implants and the February 20, 2013 PMA P040046 for NATRELLE 410 Highly Cohesive Anatomically Shaped Silicone-Filled implants.[22] These PMAs and the failures identified in the FDA Warning Letter include devices at issue in this litigation. The FDA noted:

> "Your firm failed to collect local complication data, including safety endpoint data, during the year 4 physician evaluation at a follow-up rate necessary to meet

[21] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/allergan-607690-05142020.

[22] PMA P020056 is for Inamed Silicone-Filled Breast Implants that are both Smooth & BIOCELL textured implants. PMA P040046 is for Natrelle 410 Silicone-Filled Breast Implants that have the BIOCELL texturing.

> the target follow-up rate of **(b)(4)** at year 10. This failure prevents adequate evaluation of the safety, effectiveness, and reliability of the device at this late stage in the study period (year 9) and will prevent such an evaluation at the end of the study (year 10). You are thereby in violation of the requirements established as a condition to your device's approval under 21 C.F.R. § 814.82(a)(2) and (9). Failure to promptly correct this failure may result in withdrawal of your PMA under 21 C.F.R. § 814.82(c)."

81. The FDA found that Allergan failed to comply with certain requirements of the "Large Post-approval Study" set forth in the November 17, 2006 PMA P20056, including the following:

a. Allergan was required to conduct a 10-year large post-approval study to evaluate certain safety endpoints pursuant to the protocol dated October 16, 2006. Under the redesigned study, Allergan was required to conduct a 10-year study to compare Round Responsive implants with Saline implants or national norms with regard to long-term safety….

b. Allergan was required to collect data on the following safety endpoints: long-term local complications, connective tissue diseases (CTDs), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and rupture results.

c. Allergan was required to collect local complication data from physician evaluations at 1, 4 and 10 years.

82. The FDA further noted that there had been several deficiencies issued to Allergan with regard to the Large Post-approval Study and redesigned study, such as poor follow-up rates, such that Allergan's deficiencies and failures prevent adequate evaluation of the safety, effectiveness and reliability of the implants. Allergan was directed to correct the failures or face withdrawal of its PMA.

83. Further, in conjunction with PMA P040046 and Style 410 Implants, Allergan was found to have failed to comply with the requirements that it evaluate the long-term clinical performance of Natrelle 410 implants under general conditions of use in the postmarket environment and also failed to enroll sufficient numbers of women receiving Natrelle 410 breast

implants and Natrelle saline implants as the comparison group. Under the redesigned study, Allergan was to enroll 530 subjects with Style 410 implants and 245 subjects with saline implants.

84. The FDA expressed concern that the failures to comply with the requirements of PMA P040046 set out above could impact Allergan's ability to comply with other requirements such as collecting data on safety endpoints, collecting data on effectiveness and collecting data from physician evaluations.

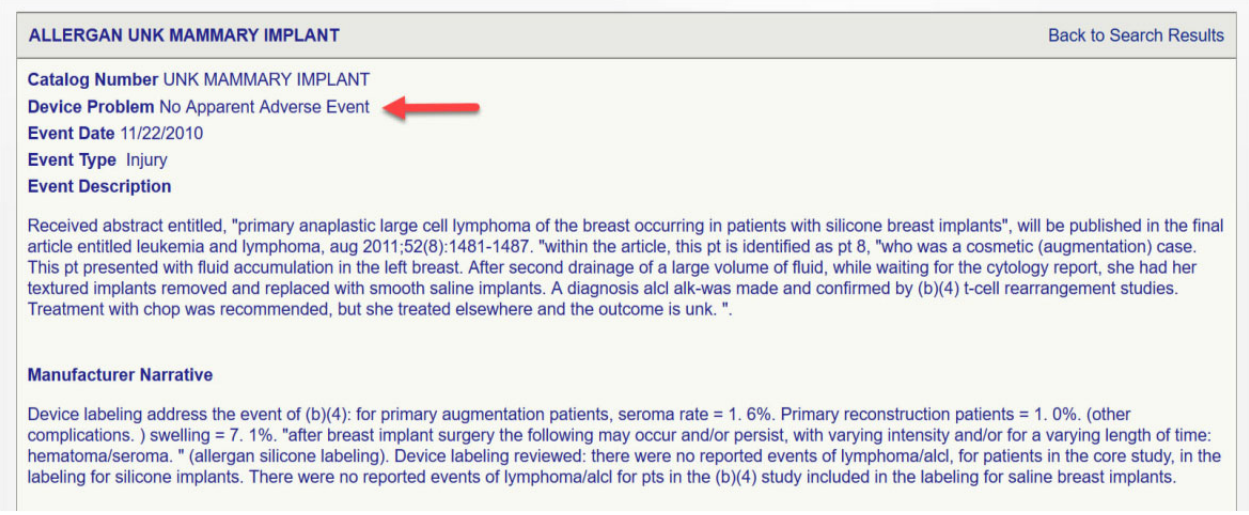
85. As with the warnings regarding the Round Responsive Implants, Allergan was directed to correct the failures found by the FDA or face withdrawal of its PMA.

86. These failures to do ongoing and long term study and analysis, to present data and reports to the FDA and to timely and adequately assess product effectiveness and safety are a violation of the PMAs, federal requirements and parallel state law requirements. Important safety information was never collected and the foundation of the PMA was undercut by Allergan's failures.

IV. ALLERGAN HEAVILY PROMOTED BIOCELL AND CONCEALED ITS RISKS

87. Allergan employed aggressive promotion and marketing of the BIOCELL line of products, and at the same time concealed and disguised the risks, including submission of adverse event reports with incorrect manufacturer names, including "Santa Barbara" and "Costa Rica," instead of using the name Allergan. As a result, consumers, healthcare professionals, and the FDA were unable to detect signals and trends in Allergan's products, depriving the FDA, physicians and consumers of the necessary information to make an informed decision about whether Allergan's products were safe and effective.

88. Allergan also inaccurately and repeatedly, on numerous occasions, reported ALCL with a "no apparent adverse event" description of the device event, thus undermining the significance of this valuable surveillance tool.[23] In one MDR, a case of BIA-ALCL was categorized as" no apparent adverse event" when the patient was known by Allergan to have required chemotherapy. The notice came to Allergan on the heels of other reports of BIA-ALCL. Likewise, Allergan's narratives of the events were misleading. For example, Allergan included a reference to seroma in the narrative section of the MDR and quoted the product label reference to seroma. The labeling contemplates seroma as a fairly common early post-operative finding, and Allergan's reference in the report obscures the clinical significance of the more ominous concern about late-appearing and chronic seromas, which are abnormal and unexpected. Chronic seroma can be an indication of chronic inflammation and cancer, and it is seen in most cases of BIA-ALCL.



ALLERGAN UNK MAMMARY IMPLANT Back to Search Results

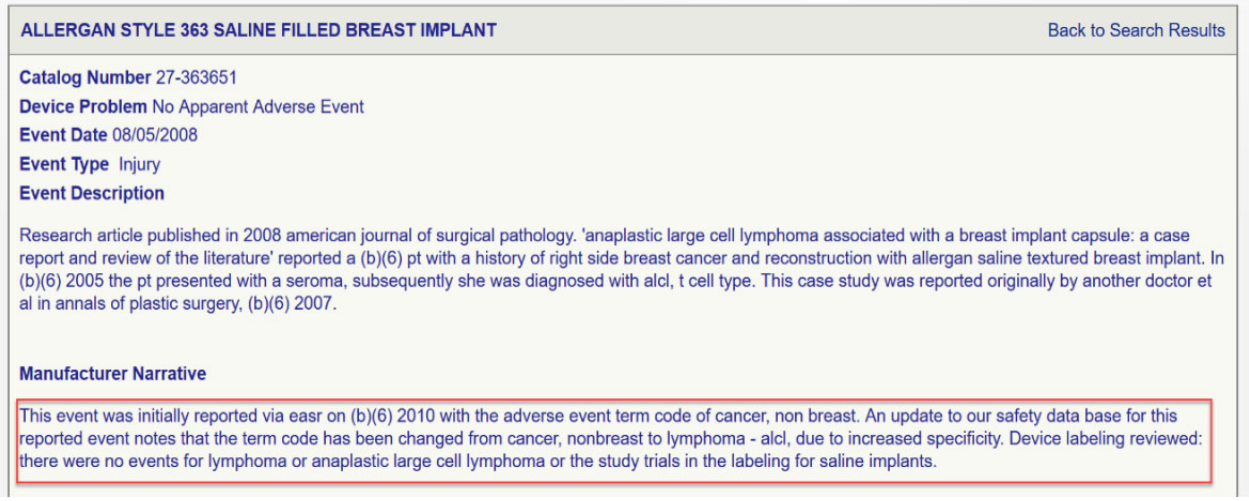
Catalog Number UNK MAMMARY IMPLANT
Device Problem No Apparent Adverse Event
Event Date 11/22/2010
Event Type Injury
Event Description

Received abstract entitled, "primary anaplastic large cell lymphoma of the breast occurring in patients with silicone breast implants", will be published in the final article entitled leukemia and lymphoma, aug 2011;52(8):1481-1487. "within the article, this pt is identified as pt 8, "who was a cosmetic (augmentation) case. This pt presented with fluid accumulation in the left breast. After second drainage of a large volume of fluid, while waiting for the cytology report, she had her textured implants removed and replaced with smooth saline implants. A diagnosis alcl alk-was made and confirmed by (b)(4) t-cell rearrangement studies. Treatment with chop was recommended, but she treated elsewhere and the outcome is unk. ".

Manufacturer Narrative

Device labeling address the event of (b)(4): for primary augmentation patients, seroma rate = 1. 6%. Primary reconstruction patients = 1. 0%. (other complications.) swelling = 7. 1%. "after breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: hematoma/seroma. " (allergan silicone labeling). Device labeling reviewed: there were no reported events of lymphoma/alcl, for patients in the core study, in the labeling for silicone implants. There were no reported events of lymphoma/alcl for pts in the (b)(4) study included in the labeling for saline breast implants.

[23] *See*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=2210596; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=2210596.



ALLERGAN STYLE 363 SALINE FILLED BREAST IMPLANT Back to Search Results

Catalog Number 27-363651
Device Problem No Apparent Adverse Event
Event Date 08/05/2008
Event Type Injury
Event Description

Research article published in 2008 american journal of surgical pathology. 'anaplastic large cell lymphoma associated with a breast implant capsule: a case report and review of the literature' reported a (b)(6) pt with a history of right side breast cancer and reconstruction with allergan saline textured breast implant. In (b)(6) 2005 the pt presented with a seroma, subsequently she was diagnosed with alcl, t cell type. This case study was reported originally by another doctor et al in annals of plastic surgery, (b)(6) 2007.

Manufacturer Narrative

This event was initially reported via easr on (b)(6) 2010 with the adverse event term code of cancer, non breast. An update to our safety data base for this reported event notes that the term code has been changed from cancer, nonbreast to lymphoma - alcl, due to increased specificity. Device labeling reviewed: there were no events for lymphoma or anaplastic large cell lymphoma or the study trials in the labeling for saline implants.

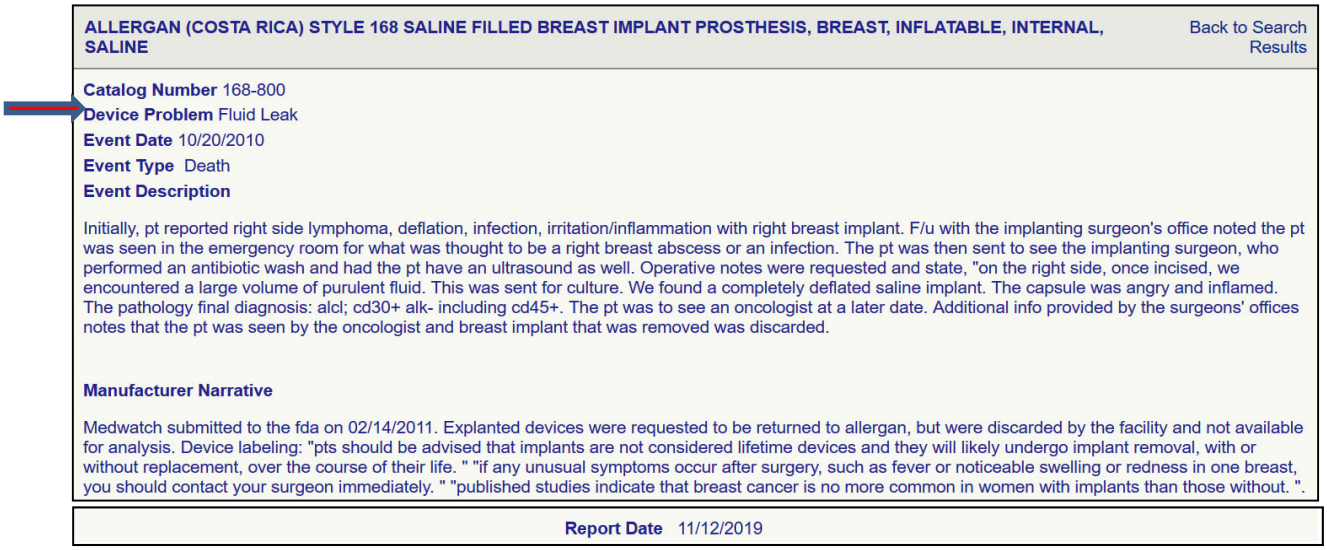
The above examples reflect some of Allergan's persistent efforts to obscure reported cases of possible BIA-ALCL:[24] [25]

89. In addition to characterizing adverse events, including cases of ALCL, as "No Apparent Adverse Event," Allergan utilized other diversionary tactics as well when reporting about a patient with ALCL. For example, in a November 12, 2019 report, Allergan referenced an event that occurred on October 20, 2010 in which the problem was described as "Fluid Leak." The patient had lymphoma, irritation, inflammation and deflation of her right breast implant, with a finding of a large volume of purulent fluid found. The capsule was described as "angry" and "inflamed." The manufacturer's narrative recites the labeling and the instructions to contact your surgeon if unusual symptoms occur after surgery and further notes that published studies

[24] *See*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 (last visited May 5, 2020) (""Based on information reported to the 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-hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing ALCL in the fluid scar capsule adjacent to the implant. ALCL has been reported globally with an implant history that includes Allergan's and other manufacturer's breast implants. You should consider the possibility of ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL.") This message was advanced by Allergan when there was a clear and substantial distinction between the risk of ALCL with BIOCELL than with other manufacturer's textured implants.

[25] *See*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=2842518.

indicate that breast cancer is no more common in women with implants than in those without. Allergan knew or should have known that lymphoma is not a breast cancer and its statements were inappropriate and unresponsive to the patient's problem. A full and complete investigation, with appropriate reporting as mandated by state law and parallel federal requirements, including 21 C.F.R. § 803.52.



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

A case of ALCL reported by Allergan as a Fluid Leak

90. Allergan also did not timely report cases of ALCL in violation of state law and parallel federal law. In a number of cases, Allergan did not report cases of ALCL that were diagnosed many years before an MDR was submitted. Delays in monitoring, identifying, reporting and properly advising and warning healthcare professionals, patients and the FDA about ALCL and its appearance in patients with BIOCELL products allowed Allergan to keep the products on the market for many years and more patients to suffer ALCL and increased risk of ALCL.

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

Event Date: 01/01/2007, 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

Event Date: 10/08/1990, Report Date: 12/11/2019

As a result of Allergan's improper characterization of device problem, its delayed and inadequate report, neither physicians nor patients were properly informed about the risks and risk profile of BIOCELL.

91. Also troubling, Allergan had a practice of improperly submitting BIA-ALCL cases or suspected cases to the FDA in the form of "Alternative Summary Reports" ("ASRs") pursuant to 21 C.F.R. § 803.19.

92. The FDA notified Allergan, beginning on July 31, 1997, that it was granted a medical device manufacturer summary reporting approval for adverse events.[26] The approval allowed Allergan to submit a periodic and abbreviated summary report to the FDA for the reporting of events "well known" to the agency and which had been reported for years to the FDA. The ASRs are submitted at set intervals to report matters that are viewed as normal and that do not require dedicated and individual attention by the agency. It is primarily a series of codes and numbers, not detailed medical and patient information.

93. The FDA was clear, however, that events contemplated by 21 C.F.R. § 803.50 and § 803.52 were not covered by the exemption and had to be reported as specified in those sections. The items that were not covered by the exemption included events requiring a 5-day report, events involving a Class III device marketed under a PMA of less than 2 years, and events the manufacturer considers unusual, unique or uncommon. FDA Principal Deputy Commissioner Amy Abernethy affirmed this opinion on May 2, 2019, and she made clear that ALCL and unique and uncommon events were not covered by the exemption.[27]

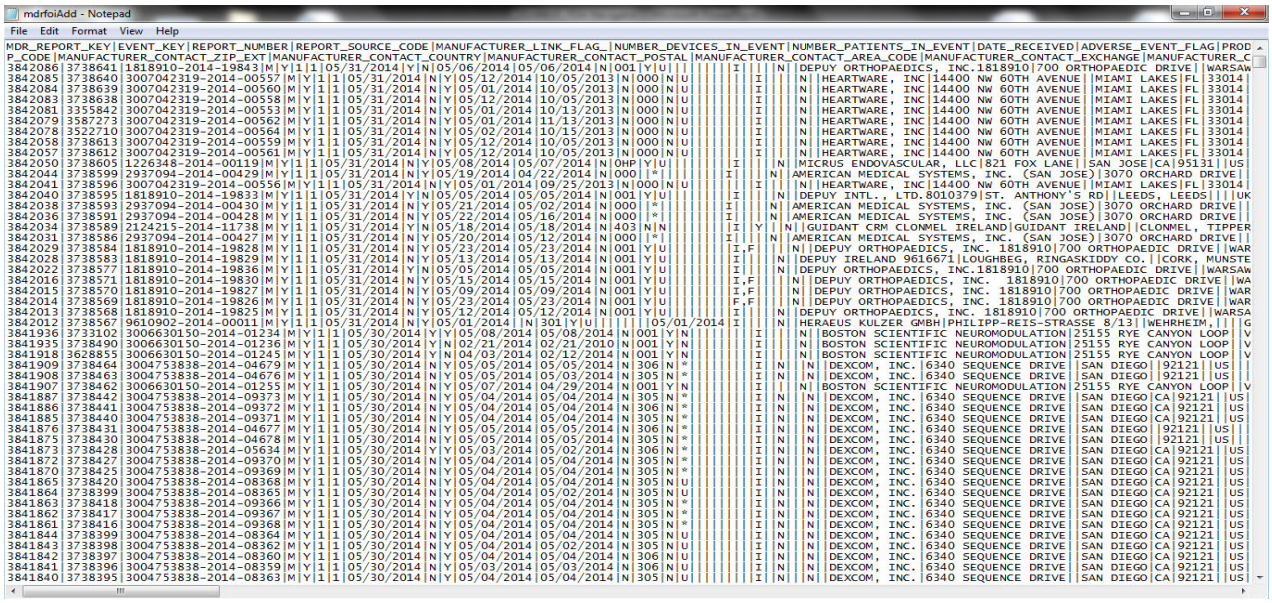
94. The distinctions between MDRs and ASRs are substantial and impactful. ASRs do not contain narratives describing the event, important patient information or details about the device. Such information may be unnecessary when common and expected device problems arise, and ASRs provide an efficient manner to report and collect routine data. With respect to a serious injury or unusual and uncommon product issue, however, using this method of reporting

[26] https://web.archive.org/web/20000914063243/http://www.fda.gov/cdrh/offerlet.html; https://web.archive.org/web/20001206165300/http://www.fda.gov/cdrh/osb/guidance/315.html.

[27] "This 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." https://www.fda.gov/news-events/press-announcements/statement-fda-principal-deputy-commissioner-amy-abernethy-md-phd-and-jeff-shuren-md-jd-director-fdas.

clearly precludes a timely flow of current and vital information. Moreover, ASRs were not publicly available through the MAUDE website during the time Allergan's BIOCELL products were on the market. Likewise, they were also not obtainable through a Freedom of Information Act request.

95. In 1999, Allergan (through the exemption obtained by its predecessor McGhan), began using ASRs for reporting complications and adverse events associated with its BIOCELL products. Allergan did not restrict the use of ASRs to the reporting of "*well-known, well-understood*" breast implant adverse events which had been seen by the agency for years. Shockingly, upon information and belief, Allergan reported dozens of cases of ALCL through the ASR system. ASRs were not intended or approved as a mechanism to report or track patient deaths, cancer, severe tissue damage and seromas, or other unusual adverse events such as BIA-ALCL. Use of ASRs to obscure notice of BIA-ALCL and related harms was improper, and each such submission constituted a non-PMA, improper, voluntary statement. 21 C.F.R. § 803.50; § 803.52; § 803.53; § 803.56. The ASR program was in place until June 2019 when the exemptions were revoked and all ASR reports were made public. Due to Allergan's improper reporting practices over a period of years and on numerous occasions, physicians, patients, and regulatory bodies and others relying on public reports to identify serious health risks associated with BIOCELL products were deprived of important information regarding the safety of the BIOCELL line.



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MDR_REPORT_KEY|EVENT_KEY|REPORT_NUMBER|REPORT_SOURCE_CODE|MANUFACTURER_LINK_FLAG_|NUMBER_DEVICES_IN_EVENT|NUMBER_PATIENTS_IN_EVENT|DATE_RECEIVED|ADVERSE_EVENT_FLAG|PROD_P_CODE|MANUFACTURER_CONTACT_ZIP_EXT|MANUFACTURER_CONTACT_COUNTRY|MANUFACTURER_CONTACT_POSTAL|MANUFACTURER_CONTACT_AREA_CODE|MANUFACTURER_CONTACT_EXCHANGE|MANUFACTURER_C

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Example of an ASR Report

ALLERGAN (COSTA RICA) STYLE 168 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE

Back to Search Results

Catalog Number 168-330

Device Problems Fluid Leak; Migration or Expulsion of Device

Event Date 06/01/2017

Event Type Injury

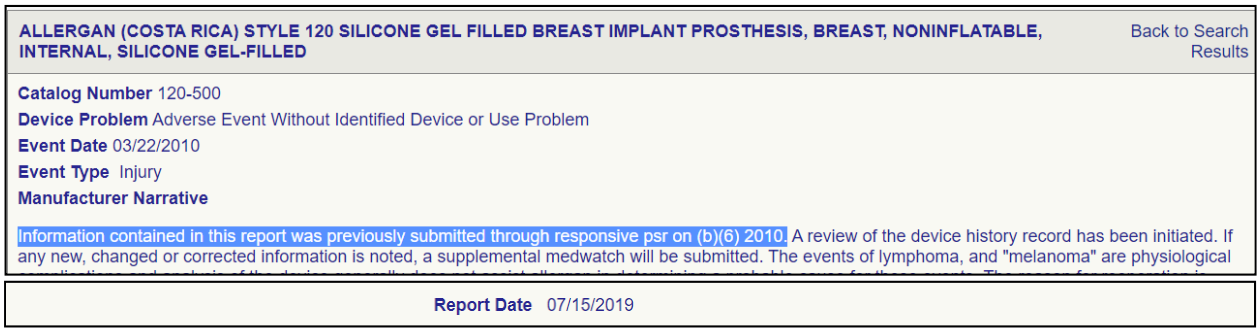
Manufacturer Narrative

Information contained in this report was previously submitted through asr on 22/jul/2018. The events of skin rash and lymphoma are physiological complications and analysis of the device generally does not assist allergan in determining a probable cause for these events. Further information from the reporter regarding event, product, or patient details has been requested. No additional information is available at this time. A review of the device history record has been completed. No deviations or non-conformances noted. Device labeling addresses: potential adverse events that may occur with saline gel-filled breast implant surgery include: implant deflation, 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. Based on information 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-hodgkin¿s 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 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. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for alcl, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out alcl. If your patient is diagnosed with peri-implant alcl, develop an individualized treatment plan in coordination with a multi-disciplinary care team. Because of the small number of cases worldwide, there is no defined consensus treatment regimen for peri-implant alcl. Deflation-breast implants are not lifetime devices. Saline breast implants deflate when the shell develops a tear or hole. Deflation can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause implants to deflate: damage by surgical instruments; folding or wrinkling of the implant shell; excessive force to the chest (e. G. , during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the causes of deflation for allergan¿s product; however, it is not conclusively known whether these tests have identified all causes of deflation.

Event Description

Patient reported implant "broke". Physician confirmed right side deflation. Patient additionally reported right side anaplastic large cell lymphoma (alcl), "rashes" and "silicone in lymph nodes. " physician has not confirmed additional events. As pathological markers confirming alcl have not been received, the event will be captured as lymphoma. The device remains implanted.

Many MDRs indicate ALCL reports were previously submitted by Allergan via ASR

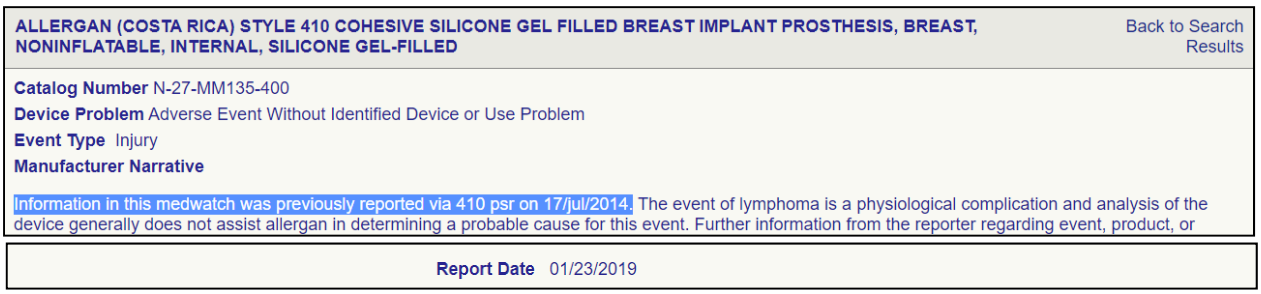


ALLERGAN (COSTA RICA) STYLE 120 SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED Back to Search Results

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



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

MDRs indicate Allergan's knowledge of ALCL years before the recall and also demonstrate its misuse of ASRs to report ALCL

96. Despite its knowledge of ALCL, Allergan disseminated a large number of voluntary statements which were not the subject of a PMA, through promotional and marketing brochures and websites, communications through sales representatives and paid consultants, which suggested the products were superior, safe and well-studied and failed to include any reference to ALCL risk. These voluntary and non-PMA statements, as well as the ones described below, are misleading. These misleading statements render the BIOCELL implants misbranded, in violation of state law and parallel federal law, including 21 U.S.C. § 321(m); 21 U.S.C. § 352(a); 21 U.S.C. § 352(q); 21 U.S.C. § 321(n).

97. For example, referring to its Natrelle Breast Implants in a YouTube video posted on the internet, Allergan noted that the "Pre-Consultation Kit" is available to help a patient prepare for a consultation with her physician. In this direct to patient appeal, Allergan noted that their implants are "FDA approved, tested, durable" and "Breast augmentation is the most

common and uncomplicated plastic surgery procedure…Decades of experience with the science of breast augmentation have greatly improved safety…enhanced technology for safer and more beautiful options than ever before."[28] The publicly available video describes textured and smooth implants without making any distinction in the significantly increased risks associated with the textured version of Allergan implants. Instead, the two types of implants were marketed as having the same potential complications, without any reference to BIA-ALCL.

98. In their Natrelle Gel-filled implant brochure Allergan represented, "Natrelle Gel-filled breast implants have been shown to be biocompatible and reliable, making it an appropriate choice." This brochure further warranted the BIOCELL products were "premium" and "proven" quality.

99. McGhan's Product Catalogue in September of 2004 stated, "The McGhan brand name has been built by providing an innovative, premium quality surgical solution with an unrivalled selection of products to meet our customer needs … INAMED Aesthetics are delighted to be at the forefront of technology and we will continue to invest to support your efforts." Further, "The BIOCELL textured surface is an integral part of the silicone elastomer shell that allows mild tissue adherence which has been associated with a reduced risk of capsular contracture."[29] With respect to the textured tissue expanders, McGhan's Product Catalogue describes them as the "Proven BIOCELL Textured Surface."

100. Allergan gave direct assurances and promises with regard to its ongoing studies and its commitment to update labeling in a timely manner:

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[28] *See*, https://www.youtube.com/watch?v=vu-0W8vSNrU.

[29] One of Allergan's textured implants, model 153, had a significant capsular contracture rate and was removed from the 2006 PMA. Neaman KC, Albert M, Hammond DC. Rupture rate and patterns of shell failure with the McGhan Style 153 double-lumen breast implant. *Plast Reconstr Surg*. 2011;127(1):47-53. doi:10.1097/PRS.0b013e3181fad248

> *"*Allergan will continue its ongoing Core Study through 10 years to further evaluate the long-term safety and effectiveness of these products. In addition, Allergan has initiated a separate 10-year postapproval study to address specific issues for which the Allergan Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Allergan will update their labeling on a regular basis with the results of these two studies. ….."[30]

101. McGhan Style 410's 2002 Brochure stated, "Superior quality, higher satisfaction and even wider choice:"

> *"*Naturally you want the best, the safest, the most predictable results. With the McGhan Style 410 range of products you can achieve these aims. For three decades we have been at the forefront of breast augmentation and reconstruction technology and our McGhan Style 410 range is widely acknowledged to be the very best breast implant available. Building on this success, and following years of research and development with the world's leading surgeons, we have created a new type of implant: The McGhan Style 410 Soft Touch." The McGhan Style 410 Soft Touch uses a softer gel while still maintaining all the characteristics that have made the McGhan Style 410 famous in our industry."

102. In addition to engaging in an aggressive marketing scheme directed to consumers and physicians boasting of the superiority, safety, quality and state of the art design and manufacturing of its implants, Allergan turned a blind eye to the risks associated with its textured BIOCELL products. Even after the first BIA-ALCL warning was required pursuant to the 2013 Allergan PMA, Allergan made a concerted effort through its agents, employees and medical consultants to pepper the literature with anti-warning messages and to mock the serious and significant ALCL risk to which patients were exposed. Such statements were voluntary, non-PMA statements and violated the PMAs and parallel state laws. For example, a paid Allergan consultant who was associated with BIOCELL studies and research stated in a book chapter that

[30] *See* discussion above regarding the May 14. 2020 FDA Warning Letter to Allergan in which its failures to comply with the study requirements.

a patient is 2 times more likely to be struck by an asteroid than to develop ALCL. Similarly, an Allergan spokesperson reported that a patient is more likely to be struck by lightning than to develop ALCL. Allergan's statements were dangerously deceptive and a misleading characterization of risk, entirely unsupported, and designed to mislead physicians and patients to minimize risk perception. *See* 21 U.S.C. § 321(m); 21 U.S.C. § 352(a); 21 U.S.C. § 352(q); 21 U.S.C. § 321(n).

103. In addition, Allergan attempted to deflect attention from the risks associated with the BIOCELL line, and its violations of federal and parallel state obligations by blaming physicians and a purported infectious process for BIA-ALCL, despite knowing this effort was based on dubious and misleading information. As part of that effort, a "14-point plan" was developed, primarily by Allergan-funded physician consultants. These voluntary, non-PMA statements included Allergan's representations to the medical community that "BIA-ALCL Mitigation Can Be Effective." Allergan boasted that aseptic technique resulted in no cases of BIA-ALCL: "Enhanced 14-point aseptic technique: Changing gloves, Antiseptic solutions, Minimal touch; Zero BIA-ALCL cases: 42,000 BIOCELL implants, 11.7 years mean follow-up; Continue to communicate the importance of enhanced aseptic surgical technique."[31] This campaign to mislead was knowingly false and in violation of state law and parallel federal requirements. *See*, *e.g.*, 21 U.S.C. § 321(m); 21 U.S.C. § 352(a); 21 U.S.C. § 352(q); 21 U.S.C. § 321(n).

[31] Power Point Presentation by Stephanie Manson Brown, MD, Vice President, Clinical Development, Allergan, March 25, 2019, presented to the FDA Medical Devices Advisory Committee , General and Plastic Surgery Devices Panel.

104. These statements, which are examples of many that contributed to shaping the opinions and understanding of the medical community, including Plaintiff's treating physicians, were non-PMA statements, and were deliberately false and misleading.

105. Upon information and belief, Allergan provided inadequate, false and misleading warnings, risk and risk profile information in both PMA and non PMA communications, in written and oral communications, to physicians and patients, through company sponsored meetings and product training sessions, and marketing, promotional and sales activities.

106. Allergan's conduct violated state law requiring that a manufacturer provide truthful, accurate, adequate warnings and risk information, and the parallel federal requirements to do the same. *See*, *e.g.*, 21 C.F.R. part 814, § 814.39; 21 C.F.R. § 801.6.

107. Had Allergan complied with applicable state laws and federal requirements, it would have disseminated strengthened, more adequate and accurate warnings, and would not have issued misleading statements that minimized or obscured the risk of BIA-ALCL, and as a result Plaintiff and her physician would have been more fully informed of the risk of ALCL and Plaintiff would not have had Allergan BIOCELL implants placed inside her body.

V. MANUFACTURING DEFECTS IN THE BIOCELL TEXTURED SHELLS AND EXPANDERS; PARALLEL FEDERAL REQUIREMENTS:

108. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing practice (CGMP), as prescribed in the regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. *See* 21 U.S.C. § 360j(f).

109. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. part 820. As explained in these regulations, manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations. These include, but are not limited to:

a. "Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351);

b. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 C.F.R. § 820.3(v);

c. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system;

d. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met;

e. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements;

f. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.;

g. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements;

h. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that

devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions;

i. Pursuant to 21 C.F.R. § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications;

j. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation;

k. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such controls shall include:

    a. Documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production;

    b. Monitoring and control of process parameters and component and device characteristics during production;

    c. Compliance with specified reference standards or codes;

    d. The approval of processes and process equipment; and

    e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

l. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure;

m. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly;

n. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality;

o. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use;

p. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality;

q. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate compute software for its intended use according to an established protocol;

r. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained;

s. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 C.F.R. § 820.3(z)(1);

t. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals;

u. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements;

v. Pursuant to 21 C.F.R. § 820.100(a), each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

> (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential

causes of nonconforming product, or other quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review."

110. Upon information and belief, and consistent with the allegations set forth, Allergan's BIOCELL line was adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with the above federal requirements *See* 21 U.S.C. § 351.

111. Upon information and belief, Allergan failed to establish and maintain CGMPs with respect to quality audits, quality testing and process validation for its BIOCELL line.

112. As a result of Allergan's failure to establish and maintain CGMPs, its BIOCELL line was defective and failed, resulting in BIA-ALCL and increased risk of BIA-ALCL and the associated symptoms in Plaintiff.

113. If Allergan had complied with the federal requirements regarding CGMPs,

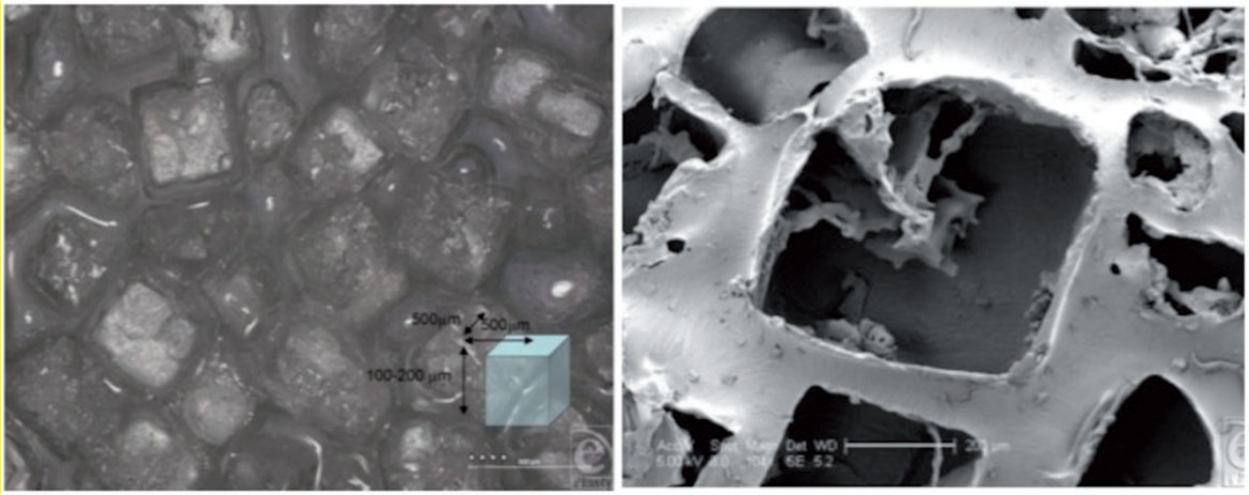
Allergan's BIOCELL line would have been designed/manufactured properly such that it would not have failed and/or been implanted into Plaintiff and would not have resulted in injuries to Plaintiff.

114. Upon information and belief, Allergan's BIOCELL line was adulterated because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture are not in conformity with the above federal requirements, it failed to meet represented specifications and/or failed to perform as represented. *See* 21 U.S.C. § 351. Further, by at least July 24, 2019, Allergan, recognizing that the BIOCELL line was dangerous to health when used in the manner prescribed, recommended, suggested or otherwise failed to meet performance standards, removed all BIOCELL products from the market. The FDA has identified that the use of BIOCELL products may cause serious injuries and death and issued a Class I recall of the BIOCELL product line, as described above.

115. Upon information and belief, Allergan's BIOCELL line was misbranded because, among other things, it was dangerous to health when used in the manner prescribed, recommended or suggested in its labeling. *See* 21 U.S.C. § 352(j). Allergan, recognizing that the device was dangerous to health when used in the manner prescribed, belatedly removed all BIOCELL products from the market. The FDA has identified that the use of BIOCELL products may cause serious injuries and death and issued a Class I recall of the BIOCELL product line, as described above.

116. Allergan used a texturing process in the manufacture of its textured implants that was contrary to and inconsistent with the PMAs, the approved design and manufacturing specifications and processes for the BIOCELL product line, including the applicable CGMPs, QSRs, other pertinent federal regulations, as well as parallel state law.

117. To texturize the surface of BIOCELL implants and Natrelle 133 Expanders, Allergan utilized a manufacturing process known as the "salt loss" technique.[32] The salt loss technique involved placing a tack coat of silicone over the implant; immersing the implant in solid particles of cubic salt (sodium chloride), such that the particles were embedded into the surface of the implant; over-coating the implant with a final layer of silicone; curing the implant in an oven; soaking the implant in warm water; and then manually scrubbing the implant with brushes in an effort to remove all solid particles and reveal the textured surface. The manual scrubbing process required gentle agitation of the surface silicone to ensure a controlled surface and to eliminate the creation of particles or damage to the implant surface. [33] [34]



Left: Allergan Biocell (Santa Barbara, Calif) light microscopy 'deep focus' composite image at 50x magnification showing the granular surface secondary to the 'salt-loss' manufacturing process. Right: The same surface in scanning electron microscopy at 104_magnification with a 200-lm scale bar and 25-lm representations of an average fibroblast (used by

[32] *See* https://patents.google.com/patent/US8313527B2/en. Allergan has multiple overlapping patents which address texturing and associated processes. Upon information and belief, none of those processes include using manual scrubbing with different techniques, supplies and equipment as utilized in the manufacture of the BIOCELL implants and expanders.

[33] *See* Michael Atlan, Gina Nuti, Hongpeng Wang, Sherri Decker, Tracyann Perry. *Breast Iimplant Surface Texture Impacts Host Tissue Response* J. Mech. Behav of Biomed Mat, Elsevier,2018, 88, pp.377 - 385. <10.1016/j.jmbbm.2018.08.035>. <hal-01919706>.

[34] *See* Munhoz et al., *Nanotechnology, Nanosurfaces and Silicone Gel Breast Implants: Current Aspects,* Case Rep. in Plast Surg and Hand Surg, 2017 at 107. Available at: https://www.tandfonline.com/doi/full/10.1080/23320885.2017.1407658#aHR0cHM6Ly93d3cudGFuZGZvbmxpbmUuY29tL2RvaS9wZGYvMTAuMTA4MC8yMzMyMDg4NS4yMDE3LjE0MDc2NTg/bmVlZEFjY2Vzcz10cnVlQEBAMA==.

permission of Dr. Ardeshir Bayat PhD, MBBS, MRCS; Plastic & Reconstructive Surgery Research, Manchester Interdisciplinary Biocentre, The University of Manchester, Manchester, United Kingdom).

118. Despite specifications and directed processes that required gentle agitation of the surface after a final layer of silicone was over-coated, upon information and belief, the scrubbing technique used by Allergan to manufacture the BIOCELL implants and Natrelle 133 Expanders was inherently and excessively variable and uncontrolled. Workers scrubbed the final cured layer of silicone in a scrubbing room using different brushes and un-validated methods that violated PMA requirements, Allergan's manufacturing and design specifications, and Current Good Manufacturing Practices, QSRs and other federal regulations, as well as parallel state law. Allergan's uncontrolled and un-validated scrubbing process resulted in final products that did not meet the PMA requirements or Allergan's own design and manufacturing specifications. For example, Allergan's uncontrolled and un-validated manufacturing processes created a "particle laden" environment on the implant surface which exposed patients to particles that caused chronic inflammation and caused or contributed to the development of ALCL. Allergan's uncontrolled and un-validated manufacturing processes also resulted in an implant surface that was unevenly textured, that included foreign, degraded and loosened fragments of silicone particles and other materials that caused chronic inflammation and caused or contributed to the development of ALCL. This constituted a defectively manufactured surface, as the manufacturing was in variance from the product specifications and processes, resulting in the presence of unintended particle residue and the production of a product different than the product approved by the FDA, causing severe harm to patients.

119. Further, Allergan's uncontrolled and un-validated manufacturing processes (which violated the PMAs, the manufacturing and design specifications, CGMPs, QSRs, other federal regulations and parallel state law) caused an uncontrolled and unintended increase in the

surface area of the implants and expanders. The unintended increase in surface area caused or contributed to the unchecked proliferation of T-cells. In addition, Allergan's uncontrolled and un-validated texturing process caused or contributed to a chronic inflammatory response in patients' bodies which caused or contributed to the development of ALCL. This inflammatory response which can lead to ALCL is exacerbated by shear forces from the excessive number of jagged and sharp particles on the implant surface, micro-movement shear forces caused by mechanical attachment and detachment of the over-aggressively textured surface to the tissue capsule, which also result from Allergan's defective manufacturing processes. The chronic inflammation caused by Allergan's defective manufacturing processes stimulates T-cells and can cause malignant mutations in T-cells, ultimately leading to anaplastic large cell lymphoma.

120. The harms described above directly resulted from the variations from the approved design and manufacturing specifications. Had Allergan utilized CGMPs and complied with QSRs, and undertaken the manufacturing process in an appropriate manner, it would have consistently produced a product in conformity with its approved specifications. Moreover, by evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, as well as utilization of standard operating procedures, Allergan could have assured the production of BIOCELL products that complied with its specifications and met the appropriate quality standards.

121. Some aspects of Allergan's non-compliant manufacturing, investigation and reporting practices pertaining to the BIOCELL texturing process were revealed in November 2015 when the French Agency for the Safety of Health Products, *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM), published a Preliminary Inspection Report of Allergan's European subsidiary that marketed Allergan's implants in Europe—Allergan Ltd

Marlow.[35] The inspection raised twelve deviations, 2 critical and 3 major ones. It also raised 8 remarks, involving one major one.

122. The French authorities (ANSM) conducted an inspection to assess whether Allergan had adequate systems and measures in place to prevent, investigate and correct serious adverse events associated with its breast implants. Specifically, ANSM investigated the 195 breast implant-related ALCL cases that had been reported at that time (April 2015), 130 cases of which were associated with Allergan's breast implants.[36]

123. In their inspection of Allergan's manufacturing procedures, the ANSM found a number of "critical" and "major" "deviations" in Allergan's manufacturing and reporting processes with respect to legal references and standards applicable to medical devices. Significantly, the French inspection documented a major deviation from standards and legal requirements in connection with Allergan's salt loss manufacturing technique for the BIOCELL implants.[37] For example, they noted that Allergan "does not take all the necessary actions to keep under control the residues that may be contained in those [breast implants], which may compromise their biocompatibility and consequently their compliance with the essential requirements applicable to medical devices." It detailed:

> "The control of texturing salt residues after the soaking step, regarding the textured Bis (BIOCELL TM), is subjected to a validation file which mentions a biocompatible acceptance threshold of 0,155 g NACl residues, but the devices used as reference in this validation are re-usable gauzes impregnated with NaCl, without demonstration of the relevance of this reference of devices versus BIs which are Class III devices intended to be implanted for several years."

[35] *See*, https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf.
[36] *See,* Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) *Preliminary Inspection Report of Allergan Ltd Marlow*.
[37] At the time of the French inspection in 2015, all manufacturing of BIOCELL occurred at Allergan's Costa Rica plant.

124. Further, another "major" deviation from standards and legal requirements was identified with respect to:

> "The implementation of actions within the scope of BIs production, particularly in terms of residue controls (salt, Xylene, D4/D5 short molecules, others...) and surface topography, associated with adequate specifications, considering especially that:
>
> -195 cases of ALCL are diagnosed worldwide to date on patients bearing BIs, among which 130 cases concern patients bearing BIs manufactured by ALLERGAN, with 90 cases confirmed (including 66 cases involving BIOCELL TM) textured BIs) and 40 cases suspected...
>
> The risk analysis of ALLERGAN BIs does not include the risks and risk reduction measures inherent in the production (ISO14971item6.2b)."

125. The French regulators summarized Allergan's regulatory violations as representing "a major risk regarding the materiovigilance, and safety of the breast implants marketed in Europe by Allergan…" Allergan was cited for its unsatisfactory assessment of the "gravity and causality" of the incidents regarding its breast implants as well as not timely reporting cases of ALCL the proper agencies and in the proper manner.

126. In addition to the concerns expressed by ANSM, researchers identified particles in the form of surface debris in Allergan's BIOCELL implants. In 2017, researchers at the Mayo Clinic, Creighton University School of Medicine, and Arizona State University published an article titled "*Textured Breast Implants: A Closer Look at the Surface Debris Under the Microscope.*" The authors of the study examined new Allergan BIOCELL textured implants from Allergan's factory. Viewing the textured "salt loss" surface, they found solid particles of silicone-"white flecks" on some surfaces of Natrelle [Allergan BIOCELL] implants. The authors opined that the silicone had shed the particles.[38]

[38] *See*, Webb et al. *Textured Breast Implants: A Closer Look at the Surface Debris Under the Microscope Plastic Surgery* 2017, Vol. 25 (3)179-183. Available at: https://journals.sagepub.com/doi/abs/10.1177/2292550317716127.

127. The particle laden environment, increased surface area, shear forces exerted by excessive jagged and sharp particles, and micro movement shear forces caused by mechanical attachment and detachment of the textured surface and the tissue capsule found in Allergan's textured breast implants and expanders are directly related to BIA-ALCL. The texturing process, together with the particle-laden surface and resulting increased surface area, implant debris shear forces and micro movement shear forces between the capsule and the shell, cause chronic physiologic inflammation and the development of BIA-ALCL in patients.

128. Pursuant to its three PMAs for BIOCELL textured breast implants, beginning in 2000 and continuing to the date of recall on July 24, 2019, Allergan was under a continuing duty to follow the specific requirements of the manufacturing and design specifications set forth in the PMA as well as the general requirements of applicable CGMPs pursuant to state law and parallel federal requirements, including 21 U.S.C. § 351; 21 C.F.R. Part 820.

129. Pursuant to the applicable CGMPs, Allergan was obligated to implement and maintain quality control systems in order to validate processes for the production of its BIOCELL textured implants. It was also required by CGMPs to conduct inspections and testing to ensure the purity and stability of its BIOCELL textured implants. Allergan failed to comply with these essential CGMPs in its texturing of its BIOCELL implants during the manufacturing process, resulting in the production of adulterated implants. As described previously, the overly aggressive and inconsistent texturing resulted in excessive particle formation and excessive manufacturing debris and contaminants on the implant surface and resulting in the various forces described above. This defective manufacturing process in violation of the PMAs and CGMPs posed a significant risk of harm to patients implanted with BIOCELL textured implants. The adulterated implants created a particle-laden environment and significantly increased the surface

area, stimulated shear forces, and caused ongoing micro movement shear forces between the implant surface and tissue capsule, causing chronic inflammation and significantly increased risk of BIA-ALCL. The violation of CGMPs at the time of manufacture was in violation of state law and parallel federal requirements set forth at 21 U.S.C. § 351; 21 C.F.R. §§ 820.70 and 820.75.

130. Pursuant to the applicable CGMPs, Allergan was obligated to establish and continuously evaluate and maintain norms and guidelines for biocompatibility, mechanical properties of the shell, modes of sterilization, packaging, and texturing with its salt loss process. Allergan failed to comply with the PMAs and these essential CGMPs, resulting in the production of adulterated implants. Allergan knew or should have known that its overly aggressive and inconsistent texturing resulted in excessive particle formation, as well as additional surface debris. The particles were excessive, sharp, irregular, rough and varying in size, outside the norms accepted within the industry or contemplated by the approved design and manufacturing specifications. The adulterated implants created a particle-laden environment and significantly increased the surface area, causes shear forces from excessive sharp and jagged particles, ongoing micro movement shear forces between the implant surface and tissue capsule, causing chronic inflammation and significantly increased risk of BIA-ALCL. The violation of CGMPs at the time of manufacture was in violation of state law and parallel federal requirements set forth at 21 U.S.C. § 351; 21 C.F.R. §§ 820.70 and 820.75.

131. Allergan's failure to comply with the PMAs and applicable CGMPs and QSRs, as previously outlined, was a violation of state law and parallel federal law requirements and resulted in the introduction of adulterated BIOCELL implants into the stream of commerce.

132. Allergan further violated state law and parallel federal requirements set forth at 21 C.F.R. § 820.30 by failing to establish and maintain ongoing procedures for validating the device

design of BIOCELL 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.

133. Allergan violated state law and parallel federal requirements pursuant to 21 C.F.R. § 820.50 by failing to establish and maintain procedures to ensure that all purchased or received products and services conformed 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.

134. Allergan violated state law and parallel federal requirements pursuant to 21 C.F.R. § 820.70(a) by failing to develop, conduct, control, and monitor production processes to ensure that its BIOCELL implants conformed to specifications, as well as maintaining process controls to ensure conformance to specifications. Allergan failed to fulfill this important process in its texturing process as outlined above.

135. Allergan violated state law and parallel federal requirements pursuant to 21 C.F.R. § 820.70(h) by failing to establish and maintain procedures for the use and removal of manufacturing materials and debris to ensure that the amount of particles and debris on the surface and embedded in the implant are limited to an amount that does not adversely affect the implants' quality.

136. Allergan violated state law and parallel federal requirements pursuant to 21 C.F.R. § 820.90(a) by failing to establish and maintain procedures to control the production and release into the stream of commerce of BIOCELL implants that failed to conform to

specifications, including failing to adequately identify, document, evaluate, segregate, and dispose of nonconforming implants.

137. Allergan violated state law and parallel federal requirements pursuant to 21 C.F.R. § 820.100(a) by failing to establish and maintain procedures for implementing preventative and corrective action to detect recurring quality problems related to the texturing process, investigating causes of nonconformities, identifying necessary action to correct and prevent recurrence of nonconforming implants, implementing necessary changes in methods to correct such quality problems, and validating the corrective and preventive action.

138. Allergan violated state law and parallel federal requirements pursuant to 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 its BIOCELL implants when necessary to comply with specifications.

139. Allergan violated state law and parallel federal requirements pursuant to 21 C.F.R. § 820.160 by failing to adequately inspect, test, and validate its BIOCELL implants after completion of assembly and immediately before delivery for use in patients, to identify and mitigate risks for adverse patient effects such as inflammation, formation of chronic seromas and solid masses, and BIA-ALCL.

140. Allergan had the technological capacity, resources, and ability to manufacture BIOCELL implants in a reasonably safe, non-adulterated manner.

141. Allergan failed to comply with state law and parallel federal requirements as outlined above and produced adulterated BIOCELL products which were unsafe, defective and failed to perform as expected and intended and which caused harm and injury to Plaintiff.

142. Allergan's implants and its manufacturing processes did not meet the requirements of Allergan's PMA-approved design and manufacturing guidelines, FDA regulations, CGMPs and QSRs, in violation of state law and parallel federal law, including 21 C.F.R. § 820 21, C.F.R. § 820.70(h), 21 C.F.R. § 820.1(a), 21 C.F.R. § 820.5, C.F.R. § 820.3(y), 21 C.F.R. § 820.70(a), (c), (e); 21 U.S.C. § 351.

143. The improper texturing techniques and particle-laden and debris covered implant surface and other out of specification characteristics described above rendered the manufacture defective, varying from the approved and intended design and manufacturing specifications. The precise provisions of the PMAs, and the design and manufacturing specifications, and specified processes, are in the exclusive control of Allergan and regulatory bodies and have not been provided to Plaintiff. Plaintiff reserves the right to amend this section with additional facts and allegations once Allergan produces all of its PMA files and specifications and manufacturing records for the BIOCELL line of products.

VI. FACTS SPECIFIC TO PLAINTIFF

144. In September 2015, Plaintiff underwent a mastectomy of the left breast after a diagnosis of invasive ductal carcinoma. In December 2015, Plaintiff was implanted with Defendants' Allergan Natrelle Silicone-Filled Breast Implant Style 410LX with a Biocell textured shell, Serial Number 20126224 (2015 Biocell implants) in her left breast.

145. Prior to the implantation of the BIOCELL implant, Plaintiff was not aware of the risk of developing BIA-ALCL that the BIOCELL implant posed. Had Plaintiff been aware of the true risk of developing BIA-ALCL, she would not have had it implanted.

146. Plaintiff did not become aware of the risk of developing BIA-ALCL from her BIOCELL implants until 2019. Due to this risk, Plaintiff underwent explantation surgery in

December 2019 to have her capsules and BIOCELL implants removed, necessitating invasive, disfiguring surgery, at significant expense.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

147. The running of any statute of limitations has been equitably tolled by reason of Allergan's fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Allergan actively concealed from Plaintiff and her physician the true risks associated with the BIOCELL line.

148. As a result of Allergan's actions, Plaintiff was unaware, and could not have reasonably known or learned through reasonable diligence, that she had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Allergan's acts and omissions.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY-DEFECTIVE MANUFACTURING (PARALLEL TO FEDERAL REQUIREMENTS UNDER 21 U.S.C. §351, AND 21 C.F.R. PART 820, ETC.)

149. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint, and further alleges:

150. At all times relevant Allergan was engaged in the business of manufacturing, selling, distributing, marketing and promoting BIOCELL implants.

151. Plaintiff was implanted with BIOCELL implants that were defective, unreasonably dangerous, not reasonably fit, suitable, or safe for their intended purpose, in violation of state law and parallel federal law, for example pursuant to 21 U.S.C. § 351, 21 C.F.R. Part 820, etc. They were adulterated upon manufacture, having been defectively

manufactured in violation of applicable specifications, the PMA design and manufacturing specifications, QSRs and CGMPs, and other state and federal requirements as discussed *supra,* including 21 C.F.R. § 820.

152. Allergan's defective manufacturing was characterized by the production of unreasonably dangerous materials and surfacing, including nonconforming materials and inappropriate unsafe components, using inconsistent and unsafe techniques and methods which were not reasonably standardized or validated, and which deviated from the intended design and manufacturing specifications, resulting in variable roughness, excessive particle formation, increased surface area, and continuous micro movement shear forces between the implant surface and the tissue capsule, and the development of chronic inflammation, tissue damage, seromas and ALCL.

153. Allergan knew or should have known that the manufacturing process was defective, unsafe, and unreasonably dangerous, resulting in the manufacture of unreasonably dangerous, defectively manufactured BIOCELL implants with an increased and unreasonable risk of causing severe injuries, including but not limited to severe inflammation, tissue damage, seromas, and BIA-ALCL.

154. Had Allergan properly manufactured the BIOCELL implants and complied with state law and the parallel federal requirements such as provisions of 21 C.F.R. Part 820, as more fully set forth above, its BIOCELL products would not have been adulterated, misbranded, defective and unsafe.

155. Allergan breached its duties under state law and parallel federal law as described to manufacture its BIOCELL implants and expanders in such a manner that they were not defective and unreasonably dangerous to patients. State law provides a remedy of money

damages for the violations. Allergan breached state law and parallel federal law requirements, including but not limited to the following, by:

a. Introducing or delivering for introduction into interstate commerce a device that was adulterated due to differences from the specifications set forth in the PMAs and supplements. 21 U.S.C. §§ 331, 351(h); 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); 21 C.F.R. Part 820;

c. Manufacturing a device that was adulterated. 21 U.S.C. §§ 331, 351(h); 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 conformed 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 implant met but 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 texturing for the use and removal of manufacturing materials to ensure that the amount of silicone particles, implant debris and other particles on the surface or embedded in the implant would be limited to an amount within industry standards and without compromising the device's quality. 21 C.F.R. §820.70(h);

h. Failing to establish and maintain procedures to control implants that fail to conform to specifications, 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, implement changes in methods to correct 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 implants was taken as necessary. 21 C.F.R. §820.22;

k. Failing to adequately inspect, test, and validate BIOCELL implants after completion of assembly and immediately before delivery for implantation into consumers, including Plaintiff, to mitigate risks which cause BIA-ALCL. 21 C.F.R. §820.16; and

l. Failing to monitor, receive, review, and evaluate and/or investigate complaints received from breast implant patients and their physicians, failing to timely identify problems with the devices and, failing to take appropriate corrective actions to ensure consumer safety. 21 C.F.R. § 820.198.

156. Allergan knew that the defectively manufactured BIOCELL implants would be implanted in Plaintiff without knowledge of the hazards involved in such use.

157. Allergan's BIOCELL products were defective when they left the control of Allergan and reached Plaintiff without substantial change.

158. Allergan's textured BIOCELL products did not perform as safely a physician or an ordinary patient would expect them to perform when used in the intended or reasonably foreseeable way, and the risk posed by the products exceeded their benefits due to the manner in which the products were manufactured. Allergan's BIOCELL products did not conform to its intended design and failed to perform as safely as the intended design would have performed.

159. Allergan's BIOCELL products left Allergan's control in an unreasonably dangerous condition that could not be contemplated by Plaintiff or her physician.

160. Allergan is strictly liable for the defective manufacture of its textured BIOCELL products pursuant to the laws of Florida.[39]

161. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

COUNT II

NEGLIGENT MANUFACTURING (PARALLEL FEDERAL REQUIREMENTS UNDER 21 U.S.C. § 351, AND 21 C.F.R. PART 820, ETC.)

162. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint, as if set forth herein and further alleges as follows:

163. At all times relevant Allergan was engaged in the business of manufacturing, selling, distributing, marketing and promoting its textured BIOCELL implants and expanders.

164. Allergan owed Plaintiff a duty to manufacture its textured implants in a reasonable manner. Allergan breached its duty to manufacture its textured implants in a reasonable manner. Allergan was required to exercise reasonable care to manufacture its BIOCELL product line consistent with the PMA and design and manufacturing specifications and processes. By failing to do so, Allergan negligently manufactured a nonconforming

[39]See *Force v. Ford Motor Co.,* 879 So. 2d 103 (Fla. Dist. Ct. App. 2004); *McConnell v. Union Carbide Corp.*, 937 So. 2d 148, 151 n.4 (Fla. 4th DCA 2006) and *Aubin v. Union Carbide Corp.*, 177 So.3d 489, 511–12 (Fla. 2015)

product that was different from the product approved by the FDA, and the breach of Allergan's duty in this manner caused injury, loss, and damage to Plaintiff. Allergan negligently manufactured BIOCELL products in violation of applicable state laws and parallel federal laws, including but not limited to, by:

a. Introducing or delivering for introduction into interstate commerce a device that was adulterated due to differences from the specifications set forth in the PMAs and supplements. 21 U.S.C. §§ 331, 351(h); 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); 21 C.F.R. Part 820;

c. Manufacturing a device that was adulterated. 21 U.S.C. §§ 331, 351(h); 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 conformed 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 implant met but 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 texturing for the use and removal of manufacturing materials to ensure that the amount of silicone particles, implant debris and other particles on the surface or embedded in the implant would be limited to an amount within industry standards and without compromising the device's quality. 21 C.F.R. §820.70(h);

h. Failing to establish and maintain procedures to control implants that fail to conform to specifications, 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, implement changes in methods to correct 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 implants was taken as necessary. 21 C.F.R. §820.22;

k. Failing to adequately inspect, test, and validate BIOCELL implants after completion of assembly and immediately before delivery for implantation into consumers, including Plaintiff, to mitigate risks which cause BIA-ALCL. 21 C.F.R. §820.16; and

l. Failing to monitor, receive, review, and evaluate and/or investigate complaints received from breast implant patients and their physicians, failing to timely identify problems with the devices and, failing to take appropriate corrective actions to ensure consumer safety. 21 C.F.R. § 820.198.

165. Plaintiff was implanted with textured BIOCELL implants that were negligently manufactured and thereby rendered defective, unreasonably dangerous, not reasonably fit, suitable, or safe for their intended purpose, and adulterated upon manufacture, having been negligently manufactured in violation of applicable specifications, the PMA specifications, PMA and federal standards and specifications, good manufacturing practices, and other state and federal requirements.

166. Allergan's negligent manufacturing, which deviated from the approved and intended design, caused its products to have variable roughness, a particle laden environment, surface debris, increased surface area, continuous micro movement shear forces between the surface of the implants and the tissue capsule, proliferation of T-cells, malignant transformation of T-cells, chronic inflammation, tissue damage, seroma formation and ALCL, and other harm.

167. Allergan knew, or should have known in the exercise of reasonable care, that the manufacturing process was not performed in a safe and reasonable manner or consistent with the design and manufacturing specifications.

168. Allergan knew that the negligently manufactured BIOCELL implants would be implanted in Plaintiff without knowledge of the hazards involved in such use. Plaintiff's injuries were a foreseeable result of Allergan's negligent manufacture of BIOCELL products.

169. Allergan violated state law and parallel federal law by acting in negligent, unsafe and unreasonable manner in the manufacture of its BIOCELL products. By manufacturing its BIOCELL products in such a way, Allergan deviated from the intended specifications and rendered the products unsafe and unreasonably dangerous. Similarly, by failing to adhere to the product specifications as required by PMA and CGMPs, Allergan violated parallel federal law.

170. The state law duties and requirements are parallel to, and not different from or in addition to, the federal requirements with regard to the manufacturing of the BIOCELL implants. Allergan is liable for its negligent manufacture of textured BIOCELL implants and textured expanders pursuant to the laws of Florida.[40]

171. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against

[40]See *Cintron v. Osmose Wood Preserving, Inc.,* 681 So.2d 859, 861 (Fla. Dist. Ct. App. 1996); JICIV FL-CLE 400-1

Allergan, as contained in the Prayer for Relief.

COUNT III

GENERAL NEGLIGENCE, NEGLIGENCE PER SE (PARALLEL FEDERAL REQUIREMENTS UNDER 21 U.S.C. § 331 AND 351; 21 C.F.R. PART 820; 21 C.F.R. § 801.6, § 820, § 814.39 and § 803.3, ETC.)

172. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

173. Allergan had a duty to exercise reasonable care and comply with existing standards in the researching, studying, reporting, warning, manufacturing, marketing, supplying, promoting, packaging, selling, testing, labeling and distributing of its BIOCELL products, and post-market vigilance regarding these actions, and to comply with the terms of the PMA.

174. Allergan breached those duties of reasonable care to Plaintiff by the actions detailed above, including, but not limited to, failing to warn Plaintiff's physicians and Plaintiff of the true risks of the BIOCELL product line, misrepresenting the true safety of BIOCELL, failing to comply with the terms of the PMA, failing to strengthen its warnings, failing to update the medical community and patients when it learned or discovered new information about the risks and safety of BIOCELL, failing to complete mandatory studies and post-market surveillance, and failing to recall BIOCELL before it did. Allergan's state law duties of reasonable care are parallel to, and not different from, federal requirements. In violating its state law duties, Allergan also violated parallel federal requirements, including 21 U.S.C. § 331, 21 U.S.C. § 351; 21 C.F.R. Part 820, 21 C.F.R. § 801.6, 21 C.F.R. § 814.39; 21 C.F.R. § 803.3.

175. In addition, upon obtaining knowledge of the reported and potential BIOCELL failures in conjunction with the development of ALCL or unexplained late or persistent seromas, Allergan was required by state law and under its PMA, parallel federal law, including 21 CFR

§§ 820.30 et seq., 21 CFR §§ 820.100 et seq., and the FDA Recognized Consensus Standard ISO 14971, to update the risk analyses for BIOCELL and take Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Allergan was required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects, pursuant to state law and parallel federal law, for example, 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq., and it negligently failed to do so.

176. These simple state common law negligence duties are parallel to the duties under federal law, including, 21 U.S.C. § 331, 21 U.S.C. § 351; 21 C.F.R. Part 820, 21 C.F.R. § 801.6, 21 C.F.R. § 814.39 and 21 C.F.R. § 803.3. Violations of the above federal requirements parallel state law in which a violation of law is evidence of negligence,

177. Allergan's breach of its duties caused Plaintiff's injuries.

178. Allergan's BIOCELL products were at all times utilized and implanted in a manner foreseeable to Allergan.

179. Under state law, as set forth below, Allergan's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence.

180. Under state law, a money damage remedy exists for violation of state law duties of care and the parallel requirements under the MDA and regulations promulgated thereunder when such violations result in an unreasonably dangerous product proximately causing injuries.

181. The laws, regulations, and terms of the PMA violated by Allergan were designed to protect Plaintiff and similarly situated persons and protect against the risks and hazards that

have been suffered as a result of being implanted with BIOCELL products. Allergan's conduct constitutes negligence per se.

182. Plaintiff and plaintiff's physician reasonably relied on Allergan's expertise with regard to its representations about BIOCELL. Plaintiff and her physician would not have utilized BIOCELL if they knew the increased risk and incidence of ALCL.

183. Allergan knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Allergan's failure to exercise ordinary care as described above.

184. Had Allergan exercised ordinary care, and complied with the then existing standards of care, Plaintiff would not have been injured. Allergan had the expertise, resources and capacity, as well as the obligation, to comply with the standards of care applicable at all times material.

185. The state law duties and requirements are parallel to, and not different from or in addition to, the federal requirements with regard to the negligence of the Allergan. Allergan is liable for its negligence related to its textured BIOCELL products which caused Plaintiff's injuries pursuant to the laws of Florida.[41]

186. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

[41]See *Cintron v. Osmose Wood Preserving, Inc.,* 681 So.2d 859, 861 (Fla. Dist. Ct. App. 1996)

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

COUNT IV

STRICT LIABILITY-FAILURE TO WARN
(PARALLEL FEDERAL REQUIREMENTS UNDER 21 C.F.R. § 801.6, § 820.70, §820.100, § 820.30, § 814.84(b)(2), § 814.39, § 803.50, ETC.)

187. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

188. Allergan designed, manufactured, inspected, labeled, distributed, marketed, sold, and otherwise released BIOCELL products into the stream of commerce.

189. In doing so, Allergan directly advertised or marketed BIOCELL products to health care professionals, patients, and consumers or persons responsible for consumers.

190. Allergan had a duty to warn of the risks associated with its BIOCELL products.

191. Allergan failed to adequately warn health care professionals and the public, including Plaintiff and her physician, about the true risks of ALCL from Allergan's BIOCELL products, including that its BIOCELL products carried a substantial risk of ALCL, that ALCL requires early diagnosis and treatment and poses a risk of progression and death, and that Allergan's BIOCELL products carry a much greater risk and incidence of ALCL than that of other products on the market.

192. Further, Allergan failed to adequately warn health care professionals and the public, including Plaintiff and her physician, about the true risks of ALCL seen with its BIOCELL products that were on the market by:

a. Failing to adequately report post-market adverse events to the FDA when known, as required by state law and parallel federal requirements, including for example 21 C.F.R. § 803.50(a);

b. Misleadingly reporting adverse events via summary reports, when it knew or should have known that such reporting violated the law and that the reports were included in a system not open to the public and not user friendly;

c. Failing to report or otherwise complete ongoing long-term studies regarding the BIOCELL product line as required by state law and parallel federal requirements, including for example 21 C.F.R. § 814.84(b)(2);

d. Failing to update and strengthen the labeling and warnings in accordance with state law and parallel federal requirements, including for example as specified in the PMA, through PMA supplements and according to the Changes Being Effected process;

e. Failing to advise patients and their physicians that it had failed to comply with requirements of its PMA which were necessary to evaluate the safety and effectiveness of the BIOCELL products.

193. Upon obtaining knowledge of the reported and potential BIOCELL failures in conjunction with the development of ALCL or unexplained late or persistent seromas, Allergan was required by state law and under its PMA, parallel federal requirements, such as 21 CFR §§ 820.30 et seq., 21 CFR §§ 820.100 et seq., and the FDA Recognized Consensus Standard ISO 14971, to use this information to routinely update the risk analyses for BIOCELL products and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Allergan was required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects pursuant to state law and parallel federal law, including 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

194. Allergan's conduct violated state law as well as parallel federal requirements, thereby causing serious injury, loss and damage to Plaintiff.

195. Under applicable state law, as well as parallel federal requirements, including the

PMA, Conditions of Approval, federal regulations, including the CBE regulations, as outlined above, Allergan had a duty to adequately warn Plaintiff and her physician regarding the risks and risk profile of the BIOCELL implants. This duty extended to the product labeling, written and oral communications, and submissions of accurate and complete adverse event reports and risk information to the FDA. Allergan breached its duty to warn and continued to market, distribute and sell its BIOCELL products in an unreasonably dangerous and defective condition when they were misbranded and adulterated. Plaintiff defines the state law duty and obligations to be parallel but not to exceed the warning obligations placed on Allergan pursuant to federal law.

196. Allergan's state law duty to warn adequately encompassed a duty to provide safety information to the FDA. Federal law also required Allergan to report adverse events and adverse safety information to the FDA, as outlined in the preceding paragraphs. Allergan violated both state and parallel federal law by failing to report such information to the FDA.

197. For years, and in most of the applicable labeling and marketing materials for the BIOCELL implants, no warning, risk, or adverse event information regarding ALCL was provided. In addition, prior to 2013, the labeling for BIOCELL implants contained no reference to ALCL. When a reference to ALCL was finally included within the 2013 DFU that accompanied Allergan's BIOCELL implants, it still did not warn adequately of the risk of ALCL. That and subsequent and other warnings and labeling used for the BIOCELL line of products failed to adequately warn of the risks, in violation of state law and the parallel federal requirements.

198. Allergan knew or should have known, based on ongoing accumulation of information that the 2013 warning and subsequent other warnings failed to adequately describe the real risk profile and the causal connection between its BIOCELL implants and BIA-ALCL,

which was significantly greater than the risk posed by "other manufacturers' breast implants." Allergan was thus obligated to act to disseminate a more adequate and accurate warning. As set forth above, Allergan deliberately obstructed and failed to disseminate critical risk information: It failed to notify physicians of the warning and caused misleading non-PMA communications to be disseminated in order to obscure and/or weaken the impact of the warnings, and protect its market share.

199. Allergan had sufficient information regarding the nature, frequency and severity of the risks associated with its BIOCELL implants, including the connection to BIA-ALCL, to adequately warn Plaintiff and her physician of those risks. Yet Allergan chose not to provide adequate warnings, thereby continuing to market and sell its dangerous BIOCELL products to uninformed, poorly informed and misinformed patients and physicians.

200. Despite Allergan's state law duty and obligation to strengthen the warnings, Allergan instead chose to actively conceal its knowledge of the risks and risk profile of its BIOCELL products, deliberately failing to disclose the true risks and risk profile to physicians, patients, and otherwise failed to comply with state law and parallel federal requirements, including for example 21 C.F.R. part 814, § 814.39(a) and § 814.39(d). It also manipulated the regulatory process to its advantage by utilizing adverse event reports and reporting data in a misleading, disguised and inadequate manner, all for its economic advantage and to the tragic disadvantage of patients, including Plaintiff.

201. As set forth above, Allergan was required by applicable state law to provide adequate warnings and strengthened PMA warnings through PMA Supplements when Allergan knew or should have known of the need to provide such warnings and strengthened warnings; yet it failed to do so. Moreover, federal requirements also required strengthening the label to

update the safety information. Allergan's state law duty to provide adequate warnings is parallel to and not different from or in addition to the federal requirements regarding adequate warnings, for example 21 C.F.R. part 814, § 814.39(a) and § 814.39(d).

202. Any such warnings and strengthened PMA warnings submitted by Allergan to the FDA for approval would have been approved by the FDA and disseminated to Plaintiff and her physician. Nothing more was required of the Defendants under the federal requirements than what was required under state law.

203. Allergan's defective and inadequate warnings made BIOCELL implants unreasonably dangerous and were a substantial contributing factor in causing the injuries to Plaintiff.

204. But for Allergan's defective and inadequate warnings, Plaintiff's injuries would not have occurred.

205. Had Allergan properly warned as required by state law, and properly and timely reported adverse events, the actual risks, and risk profile, as required, the information would have been reported through the MAUDE database and other means and disseminated to Plaintiff and her physician. Plaintiff would not have consented to the use of Allergan's BIOCELL products, and Plaintiff's physician would not have recommended them or prescribed them if they had been properly warned as required by federal and state law. For those who already had BIOCELL implants, the patients could have exercised reasonable judgment to remove the implants to diminish the risk of ALCL. Ultimately, despite Allergan's efforts to the contrary, the belated and more accurate disclosure of the risks and incidence of ALCL resulted in the request by the FDA that the BIOCELL products be recalled. 21 C.F.R. § 801.6; *See* 21 C.F.R. part 814, § 814.39(d).

206. Allergan is strictly liable for the failure to adequately warn of the risks and risk profile of the BIOCELL implants pursuant to the laws Florida.[42]

207. Allergan acted with wanton and willful disregard for the rights and health of Plaintiff.

208. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

COUNT V

NEGLIGENT FAILURE TO WARN (PARALLEL FEDERAL REQUIREMENTS UNDER 21 C.F.R. § 801.6, § 820.70, §820.100, § 820.30, § 814.84(b)(2), § 814.39, § 803.50, ETC.)

209. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint, and further alleges as follows:

210. At all times relevant, Allergan owed to Plaintiff and her physician a duty of reasonable care. The duty of reasonable care included a duty to adequately warn of the significant harm and true risk profile related to its BIOCELL products due to their inherent and

[42]See *Brewer v. Stop Stick, Ltd.,* No. 2:04-CV-613FTM33DNF, 2005 WL 2614537 (M.D. Fla. Oct. 14, 2005); *Union Carbide Corp. v. Aubin,* 97 So.3d 886, 898 (Fla. 3d DCA 2012); *McConnell v. Union Carbide Corp.,* 937 So.2d 148, 151–52 (Fla. 4th DCA 2006); *Union Carbide Corp. v. Kavanaugh,* 879 So.2d 42, 45 (Fla. 4th DCA 2004); *Scheman–Gonzalez v. Saber Manufacturing Co.,* 816 So.2d 1133 (Fla. 4th DCA 2002); *Ferayorni v. Hyundai Motor Co.,* 711 So.2d 1167 (Fla. 4th DCA 1998)

hidden dangers, including the heightened risk of developing BIA-ALCL, and to provide accurate, non-misleading information regarding the risks and risk profile to physicians, patients, and the FDA. This duty applied post-sale and post-PMA and also required Allergan to provide adequate warnings when ongoing and new information was learned about the BIOCELL products and the risk of ALCL. These state law duties were parallel to and no different from or in addition to the parallel federal requirements, including for example 21 C.F.R. § 801.6; 21 C.F.R. § 814.82(a)(9); *supra*. Doing so would have resulted in dissemination of accurate and necessary risk and risk profile information and warnings to Plaintiff and her physician, and would have resulted in the Plaintiff not having the BIOCELL implants surgically implanted into her body. Plaintiff would not have consented to the use of BIOCELL, and physicians would not have recommended BIOCELL if adequate warnings and risk profile information had been disclosed with regard to ALCL.

211. Allergan breached its duties of reasonable care to Plaintiff and Plaintiff's physician by the actions detailed above, including, but not limited to, failing to warn Plaintiff's physician and Plaintiff of the true risks of the BIOCELL product line, misrepresenting the true risks of BIOCELL, failing to comply with the terms of the PMA, failing to update the medical community, patients and the FDA when it learned or discovered new information about the risks and safety of BIOCELL, and otherwise failing to recall BIOCELL before it did.

212. Allergan's breach of its duties caused Plaintiff's injuries.

213. Allergan's BIOCELL products, including its textured implants and expanders, were distributed and manufactured in violation of state law duties of care and the Federal Food Drug & Cosmetic Act and the Medical Device Amendments ("MDA"), 21 U.S.C. § 351, and regulations promulgated pursuant thereto.

214. Allergan consistently under-reported and withheld information about the risk of ALCL and misrepresented the efficacy and safety of BIOCELL products, actively misleading the medical community, patients, the public at large, and Plaintiff.

215. Allergan knew, and continues to know, that its disclosures to the public and Plaintiff were and are incomplete and misleading; and that Allergan's BIOCELL product line placed patients at a significantly increased risk and incidence of ALCL when compared to other similar products.

216. Allergan suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

217. As a result, Allergan actively and intentionally misled the public, including the medical community, health care providers, and patients, into believing that Allergan's BIOCELL products were and are safe and effective, leading to the prescription for and implantation of BIOCELL products into patients such as Plaintiff. For example, Allergan failed to timely and appropriately acknowledge and report the risk and incidence of BIA-ALCL or the predominance of its BIOCELL products among the diagnoses and deaths of patients with ALCL.

218. Allergan's parallel federal and state law duties required it to truthfully, accurately and timely communicate safety information to the FDA, to Plaintiff's physicians and Plaintiff. This duty was ongoing. Allergan breached its duties and misrepresented the risks and benefits of its BIOCELL product line, and failed to include adequate warnings on its labeling, in violation of state law and parallel federal law, for example 21 C.F.R. part 814, § 814.39(d). The conduct of Allergan, by inadequately and inaccurately warning and failing to provide accurate risk and risk profile information, was negligent, in violation of applicable state statutes and common law,

which do not impose duties or requirements different from or in addition to those imposed by the parallel federal requirements, and those failures caused Plaintiff's injuries.

219. Allergan's breaches of its duty of care included those specified above, including:

a. Failing to adequately and accurately warn of the risks, and deliberately preventing physicians and patients from learning of the risks and true risk profile, of the BIOCELL line of products;

b. Failing to timely and accurately communicate information essential to an accurate assessment of risks versus benefits of Allergan's BIOCELL product line;

c. Failing to report when implants failed to meet performance specifications and expectations;

d. Failing to revise and update product labeling to reflect its knowledge of the risk of BIA-ALCL;

e. Providing inadequate, inaccurate, and misleading information, warnings, risks, and risk profile information in written and oral communications;

f. Failing to warn, or report to the FDA, and the medical community, and patients, its knowledge regarding the risk of BIA-ALCL upon receiving the information; and

g. Failing to advise patients and their physicians that it had failed to comply with requirements of its PMA which were necessary to evaluate the safety and effectiveness of the BIOCELL products.

220. Further, Allergan engaged in non-PMA statements, actions, and communications that violated Allergan's state law duty of care to act reasonably in providing information to physicians and patients, and to the FDA and the parallel federal duties set forth at 21 C.F.R. part 814, § 814.39(d); 21 C.F.R. § 801.6; 21 U.S.C. § 352(q). These statements included, but are not limited to, statements made:

a. In promotional and marketing documents;

b. By sales representatives, marketing representatives and executives;

c. By paid consultants;

d. At physician training and information sessions;

e. At professional conferences and other events and meetings sponsored by Allergan.

221. Allergan is liable for its negligent failure to adequately warn of the risks and risk profile of the BIOCELL implants pursuant to the common law and statutory scheme of Florida.[43]

222. Plaintiff and her physician reasonably relied on Allergan's incorrect, misleading and negligent warnings and communications and made decisions regarding implantation of Allergan's BIOCELL products based upon Allergan's incorrect, misleading and negligent statements. Plaintiff and her physician were unable to identify the inherent and hidden dangers of Allergan's products. Neither Plaintiff nor her physician would have chosen Allergan's BIOCELL products had adequate, accurate warnings and risk information been relayed, and Plaintiff would not have suffered the losses described.

223. Allergan's conduct was careless, negligent and undertaken with wanton and willful disregard for the rights and health of Plaintiff.

224. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

[43]See *Brewer v. Stop Stick, Ltd.,* No. 2:04-CV-613FTM33DNF, 2005 WL 2614537,*2 (M.D. Fla. Oct. 14, 2005); SUBSTANTIVE INSTRUCTIONS, JICIV FL-CLE 400-1;

COUNT VI

NEGLIGENT MISREPRESENTATION (PARALLEL FEDERAL REQUIREMENTS UNDER 21 C.F.R. PART 814, § 814.39(d); 21 C.F.R. § 801.6, ETC.)

225. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

226. Specific defects in the BIOCELL line of products as specified above in this Complaint rendered it defective and unreasonably dangerous, and not fit for its intended purpose.

227. At all relevant times, Allergan was engaged in the business of selling BIOCELL implants for use, and in fact did sell the BIOCELL line of products used by Plaintiff's implanting surgeon. In the course of marketing the BIOCELL line of products, Allergan made untrue representations of material facts and omitted material information to Plaintiff, Plaintiff's physician, the FDA and the public at large. Allergan made these misrepresentations and omissions in statements intended to induce physicians to recommend and use the BIOCELL line of products. Allergan's characterizations of its product, its representations regarding safety and superiority, biocompatibility, etc., some of which are described in the preceding paragraphs, and its simultaneous omission of important safety risks associated with its textured BIOCELL product line, constitute negligent misrepresentation in violation of its duty of care to exercise care with regard to the accuracy of statements and representations regarding its BIOCELL product line.

228. Allergan had a duty to reasonably and accurately represent its product characteristics and safety profile pursuant to state and parallel federal law, including 21 C.F.R. part 814, § 814.39(d); 21 C.F.R. § 801.6; 21 U.S.C. § 352(a)(1), (f)(2), (q).

229. Plaintiff would not have consented, and Plaintiff's physician would not have recommended and implanted the BIOCELL line of products in Plaintiff had they known the actual safety risks related to the BIOCELL product line and that Allergan's product representations were untrue.

230. Allergan was negligent in making misrepresentations and omitting material information when Allergan knew, or had reason to know, that its products were defective and unreasonably dangerous, and that the information provided was not accurate.

231. Plaintiff and Plaintiff's physician would reasonably be expected to use the BIOCELL line of products in light of Allergan's hard-hitting, glossy, and extensive marketing and sales campaign where safety, research, testing, state-of-the art design and manufacturing, proven attributes, biocompatibility and other product qualities were aggressively and unequivocally touted. Allergan intended to induce Plaintiff and Plaintiff's physician to rely on its misrepresentations and omissions to use these devices in lieu of safer implants.

232. Plaintiff and Plaintiff's physicians relied on Allergan's misrepresentations and were justified in relying on the misrepresentations and omissions about the safety risks related to the BIOCELL line of products.

233. The state law duties and requirements are parallel to, and not different from or in addition to, the federal duties and requirements that require Allergan to accurately represent and refrain from misrepresenting the safety risks and characteristics of the BIOCELL implants. *See*, *e.g.*, 21 C.F.R. part 814, § 814.39(d); 21 C.F.R. § 801.6; 21 U.S.C. § 352(a)(1), (f)(2), (q). Allergan was required to monitor, investigate and report adverse events and to provide strengthened warnings and to then seek approval from the FDA for updated warnings given the serious risk to life and health that BIOCELL products pose, when such risk was known or should

have been known to Allergan. *See*, *e.g.*, 21 C.F.R. part 814; § 814.20(14)(e), § 814.39, § 814.80, § 814.82.

234. Allergan, by commission, omission and failure to act, breached its duties and negligently misrepresented the safety profile and true risks associated with its BIOCELL products. It promoted the product line aggressively, with strong representations far above an expected sales pitch, causing patients and their physicians to utilize the BIOCELL line and wrongly believe it to be superior in safety and efficacy.

235. Allergan knew or should have known sufficient information regarding the serious health risks posed by its BIOCELL products, it was compelled to strengthen its warnings, and to refrain from misstating the characteristics of the product line to physicians and patients, including Plaintiff. Because Plaintiff's physician, Plaintiff and the FDA were not aware of the information known to or knowable by Allergan, the safety of the BIOCELL product line was continuously misrepresented. Allergan is liable for the negligent misrepresentations it made regarding the BIOCELL implants pursuant to the laws of Florida.[44]

230. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

[44]See *Gilchrist Timber Co. v. ITT Rayonier, Inc*., 696 So. 2d 334, 337 (Fla. 1997) (pecuniary losses only); SUBSTANTIVE INSTRUCTIONS, JICIV FL-CLE 400-1; 409.8;

COUNT VII

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY (PARALLEL FEDERAL VIOLATIONS UNDER 21 C.F.R. §820.1(a), 21 C.F.R. §820.5, 21 C.F.R. §820.3(y), 21 C.F.R. §820.70(a), (c), (e); 21 U.S.C. §351, ETC.)

231. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

232. At all times relevant, Allergan manufactured, distributed, advertised, promoted, and sold the recalled BIOCELL implants and impliedly warranted to Plaintiff that the defective implants were of merchantable quality and safe for their ordinary and intended use in the human body as breast implants for patients undergoing breast surgery for purposes of breast reconstruction or augmentation.

233. Allergan was aware that consumers, including Plaintiff, relied upon Allergan's expertise in the development, manufacturing, research and sales of its BIOCELL line of products.

234. Plaintiff, as a patient seeking a breast reconstruction procedure, was a foreseeable user of Allergan's BIOCELL products.

235. The BIOCELL line of products were expected to reach and did in fact reach consumers, including Plaintiff, without substantial changes in the condition in which the products were manufactured and sold by Allergan.

236. Allergan represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the BIOCELL line of products were safe and reliable; at the same time, Allergan withheld and concealed information about the substantial risks of serious injury and/or death associated with using the BIOCELL products.

237. Allergan represented that the BIOCELL line of products was safe and superior to other breast implant products and concealed information which demonstrated that the BIOCELL line of implants were not safer than the alternatives available on the market.

238. Allergan represented that the BIOCELL line of products were more efficacious than other alternative breast implants, especially with respect to the risk of capsular contracture, and concealed information regarding the true efficacy of the implants.

239. In reliance upon Allergan's implied warranties, Plaintiff used the BIOCELL line of products in a foreseeable manner as intended, recommended, promoted, and marketed by Allergan.

240. Allergan breached the implied warranty of merchantability in connection with the sale and distribution of recalled BIOCELL implants. They were not in the condition as represented or manufactured in accordance with specifications, in violation of state law and parallel federal law, for example 21 C.F.R. § 820.1(a), 21 C.F.R. § 820.5, 21 C.F.R. § 820.3(y), 21 C.F.R. § 820.70(a), (c), (e); 21 U.S.C. § 351. At the point of sale, the implants were not of merchantable quality, safe and fit for their intended use, in violation of Fla. Stat. Ann. §§ 672.314, *et seq*.

241. Had Plaintiff known BIOCELL implants were unsafe for use in the human body or were not manufactured in accordance with specifications, she would not have purchased them and consented to have them implanted, and Plaintiff's physicians would not have recommended them.

242. As a result of Allergan's wrongful acts and omissions, Plaintiff suffered damage and injury as pled throughout this complaint. Allergan has refused to provide appropriate warranty relief notwithstanding the substantially increased risk of developing BIA-ALCL.

Plaintiff reasonably expected, at the time of purchase, that the recalled BIOCELL implants would not present a substantial risk of bodily harm due to BIA-ALCL.

243. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

COUNT VIII

BREACH OF EXPRESS WARRANTY

244. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

245. At all times relevant, Allergan manufactured, distributed, advertised, promoted, and sold the recalled BIOCELL implants, including the product sold to and implanted in Plaintiff.

246. Pursuant to 21 U.S.C. § 360k, the statements made by Allergan in the PMAs that continued until July 24, 2019, the date of the world-wide recall, as well as statements that were non-PMA described above, constitute a violation of the PMA, because the FDA's conditional approval of the BIOCELL devices warned Allergan that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws." Allergan's violations of these warranties are also a violation of parallel state law.

247. Allergan misrepresented the safety and efficacy of the BIOCELL implants, and wrongly minimized the associated risks in its voluntary, non-PMA statements. As previously described, Allergan relentlessly marketed its BIOCELL product line and encouraged patients to undergo BIOCELL implantation with express representations as set forth above and including:

a. That breast augmentation is the most common and uncomplicated plastic surgery;

b. Decades of experience with the science of breast augmentation have greatly improved safety;

c. Its implants are tested and durable;

d. Its implants have enhanced technology for safer and more beautiful options than ever before;

e. Their implants have been shown to be biocompatible and reliable, making the line an appropriate choice;

f. BIOCELL products are premium and proven quality;

g. The products are innovative, premium quality;

h. The products have "proven BIOCELL textured surface."

i. Allergan noted it would continue its long-terms studies to look at long term complications, including cancer and would update labeling on a regular basis;

j. BIOCELL has "super quality, higher satisfaction and even wider choice."

k. "Naturally you want the best, the safest, the most predictable results. With the …410 range of products, you can achieve those aims."

l. For three decades we have been at the forefront of breast augmentation and reconstruction technology, and our …style 410 range is widely acknowledged to be the very best breast implant available."

248. Allergan also specifically misrepresented the risk of BIA-ALCL for patients implanted with BIOCELL products. This misrepresentation resulted in injury to patients, including Plaintiff.

249. Allergan's voluntary, non-PMA statements, as more specifically outlined in the preceding paragraphs as well as other voluntary non-PMA statements in other similar voluntary statements such as marketing and advertising to physicians and patients, constituted express warranties which were false and misleading, and failed to adequately warn of the risks.

250. Plaintiff and her physician relied upon the statements made by Allergan.

251. The voluntary non-PMA express warranties were improper, false and misleading statements, not approved by the FDA, and were not the subject of pre-market approval.

252. Allergan breached its express warranties pursuant to Fla. Stat. Ann. §§ 672.313, *et seq*.

253. Allergan breached its express warranties to Plaintiff. These claims parallel and do not modify or exceed applicable federal requirements.

254. Allergan's conduct was undertaken with disregard for the rights and health of the Plaintiff, and other patients.

255. As a proximate result of Allergan's wrongful conduct, Plaintiff has been severely harmed, and has endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity and other economic and non-economic damages. The losses are permanent and continuing in nature.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

COUNT IX

PUNITIVE DAMAGES

284. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

285. The acts and omissions of the Allergan as set forth herein constitute intentional, fraudulent, malicious, reckless and/or gross misconduct, and wanton and willful disregard of the rights and health of Plaintiff. Accordingly, Plaintiff is entitled to an award of punitive damages as authorized by Fla. Stat. Ann. § 768.72, *et. seq.*

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Allergan, as contained in the Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgement against Defendant, and each of them, individually, jointly and severally, for the following relief:

1. Awarding compensatory damages, including all non-economic and economic damages or other damages allowed by law;
2. Awarding of medical monitoring not otherwise provided;
3. Awarding pre-judgment and post-judgment interest to Plaintiff;
4. Awarding all statutory damages and relief;
5. Awarding the costs and the expenses of this litigation to Plaintiff;
6. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law;
7. Awarding punitive and/or treble damages as provided by law; and
8. Granting all such other relief as the Court deems necessary, just, equitable, and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims in this Complaint so triable.

DATED: June 30, 2020

RESPECTFULLY SUBMITTED,

/s/ Virginia Buchanan
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