IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY CASE NO.634 MASTER DOCKET NO.: BER-L-
	HON. RACHELLE L. HARZ, J.S.C.
Plaintiffs alleging personal injuries and associated damages, v. ALLERGAN, INC., ALLERGAN USA, INC., and DOEs 1- 100; This document relates to: ALL ACTIONS.	MASTER LONG FORM COMPLAINT AND JURY DEMAND

MASTER LONG FORM COMPLAINT AND JURY DEMAND

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Plaintiffs, through Plaintiffs' Liaison Counsel, file this Master Long Form Complaint against Defendants, Allergan, Inc., Allergan USA, Inc. ("Allergan")[1] and DOEs 1-100 (collectively "Defendants"), as an administrative method to set forth common facts and claims which individual Plaintiffs, their spouses, estates, beneficiaries, representatives, or others may assert against Allergan in this litigation.

The Master Long Form Complaint does not necessarily include all claims or allegations that may be asserted in all of the personal injury actions filed in, or transferred to, this Court. The Master Long Form Complaint does not constitute a waiver or dismissal of any claims that may be asserted in any individual action, and Plaintiffs may amend the Master Long Form Complaint as circumstances may warrant.

Plaintiffs, complaining against the Defendants, say as follows:

INTRODUCTION

1. Plaintiffs are patients who had Allergan's BIOCELL breast implants and/or expanders implanted into their bodies. Evidence has emerged over time that these implants and expanders cause a form of cancer known as Breast-Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

2. On July 24, 2019, Allergan announced a worldwide recall of BIOCELL[2] textured breast implants and tissue expanders (collectively referenced herein as "BIOCELL," "BIOCELL line," "BIOCELL implants," or the "BIOCELL product line"). This followed the U.S. Food and

[1] Allergan, Inc. and Allergan USA, Inc. are the sole named Defendants pursuant to the Proper Party Stipulation filed on August 6, 2020, (which is hereby incorporated by reference), although the conduct described herein may be attributable in whole or in part to Allergan, Inc. and Allergan USA, Inc.'s Related Parties, as defined therein. Plaintiffs reserve all rights pursuant to the Proper Party Stipulation.

[2] BIOCELL is the tradename of Allergan's texturing process and refers to the intended textured silicone elastomer shell on the implants and the tissue expanders.

Drug Administration's ("FDA") request to Allergan to recall the BIOCELL product line due to the risk of BIA-ALCL.

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 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. The placement of tissue expanders was intended to stretch the breast tissue to accommodate the breast implants. More specifically, a tissue expander was an empty breast implant that was gradually filled with normal saline over a period of weeks to months, causing the progressive expansion of the breast tissue until it reached the desired size. In this type of reconstruction, a pocket was made under or above a large muscle in the chest, and the tissue expanders were placed in that space. After the tissue expansion was completed, a second surgery was performed to remove the expanders and insert permanent breast implants.

5. Specific manufacturing processes were used by Allergan for "texturing" of the implants, including a process known as the "salt loss technique." Allergan began marketing the BIOCELL textured breast implants in 1988 (including both saline and silicone filled implants). The BIOCELL product line has been sold and/or implanted in the United States pursuant to multiple regulatory status classifications, including but not limited to 510(k) clearance ("510(k)"), Investigational Device Exemption ("IDE"), Premarket Approval ("PMA"), pre-PMA, and non-

IDE. For example, the BIOCELL tissue expanders have been sold through 510(k) clearance (including Allergan's Natrelle 133 tissue expanders).

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, their patients, about serious health risks, (c) defective design of the BIOCELL line, (d) deliberate, fraudulent concealment, misrepresentation and obstruction of serious health risks, (e) failure to complete mandatory studies necessary to determine the safety, reliability and effectiveness of its products and to otherwise comply with the terms of the PMA, (f) failure to comply with current good manufacturing practices as required, (g) failure to comply with required quality system regulations, and (h) failure to utilize reasonable care, all in violation of New Jersey law, which paralleled, and did not exceed federal requirements (where applicable), which were similarly violated.

7. Plaintiffs' claims against Allergan are not based upon an implied or private causes of action pursuant to applicable federal safety statutes and regulations; rather, Plaintiffs' claims are brought pursuant to New Jersey law, which parallels and does not add to or change the parallel federal requirements.

THE PARTIES

8. Plaintiffs include individuals, in many cases breast cancer survivors, who were implanted with BIOCELL textured breast implants, tissue expanders, or both, for various reasons including but not limited to as part of a reconstructive surgery, due to prophylactic mastectomy due to the presence of the BRCA gene, and for breast augmentation. As a result of having the BIOCELL products implanted, Plaintiffs (1) have been diagnosed with BIA-ALCL and endured

invasive evaluation, explant of the BIOCELL implants, capsulectomy, capsulotomy, further reconstruction, chemotherapy, radiation treatments, and, at times, re-implantation of alternative implants[3]; (2) have not been diagnosed with BIA-ALCL but have suffered injuries including for example the implantation of the BIOCELL implants, fear of developing BIA-ALCL, explantation surgery, foreign body response, inflammation, fibrosis, scarring, increased risk to develop ALCL, evaluation, treatment, and explant of the BIOCELL textured implants due to the risk of BIA-ALCL, with reconstruction and re-implantation of alternative implants for some[4]; or (3) have the BIOCELL implants in their bodies, suffering injuries including for example the implantation of the BIOCELL implants, fear of developing BIA-ALCL, foreign body response, inflammation, fibrosis, scarring, and increased risk to develop ALCL, evaluation, treatment, and desire or intend to have the implants explanted due to the risk of BIA-ALCL, but, due to medical, economic, or other reasons, have not yet undergone explantation. In addition, in some cases the spouses of patients are parties with consortium claims, and the estates and survivors of deceased patients are parties and have claims arising from the pain and suffering and wrongful death of patients who have died due to BIA-ALCL.

9. As a proximate result of Allergan's wrongful conduct, Plaintiffs have been severely harmed, and have endured aggravation or activation of preexisting conditions, the effects of BIA-ALCL, including scarring, pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, inconvenience, loss of enjoyment of life, fear of developing BIA-ALCL, death for certain patients, incurred costs for medical care and treatment, loss of wages and wage earning

[3] Following explantation of the recalled implants, many Plaintiffs have been advised by their medical professionals that they cannot safely undergo reimplantation of an alternative device and others have chosen to forego the implantation of an alternative device in fear of further harm.

[4] *See* footnote 3.

capacity, and other economic and non-economic damages. The losses are permanent and continuing in nature.

10. Allergan, Inc. and Allergan USA, Inc. consist 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, Inc. and Allergan USA, Inc. do 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. Allergan, Inc. and Allergan USA, Inc. have shared responsibility for the damages sustained by Plaintiffs.

11. 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 on or about May 8, 2020. Allergan USA, Inc. was involved in the business of designing, manufacturing, developing, studying, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, warranting 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 Plaintiffs.

12. 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 on or about May 8, 2020. Allergan, Inc. was involved in the business of designing, manufacturing, developing, studying, preparing, processing, inspecting, testing, packaging, promoting, marketing,

distributing, labeling, warranting 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 Plaintiffs. Allergan, Inc., is the registered holder of the BIOCELL trademark. Allergan, Inc. also announced the recall of BIOCELL products.

13. Allergan, Inc., acquired Inamed Corporation on March 27, 2006 and took over the manufacturing, marketing, studying, selling and distributing of BIOCELL products.

14. 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.

15. 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.

16. 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.

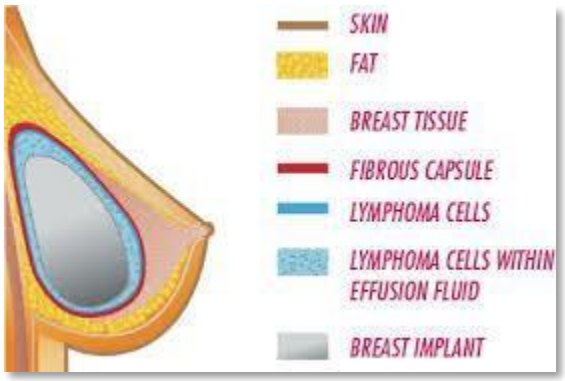
17. At all relevant times, Allergan, Inc. and Allergan USA, Inc. acted in all aspects as the agent and alter ego of each other. The Allergan Defendants carried out a joint venture, scheme, business plan, or policy in all respects, carried on the business of the other upon joinder, acquisition or merger, 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.

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

FACTUAL BACKGROUND

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

19. BIA-ALCL is a subtype of non-Hodgkin's lymphoma, a cancer of the immune system. It often presents as a late-onset seroma, a non-resolving fluid collection around a breast implant, as a solid mass in the scar tissue surrounding the implant, or in an adjacent axillary lymph node. A patient with BIA-ALCL may have some, all, or variations of severe inflammation, 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 numerous cases reported 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 discovered in an advanced state, BIA-ALCL has a dire prognosis and a high mortality rate.[5]



Implant Diagram Reflecting Seroma (Effusion Fluid)

[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.

20. Allergan's concealment and manipulation of information about BIA-ALCL, and the connection to the BIOCELL implants, caused physicians and patients to be uninformed and misinformed about the risk of BIA-ALCL, resulting in BIOCELL implants being implanted when they otherwise would not have been, and caused delays in patients being properly evaluated, diagnosed, and treated for BIA-ALCL, and caused significant underreporting of BIA-ALCL cases.[6]

21. The recommended diagnostic testing for BIA-ALCL is painful and 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 reportedly presenting from six months to 26 years or more post-implant.[7] BIA-ALCL is treated with extensive, disfiguring surgery to remove the implant and the surrounding capsule and tissue, and when the disease has spread past the capsule, can include the removal of ribs, lymph nodes, and other muscle and tissue. Treatment may include additional reconstructive surgery, chemotherapy, radiation, stem cell transplant, and other medical interventions. This cancer causes permanent physical and emotional 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.

[7] 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 knew or should have known well before this date of the falsity of these representations, and the association between ALCL and its BIOCELL implants.

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

23. 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 implants and the risk of ALCL associated with them, and on an ongoing basis.

24. Allergan was required by New Jersey law 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.

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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.

Further, Allergan was required by New Jersey law to warn physicians, and as a result patients, and the FDA and other regulatory bodies, about the true risk profile of BIA-ALCL.

25. Allergan's duties under state law are parallel to Allergan's continuing, parallel federal post-market duty to learn of published and unpublished reports involving BIOCELL implants, take that information into consideration in connection with its ongoing duty to ensure the adequacy of the warnings given in the labeling and other communications with doctors and patients, 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.

26. Allergan also had a duty under New Jersey law and a parallel federal duty to find, investigate, and report adverse events to third parties, including 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 was triggered when Allergan became aware of information from ***any*** source that reasonably suggested 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).

27. Allergan received complaints and reports from physicians and patients with regard to the connection between the BIOCELL implants and BIA-ALCL, yet it failed to reasonably investigate those complaints and reports, failed to adequately warn physicians and patients about the risk of BIA- ALCL associated with its BIOCELL implants, and failed to adequately report and warn of this information to the FDA and other regulatory bodies. 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, Allergan conceded that it had received 104 reports of confirmed, suspected, and pending confirmation ALCL cases associated with BIOCELL implants between at least 2007 and 2015.[11]

28. Despite these reports and Allergan's obligations under New Jersey law to act reasonably, including to find, investigate, warn about, and report adverse events, including to the FDA, 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 June 23, 2010. That report was from an event that occurred more than three years earlier, on or about June 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

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[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/.

[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.

accurate reporting of these events is an important part of product safety surveillance and plays a vital role in tracking medical devices 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
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

29. Under New Jersey law, as a manufacturer, Allergan has and is deemed to have, unique knowledge concerning the nature, frequency, detectability, severity, and treatability of the complications and risks associated with its devices. Under New Jersey law, the manufacturer is required to act reasonably in understanding and warning about the risks and complications that may be associated with a medical device, including to third parties such as the FDA. Similarly, New

Jersey law parallels the extensive post-market requirements under the FDA Regulations related to knowing of risks and complications, 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); and

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").

30. As discussed *infra*, the duties under New Jersey law to monitor, investigate, evaluate, and timely warn of injuries and other important safety information regarding a medical device are no different from, and are not in addition to, the federal requirements, all of which Allergan violated when it failed to monitor, investigate, evaluate, and timely warn regarding BIA-ALCL risk and incidence and to take the necessary steps to continually evaluate the safety, effectiveness and reliability of its BIOCELL product line, and to take necessary steps to warn, strengthen warnings, and take other measures to assure compliance with its state law obligations.

II. THE RECALL OF THE BIOCELL LINE OF IMPLANTS

31. On July 24, 2019, Allergan announced a global recall and discontinuation of marketing and sales of the BIOCELL product line after the Food and Drug Administration requested the recall. The recall was requested by the FDA because BIA-ALCL was occurring more frequently than previously understood by the FDA and nearly always in conjunction with Allergan's BIOCELL implants. At the time of the BIOCELL recall, the FDA indicated that based on information available to it, 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

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

it, 481 were attributed to Allergan implants. Out of the 531 ALCL cases with a clearly identified 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 identified this recall as a "Class I recall, the most serious type of recall," and warned that "use of these devices may cause serious injury or death."

32. On August 20, 2020, the FDA provided "an update on adverse events reported to the Agency related to breast implants, including" BIA-ALCL, as of January 5, 2020. The FDA had documented a total of 733 unique BIA-ALCL cases and 36 patient deaths globally, which reflected "an increase of 160 new cases and 3 deaths since the early-July, 2019 update." Of the 733 total cases of BIA-ALCL, 620 cases were for Allergan implants, and 47 cases involved implants from an unknown manufacturer. 496 of the 733 cases were reported to have textured implants, and 209 cases did not specify the implant surface. Of the 36 total patient deaths, "15 of the 16 patients for which the manufacturer of the implant is known, are reported to have had an Allergan breast implant at the time of their BIA-ALCL diagnosis. In terms of implant surface, of the 36 cases reported of patient deaths, 16 cases reported textured implants, and 19 cases did not contain information on the implant surface." The reported incidence of BIA-ALCL continues to increase

[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.

as information that Allergan knew or should have known, and which Allergan withheld from the public in violation of New Jersey law becomes known.

33. 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 implants in those countries. Regulatory agencies took these strong regulatory actions due to the causal association between the BIOCELL implants and BIA-ALCL.

34. The recalled BIOCELL implants are:

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

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

Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:

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15 CE marking is a certification mark used in Europe to permit marketing of a medical device.

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 exceeded 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 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]

35. As to each of the BIOCELL implants, safer alternative designs were available which were practical, feasible, and which would have reduced or likely completely removed the risk of injury posed by the BIOCELL implants. For example, "Smooth" breast implants were on the market at all 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 the 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 BIA-ALCL cases.

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

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

36. McGhan Medical Corporation, Allergan's predecessor, began marketing BIOCELL implants in or about 1987.

37. 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 implants.

38. 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, remained available for augmentation and reconstruction during this time period, but were not PMA devices.

39. 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.

40. 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

A. THE BIOCELL TISSUE EXPANDERS WERE 510(K) DEVICES

41. Allergan was granted 510(k) clearance for Allergan textured tissue expanders in 2011 and 2015. Clearance for the Natrelle 133 Plus Tissue Expander was granted in January 2011. Clearance for the Natrelle 133 Tissue Expander With Suture Tabs (K143354) was granted in August 2015. The tissue expanders were always 510(k) devices, were never submitted for PMA, and were never regulated as PMA devices.

B. THE BIOCELL PMAs

42. The BIOCELL product line received PMA on May 20, 2000, November 17, 2006, and February 20, 2013. The BIOCELL breast implant product line was categorized as a Class III Medical Device. The duties of a Class III medical device manufacturer such as Allergan do not end with PMA approval. Rather, federal requirements impose a number of ongoing manufacturer responsibilities, which are paralleled by their duties under New Jersey law. This includes the requirement that they strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA. This is pursuant to applicable federal regulations, including, but not limited to, 21 C.F.R. parts 803, 814 and 820. Allergan was required

to comply with these federal requirements, and to conduct ongoing safety studies and to notify the FDA of any unexpected serious problems with the device.

43. 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 applicable federal requirements. Allergan was prohibited by federal law (and parallel New Jersey law) from marketing BIOCELL implants if they were adulterated.

44. 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, a restricted device is deemed misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. § 352(q). In the PMAs for BIOCELL implants, the devices were designated as restricted devices, subject to 21 U.S.C. § 352(q). Thus, Allergan had a federal duty not to advertise the BIOCELL implants in a manner that was false or misleading. Allergan was prohibited by federal law (and parallel New Jersey law) from selling and distributing misbranded products.

45. Allergan was required by the terms of the PMAs, and applicable federal requirements, all of which were paralleled by applicable duties under New Jersey law, 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.[18] 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

[18] 21 C.F.R. 814.20(e).

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).

46. Allergan failed to comply with these obligations under New Jersey law and parallel federal law. The state law duties identified in this Master Complaint do not exceed or modify the requirements imposed by federal law, which are parallel. State law precludes the sale of adulterated and misbranded products as well as those that contain inadequate warnings based upon the information that was known or should have been known to the manufacturer. New Jersey law also required Allergan to adhere to all applicable design and manufacturing specifications, as did federal law to the extent applicable. But for Allergan's violations of the aforesaid state law duties, and federal requirements, Plaintiffs' injuries would not have occurred.

C. ALLERGAN'S PMA FOR THE BIOCELL IMPLANTS INCLUDED CONDITIONS THAT WERE NEVER MET BY ALLERGAN, INCLUDING THE REQUIREMENT TO DISSEMINATE STRENGTHENED WARNINGS BEFORE OBTAINING FDA APPROVAL FOR THE STRENGTHENED WARNINGS

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

48. The FDA set forth in the PMA certain "Conditions of Approval." These Conditions of Approval constituted specific federal requirements applicable to the BIOCELL product line. 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 involved 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)."

49. 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.

50. The duty to warn under New Jersey law was parallel to the duties under the PMA and applicable federal statutes and regulations. 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 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. Specifically, the Conditions of Approval for the BIOCELL implants 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."

51. 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 of approval specified in the PMA approval order for the device.").

52. 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). As cited above, the Conditions of Approval directed and required Allergan to disseminate strengthened labeling pending FDA approval, pursuant to the CBE regulations.

53. Pursuant to the PMA Conditions of Approval, 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 BIA-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).

54. The applicable regulatory history, 73 Fed. Reg. 49603, provided 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…
>
> 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…**

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

> 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…

55. 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]

56. 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 paralleled by the New Jersey state law duty to maintain adequate warnings.

57. On or about November 17, 2006, Allergan was granted PMA approval to market a segment of the BIOCELL product line, 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 PMA built upon and included materially similar Conditions of Approval to those already in effect for the BIOCELL product line, referenced in the PMA as "enclosed Conditions of Approval," and also included additional requirements:

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

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

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.

58. 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 and to patients, once the BIOCELL line was on the market. 21 C.F.R. part 814, § 814.39(d). State law requirements parallel these federal requirements, also requiring the timely submission and dissemination of appropriately strengthened labeling to be directed to physicians and patients to warn of the risk of BIA-ALCL.

59. On February 20, 2013, Allergan was granted PMA for a segment of the BIOCELL product line known as the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants ("Natrelle 410"). The PMA included conditions of approval, including 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.

60. 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.

61. 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."

62. 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 Allergan. Allergan's violations of state law and parallel federal requirements included the failure to disclose and adequately warn of the risk of BIA-ALCL in a timely fashion as aforesaid, and on an ongoing basis after each segment of the BIOCELL line was on the market. Allergan continually acquired new information regarding the association and causal connection between its BIOCELL implants and the development of BIA-ALCL and knew or should have known that the BIOCELL implants involved much greater frequency of BIA-ALCL than other textured breast implants manufactured by other manufacturers.

Allergan failed to comply with its duties under New Jersey law and the parallel federal requirements, and as a result safety and risk information was not adequately or accurately included in the warnings in the product labeling, or communicated to physicians, patients, the medical community, or to the FDA.

63. On information and belief, the 2013 Directions for Use for the Natrelle 410 breast implants contained the first "warning" provided for the BIOCELL implants in the United States with regard to the association between the BIOCELL implants and BIA-ALCL.

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.

64. After inclusion of the 2013 warning, Allergan obtained risk information on an ongoing basis, and Allergan knew or should have known that the warning was inadequate and insufficient. Allergan failed to take the steps required under New Jersey law and the parallel federal requirements to adequately describe the nature, severity, frequency, or causal connection of BIA-ALCL to the BIOCELL implants. Allergan 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, and the parallel federal requirements, earlier and stronger warnings and more adequate and accurate statements of the risks and risk profile, which adequately disclosed what Allergan knew or should have known would have been provided to physicians and patients for the BIOCELL line from that point forward.

65. Allergan also continuously undermined the warnings that were provided in order to obscure the risks and risk profile of the BIOCELL implants. This included understating or completely obscuring or hiding the risk of BIA-ALCL in its non-PMA strategies and communications. Allergan knew that physicians who were already familiar with the BIOCELL product line, including many who had used BIOCELL implants for a period of time, were unaware of the new warnings. Allergan failed to notify them of new warnings, and where the new warnings were provided, Allergan misled physicians about the nature and context of the 2013 and other BIA-ALCL warnings provided in connection with the BIOCELL implants. This non-PMA conduct and these non-PMA statements included efforts by Allergan to reassure physicians who became aware of the warnings that the warnings were of no significance, that the BIOCELL implants' risk profile was not impacted, and led physicians who had expressed concerns about possible risks to believe 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 non-PMA tactics and misleading non-PMA communications and interactions was to obstruct knowledge of, and/or weaken the impact of the warning(s) provided. In conjunction with these efforts, none of which were subject to PMA, Allergan did not adequately share, disseminate, or warn about literature and internal reports linking the BIOCELL implants and BIA-ALCL. Consequently, physicians were either unaware of the risks, or unaware of the extent of the risks and the significantly increased risk for the BIOCELL implants as contrasted to others, and they therefore failed to adequately disclose the risk of BIA-ALCL. As a result, Plaintiffs' physicians continued to recommend and utilize the BIOCELL implants without knowledge, or with insufficient knowledge, of the risk of BIA-ALCL when recommending BIOCELL implants to their patients during informed consent discussions. Had

Plaintiffs' physicians been adequately warned of the risk of BIA-ALCL associated with BIOCELL implants, Plaintiffs' physicians would have provided this information to their patients and other, safer, implants would have been recommended and used.

D. THE FDA WARNED ALLERGAN THAT IT FAILED TO COMPLY WITH 21 C.F.R. § 814.82(A) POST APPROVAL STUDY REQUIREMENTS

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

67. Under the provisions of 21 C.F.R. § 814.82(a)(2) and (9), the FDA imposed post approval study requirements as a condition of device approval, based on the regulations providing for such requirements 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 of approval that the applicant continue to evaluate the safety, effectiveness and reliability of the device, including the number of patients to be evaluated. Such requirements were imposed here, which were parallel to Allergan's duties under New Jersey law.

68. In its May 14, 2020 Warning Letter to Allergan, the FDA communicated the finding 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

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

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 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)."

69. 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.

70. The FDA further noted that there had been several deficiencies issued to Allergan with regard to the Large Post-approval Study and redesigned study, including deficient follow-up rates, such that Allergan's deficiencies and failures prevented adequate evaluation of the safety,

[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.

effectiveness and reliability of the implants. Allergan was directed to correct the failures or face withdrawal of its PMA.

71. Further, in conjunction with the 2013 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.

72. 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.

73. 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.

74. These failures to comply with PMA Conditions of Approval, including the failure to conduct 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 material violations. Important safety information was never collected and the foundation of the PMAs was undercut by Allergan's failures, thus invalidating the foundational safety assumptions of the PMA. These violations are paralleled by Allergan's violations of New Jersey law, in failing to adequately avail itself of important safety information, and take that into account, for example in providing warnings, and providing voluntary, non-PMA statements and information.

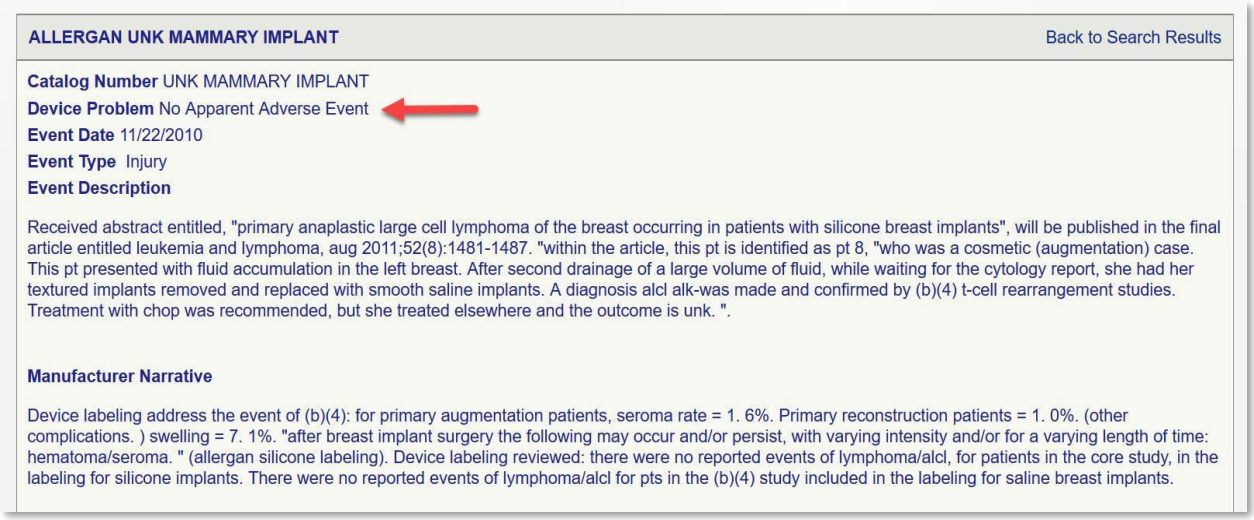
IV. ALLERGAN HEAVILY PROMOTED THE BIOCELL IMPLANTS AND CONCEALED OR OBSCURED THE RISKS AND TRUE RISK PROFILE

75. Allergan employed aggressive promotion and marketing of the BIOCELL line, and at the same time concealed and obscured the risks, including through the inadequate submission of adverse event reports, for example with incorrect manufacturer names, including the outrageous use of "Santa Barbara" and "Costa Rica," instead of using the name Allergan in the field for manufacturer name. As a result, physicians, patients, and the FDA searching for Allergan's adverse events were respectively deprived of important safety information, and unable to detect safety signals and trends in Allergan's products. This ultimately deprived physicians and patients of the necessary information to make an informed decision about whether the BIOCELL implants were safe and effective, and whether to utilize them.

76. Allergan also inaccurately and repeatedly, on numerous occasions, reported ALCL with a "no apparent adverse event" description of the device event in MDR's, thus undermining the significance of this surveillance tool, and keeping important information from physicians and patients.[23] In one MDR, a case of BIA-ALCL associated with Allergan's implants was categorized as "no apparent adverse event" when the patient was known by Allergan to have required chemotherapy for the disease. Notice of this complication came to Allergan in the same time frame as 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 an MDR and quoted the product label reference to seroma. This was deliberately misleading as the labeling contemplates seroma as a fairly common early post-operative finding, and Allergan's reference in

[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

the report obscures the clinical significance of the more ominous finding of late-appearing and chronic seromas, which were known by Allergan to be abnormal and unexpected. Chronic seroma can be an indication of chronic inflammation and cancer, and it often seen as a precursor to a BIA-ALCL diagnosis.



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.

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 illustrate Allergan's persistent efforts to obscure reported cases of BIA-

ALCL.[24] [25]

77. In addition to mischaracterizing 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 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, was mandated by state law and parallel federal requirements, including 21 C.F.R. § 803.52. This information and the other similar information recited herein should have been disseminated to physicians and patients to utilize in making treatment decisions.

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[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 manufacturers' textured implants.

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

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

78. Allergan also did not timely warn of or report cases of BIA-ALCL in violation of state law and parallel federal law. In a number of cases, Allergan did not warn of or report cases of BIA-ALCL that were diagnosed many years before an MDR was submitted. Delays in monitoring, identifying, reporting and properly advising and warning physicians, patients, and the FDA about BIA-ALCL and its appearance in patients with BIOCELL implants allowed Allergan to keep the products on the market for many years with a misleadingly benign risk profile, and caused more patients to be implanted with Allergan's textured implants and later suffer a diagnosis of BIA-ALCL and/or increased risk of BIA-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 deliberate obscuring of adverse events, and thus risk and risk profile information, neither physicians nor patients were properly or adequately informed about the risks and risk profile of BIOCELL implants.

79. In violation of federal law and parallel state law, Allergan improperly submitted BIA-ALCL reports to the FDA in the form of "Alternative Summary Reports" ("ASRs") pursuant to 21 C.F.R. § 803.19. This effectively prevented physicians, patients, and the FDA from knowing or appreciating the true risk and risk profile information.

80. 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 *only* for the reporting of events "well known" to the agency and which had been reported for years to the FDA.

[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.

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, and do not provide adequate information to understand the risks and complications being reported.

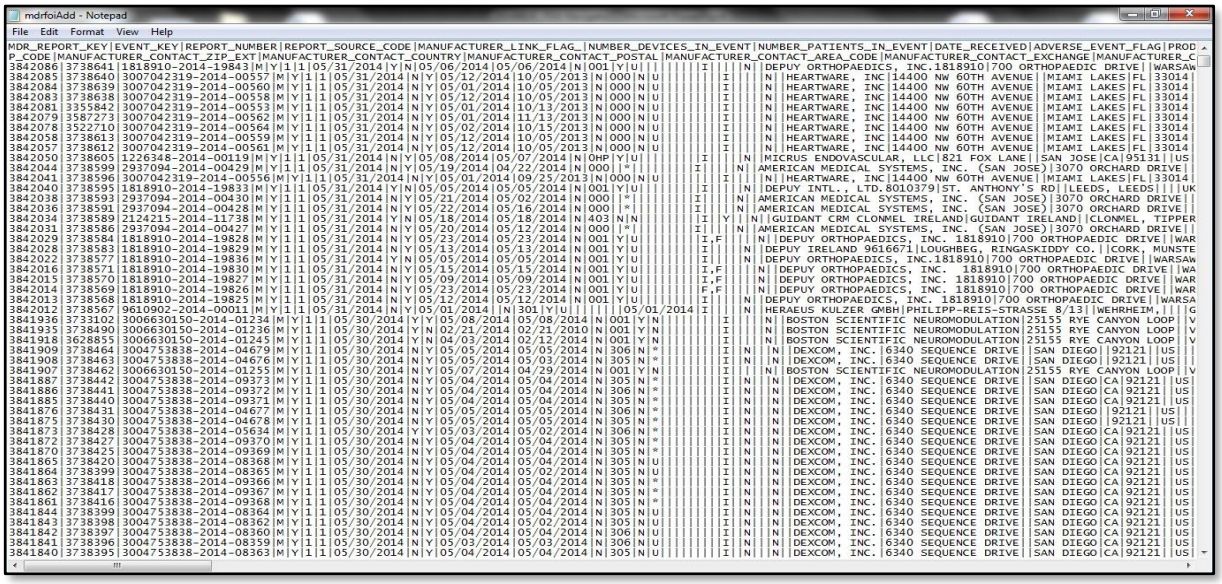
81. The FDA was clear, however, that events contemplated by 21 C.F.R. § 803.50 and § 803.52 *were not covered* by the exemption and had to be reported as specified in those sections. The items that were not covered by the exemption included events requiring a 5-day report, events involving a Class III 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 BIA-ALCL was a unique and uncommon event not covered by the exemption.[27]

82. 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 is expected to be less significant since indicating common and expected device issues. However, with respect to a serious injury or unusual and uncommon product issue, using this method of reporting clearly obstructs the required flow of 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. Thus, the improper use of ASR's had a material impact in preventing risk and risk profile information from reaching physicians, patients, and the FDA.

[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.

83. In 1999, Allergan (through the exemption obtained by its predecessor McGhan), began using ASRs for reporting complications and adverse events associated with its BIOCELL implants, including for diagnoses of BIA-ALCL. 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 BIA-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.

84. Due to Allergan's improper reporting practices over a period of years, physicians, patients, and regulatory bodies and others relying on public reports to identify serious health risks associated with BIOCELL implants were deprived of important information regarding the safety and risk profile of the BIOCELL line.



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 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. This is a known potential adverse event addressed in the product labeling.

Report Date 01/23/2019

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

85. Despite its knowledge of the true risk profile for the BIOCELL implants and ALCL, in order to maximize its profits, Allergan disseminated a large number of voluntary statements which were not the subject of a PMA, through avenues such as promotional and marketing brochures and websites, and communications through sales representatives and paid consultants, which suggested the products were superior, safe, and well-studied and failed to include any reference to the ALCL risk. These voluntary and non-PMA statements were misleading. These misleading statements violated New Jersey law, and rendered the BIOCELL implants misbranded, in violation of 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).

86. For example, referring to its Natrelle Breast Implants in a YouTube video posted on the internet, Allergan noted that the "Pre-Consultation Kit" was available to help a patient prepare for a consultation with her physician. In this direct to patient appeal, which was also seen and relied on by Plaintiffs' physicians, Allergan noted that their implants were "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.

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

87. In their Natrelle Gel-filled implant brochure Allergan made further non-PMA voluntary statements, as it 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 implants were "premium" and "proven" quality.

88. 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." These and the other voluntary, non-FDA approved statements identified herein are illustrative of marketing that was false, presented a misleading risk benefit profile, and was intended to and did result in inducing physicians to recommend the BIOCELL implants, and consequently resulted in implantation into Plaintiffs.

89. Allergan gave direct assurances and promises and warranted that it would update the BIOCELL labeling when necessary to more adequate warn and present risk information, including with regard to cancer:

> *"*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

[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

> 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**. ….."

90. McGhan Style 410's 2002 Brochure promised, "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."

91. In addition to engaging in aggressive marketing directed to consumers and physicians boasting in non-PMA statements 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 counteract the potential impact of the warning. For example, Allergan peppered the literature and professional meetings with statements intended to deflect and obscure the warnings, literature discussing this risk, and the serious and significant ALCL risk to which patients were exposed. Such statements were voluntary, non-PMA statements violated New Jersey law, and violated the PMAs (where applicable). For example, a paid Allergan consultant who was associated with BIOCELL studies and research stated in a book chapter that 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 and maximize Allergan's profits. *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).

92. In addition, Allergan attempted to deflect attention from the risks associated with the BIOCELL line, and its violations of New Jersey law and parallel federal requirements by blaming physicians and disseminating dubious and misleading information. As part of that effort, a "14-point plan" was developed, primarily by Allergan-funded physician consultants, as a way for physicians to allegedly effectively mitigate BIA-ALCL by allegedly avoiding bacteria during implantation. 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."[30] This campaign, designed to mislead plastic surgeons throughout the country, 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).

93. These statements, which are examples of many that contributed to shaping the opinions and understanding of the medical community, including Plaintiffs' treating physicians, were non-PMA statements, and were deliberately false and misleading. Allergan's non-PMA statements, including the creation and dissemination of the "14-point plan", was meant to deflect

[30] 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.

the cause of BIA-ALCL away from the implants' texture to the implanting physicians' allegedly non-sterile technique, which was not accurate.

94. 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, including those of plastic surgery trade associations, product training sessions, and marketing, promotional and sales activities.

95. 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.

96. 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 Plaintiffs and their physicians would have been more fully informed of the risk of BIA-ALCL and Plaintiffs would not have had Allergan BIOCELL implants implanted inside their bodies.

V. MANUFACTURING DEFECTS IN THE BIOCELL TEXTURED SHELLS

97. New Jersey law required Allergan to manufacture the BIOCELL implants in conformance with the design specifications, and in fulfilling that duty, to take reasonable steps to ensure that the manufacturing process resulted in the output of implants in conformance with the design specifications, including the application of reasonable care to confirm this. These state law obligations paralleled federal requirements to ensure manufacture in conformance with the design specifications. In recognition of this requirement, the federal regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. part 820. As explained in these

regulations, Allergan was required to adopt 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:

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

(2) Monitoring and control of process parameters and component and device characteristics during production;

(3) Compliance with specified reference standards or codes;

(4) The approval of processes and process equipment; and

(5) 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 requirements 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.

98. "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);

a. 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;

b. 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;

c. 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:

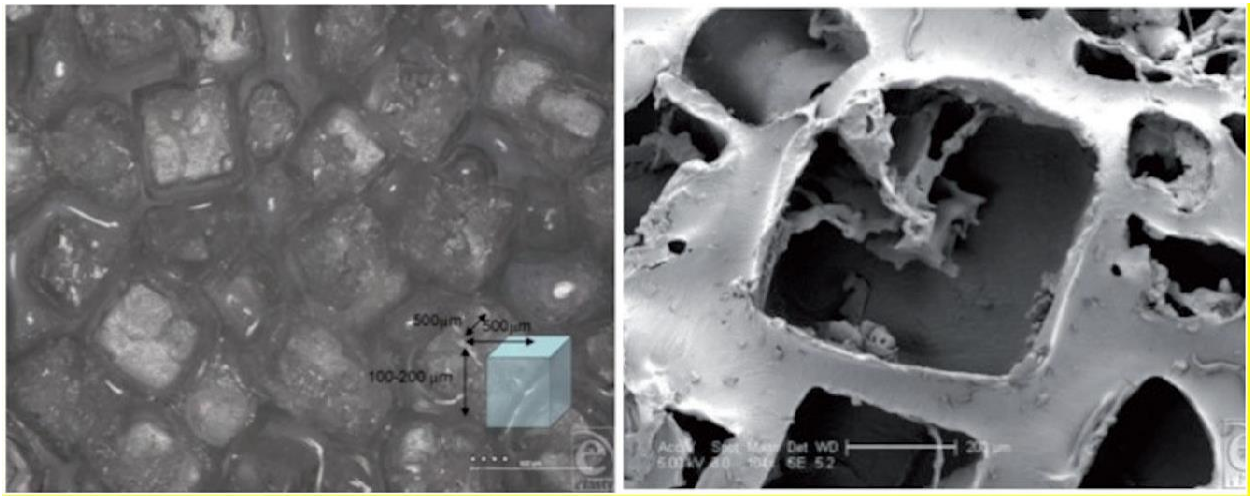
> (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems;
>
> (2) Investigating the cause 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."

99. Allergan used a texturing process in the manufacture of its textured implants.

100. To texturize the surface of BIOCELL implants, Allergan utilized a manufacturing process known as the "salt loss" technique.[31] 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 coherent textured surface. The manual scrubbing process was intended to

[31] *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.

ensure a controlled textured surface and did not provide for the creation of clinically significant particles on or damage to the implant surface.[32]



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

101. Despite specifications and directed processes that required gentle agitation of the surface after a final layer of silicone was over-coated, and most important resulting in conformance with the design specifications for an intact, consistent surface, 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, and otherwise failed to output BIOCELL implants with external surfaces in compliance with the design specifications. For example, on information and belief workers scrubbed the final cured layer of silicone in a scrubbing room using different brushes and applied non-validated methods that resulted in implants that violated the specifications. This violated New Jersey law, as well as Current Good

[32] *See* Michael Atlan, Gina Nuti, Hongpeng Wang, Sherri Decker, Tracyann Perry. *Breast Implant 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>.

Manufacturing Practices, QSRs, and other federal requirements. Allergan's uncontrolled and non-validated scrubbing process, as employed, resulted in final products that did not meet the specifications. For example, the processes created a "particle laden" environment on the implant surface, far more prevalent and dangerous than any benign particles that might have been anticipated, which exposed patients to particles that were shed into their tissue, caused chronic inflammation, and caused or contributed to the development of BIA-ALCL. Allergan's manufacturing processes also resulted in an implant surface that did not conform to the specifications due to the presence and extent of uneven texturing, that caused tissue damage on implant, and included foreign, degraded and loosened fragments of silicone particles and other materials that caused chronic inflammation and caused or contributed to the development of BIA-ALCL. This constituted a defectively manufactured surface, as the manufacturing was in variance from the product specifications and processes, resulting in the production of a product different than the product approved by the FDA, causing severe harm to patients.

102. Further, Allergan's manufacturing processes caused an unintended increase in the surface area of the BIOCELL implants. The unintended increase in surface area caused or contributed to the dangerous proliferation of T-cells. In addition, Allergan's 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 damage caused to the tissue by shear forces from the excessive number of jagged and sharp particles on the implant surface, and micro-movement shear forces caused by mechanical attachment and detachment of the textured surface to the tissue capsule. The chronic inflammation caused by Allergan's defective manufacturing processes stimulates excessive T-

cells and can cause malignant mutations in T-cells, ultimately leading to BIA-ALCL in some women.

103. The labeling for the BIOCELL implants, including the Directions for Use, described the intended output of the surfaces, including description of the exterior shell as, "a sac of silicone elastomer (rubber)," "barrier shell technology resulting in a low diffusion silicone elastomer shell..," and in describing this surface, described, "finely powdered silica that is tightly bound to the silicone rubber pouch." The defective manufacturing process yielded BIOCELL implants that did not comport with these descriptions. The harms described above directly resulted from the variations from the specifications. Had Allergan undertaken the manufacturing process in an appropriate manner, it would have consistently produced a product in conformity with its approved specifications. Moreover, by consistent and proper application of cGMP's, proper evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, as well as utilization of necessary standard operating procedures, Allergan would have assured the production of BIOCELL products that complied with its specifications.

104. 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.[33] The inspection raised twelve deviations, 2 delineated as critical and 3 delineated as major. The inspection also yielded 8 remarks, including one major one.

[33] *See*, https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf.

105. The French authorities (ANSM) had 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.[34]

106. 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. Significantly, the French authority documented major deviations from standards and legal requirements in connection with Allergan's salt loss manufacturing technique for the BIOCELL implants.[35] 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."

107. 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:

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[34] *See*, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) *Preliminary Inspection Report of Allergan Ltd Marlow*.

[35] At the time of the French inspection in 2015, all manufacturing of BIOCELL occurred at Allergan's Costa Rica plant.

> -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)."

108. The French regulators summarized Allergan's 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 to the proper agencies and in the proper manner.

109. In addition to the concerns expressed by ANSM, researchers identified unanticipated 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.[36]

110. 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

[36] *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.

textured BIOCELL implants as a result of the defective manufacturing process 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 micromovement shear forces between the capsule and the shell, cause chronic physiologic inflammation and the development of BIA-ALCL in patients.

111. Pursuant to New Jersey law and its 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 use reasonable care in the manufacture of its breast implants by adhering to the parallel federal specifications set forth in the PMA, as well as the requirements of applicable CGMPs, including 21 U.S.C. § 351; 21 C.F.R. Part 820.

112. Pursuant to New Jersey law Allergan was required to produce BIOCELL implants in compliance with the applicable specifications, and to act as a reasonable manufacturer, in all respects, including compliance with the applicable specifications, applicable CGMPs, and implementation of quality control systems in order to validate processes for the production of its BIOCELL implants. It was also required by New Jersey law and the parallel federal requirements to conduct inspections and testing to ensure the conformance of its BIOCELL implants. Allergan failed to comply with these state and federal requirements, resulting in the production of unreasonably dangerous, non-conforming, adulterated implants.

113. Allergan's failure to comply with New Jersey law and parallel federal law requirements, resulted in the introduction of non-conforming, adulterated BIOCELL implants into the stream of commerce. If Allergan had complied with New Jersey law and the parallel federal requirements, Allergan's BIOCELL line would have been manufactured such that it would have conformed to the specifications and would not have resulted in injuries to Plaintiffs.

114. 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 were limited to an amount that did not adversely affect the implants' quality or safety.

115. 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.

116. 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.

117. 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.

118. 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.

119. The complete specifications, underlying and related internal documentation are in the exclusive control of Allergan and have not been provided in full to Plaintiffs. Plaintiffs reserve the right to amend this section with additional facts and allegations once Allergan produces all of its relevant files for the BIOCELL implants.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

120. 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 Plaintiffs and their physicians the true risks associated with the BIOCELL line.

121. As a result of Allergan's actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that they 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 wrongful conduct, as set forth herein.

FIRST COUNT
(MANUFACTURING DEFECT)

122. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

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

124. Plaintiffs were implanted with BIOCELL implants that failed to meet their specifications, were defective, unreasonably dangerous, not reasonably fit, suitable, or safe for their intended purpose, in violation of New Jersey law.

125. 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 processes and specifications, resulting in variable roughness, excessive and irregular particle formation beyond any particle formation that was reasonably contemplated per the specifications, increased surface area, and continuous micro movement shear forces between the implant surface and the tissue capsule, and the resulting development of chronic inflammation, tissue damage, seromas, and ALCL, none of which was intended or provided for by the design and manufacturing specifications, formulae, processes, and performance standards of Allergan.

126. Allergan knew or should have known that the manufacturing process as implemented 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, none of which was intended by the design and manufacturing specifications. Allergan is strictly liable.

127. Allergan breached its duties under New Jersey law and parallel federal requirements as described, in the defective manufacture of its BIOCELL implants, resulting in the failure to comply with the applicable specifications. The requirements under New Jersey law were parallel to, and not different from or in addition to the applicable federal law requirements, including but not limited to the requirement to comply with the PMA specifications, and for example, 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 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 salt-loss 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 and contemplated by the specifications, 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 salt-loss 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 patients, including Plaintiffs, 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.

128. Allergan knew that the defectively manufactured BIOCELL implants would be implanted in Plaintiffs by physicians, without knowledge of the hazards involved in such use.

129. Allergan is strictly liable for the defective manufacture of the BIOCELL implants.

130. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

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

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

SECOND COUNT
(FAILURE TO WARN)

132. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

133. Allergan had a duty to warn of the risks associated with the BIOCELL implants, including providing accurate and adequate warnings and information regarding the risks, risk profile, complications, and frequency, severity, permanence, and treatability of the risks and complications. Allergan violated its duty to warn, failing to provide adequate warnings and information with regard to the risks, risk profile, complications, and frequency, severity, permanence, and treatability of the risks and complications. This rendered the BIOCELL line of products not reasonably fit, suitable, or safe for their intended purposes.

134. Allergan failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, about the risk of ALCL from Allergan's BIOCELL implants, and that Allergan's BIOCELL implants presented a greater risk and incidence of ALCL than that of other alternative products on the market.

135. Allergan's duty to warn under New Jersey law was parallel to, and not different from or in addition to federal requirements.

136. The parallel federal requirements included the terms and conditions of the PMAs, including the conditions of approval, which among other things required Allergan to disseminate and submit for approval more accurate, adequate, and strengthened warnings. The PMA contains the most specific federal requirements for the BIOCELL implants. Additional applicable federal requirements included the applicable federal regulations, cited to and described herein.

137. Allergan knew or should have known of the reported and potential BIOCELL complications associated with the development of ALCL or unexplained late or persistent seromas. Allergan violated its obligations under New Jersey law, and the parallel federal requirements, by

failing to strengthen the warnings, and failing to warn of and provide risk and risk profile information that Allergan knew or should have known with regard to the connection between the BIOCELL implants and ALCL. Allergan instead chose to actively conceal its knowledge of the risks and risk profile of its BIOCELL implants, deliberately failing to disclose to, and obscuring the true risks and risk profile from, physicians, patients, and the FDA, including for example in violation of 21 C.F.R. part 814, § 814.39(a) and § 814.39(d). Allergan also manipulated the regulatory process to its advantage by, for example, utilizing adverse event reports and reporting data in a misleading, disguised and inadequate manner, and submitting proposed warning language to the FDA that Allergan knew to be inadequate and misleading, thus delaying or preventing disclosure of critical risk information, all for its economic advantage and to the tragic disadvantage of patients, including Plaintiffs.

138. Allergan failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, and the FDA, about the true risks of ALCL with its BIOCELL implants, by for example:

a. Failing to adequately warn of and 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 obscured the existence, frequency, and true nature of the reported complications;

c. Failing to report the results of, or complete, ongoing long-term studies regarding the BIOCELL implants 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 and applicable federal regulations, through PMA supplements, and pursuant 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 implants.

139. Under New Jersey law, as well as parallel federal requirements, including but not limited to the PMA, Conditions of Approval, and the federal regulations, as outlined above, Allergan had a duty to adequately and accurately warn Plaintiffs and their physicians regarding the risks and risk profile of the BIOCELL implants. This duty extended for example to the product labeling including the DFU and any approved patient labeling, approved or non-approved written and oral communications, statements by sales representatives, statements in company sponsored seminars and dinners, and extended to submissions of accurate and complete adverse event reports and risk information to the FDA. Allergan breached its duty to warn under the parallel New Jersey and federal requirements.

140. When a reference to ALCL was finally included, for example within the 2013 DFU that accompanied one line of Allergan's BIOCELL implants, Allergan still did not warn adequately of the risk of ALCL, in part because the risk was presented as generic information, generally applicable to breast implants, and as if there was no compelling scientific data demonstrating an association and causal connection between the BIOCELL implants and ALCL. All of these warnings for the BIOCELL implants failed to adequately warn of the risks and risk profile, in violation of New Jersey law, which was parallel to and did not require anything different from or in addition to the federal requirements.

141. Allergan knew or should have known, based on ongoing accumulation of, and availability of information, that the warnings mentioning a risk of ALCL failed to adequately describe the risks and risk profile and the causal connection between its BIOCELL implants and BIA-ALCL, which was significantly greater than the risk posed by other forms of breast implants,

and "other manufacturers' breast implants." Allergan was thus obligated under New Jersey law, and parallel federal requirements, to disseminate, and seek approval for, a more adequate and accurate warning. Instead, Allergan deliberately obstructed and failed to disclose and disseminate critical risk information, failed to notify physicians of the warnings, and caused misleading non-PMA communications to be disseminated, including but not limited to in the form of discussions between sales representatives and physicians, in order to obscure and/or weaken the impact of the warnings, and protect Allergan's market share.

142. 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 Plaintiffs and their physicians of those risks. Yet Allergan chose not to take the necessary steps to provide adequate warnings, thereby continuing to market and sell its dangerous BIOCELL products to uninformed, poorly informed and misinformed patients and physicians.

143. As set forth above, Allergan was required by New Jersey law to provide adequate warnings 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).

144. Any such warnings and strengthened PMA warnings submitted by Allergan to the FDA for approval, whether or not disseminated prior to approval, would have been approved by the FDA and disseminated to Plaintiffs and their physicians. The requirements of the Defendants under New Jersey law were no greater than the federal requirements.

145. Had Allergan properly warned as required by New Jersey law, including the requirement to disseminate adequate and accurate warnings and information regarding the ALCL risk known to Allergan, and the requirement to properly and timely report adverse events, the actual risks, and risk profile, the information would have been reported through the MAUDE database and other means such as strengthened labeling and warnings, and disseminated to Plaintiffs and their physicians. Plaintiffs' physicians would not have recommended or prescribed the BIOCELL implants, or if offering them as an option would have done so as part of a modified informed consent discussion, for example with a more accurate risk benefit profile and more and different information provided as to other options, and Plaintiffs would not have consented to the use of Allergan's BIOCELL products. For those who already had BIOCELL implants, the patients could have exercised reasonable judgment to remove the implants earlier to diminish the risk of ALCL. Ultimately, the belated and more accurate disclosure of the risks and incidence of ALCL, which should have been made years earlier, resulted in the request by the FDA that the BIOCELL products be recalled.

146. Allergan is strictly liable for the failure to adequately warn.

147. Allergan acted with wanton and willful disregard for the rights and health of the Plaintiffs.

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

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

THIRD COUNT
(BREACH OF EXPRESS WARRANTY)

149. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

150. Allergan represented 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 including but not limited to:

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 had "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."

151. Allergan also specifically misrepresented and minimized the risk of BIA-ALCL for patients implanted with BIOCELL implants, in non-PMA voluntary statements.

152. Allergan's voluntary, non-PMA statements, as more specifically outlined in the preceding paragraphs as well as other similar voluntary non-PMA statements in marketing and advertising to physicians and patients, constituted express warranties which were false and misleading, under New Jersey law. New Jersey law required nothing more or in addition to parallel federal requirements with regard to non-PMA voluntary statements. For example, pursuant to the terms of the PMA, Allergan's "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws."

153. Plaintiffs and their physicians relied upon the express warranty statements made by Allergan.

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

155. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

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

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

FOURTH COUNT
(DESIGN DEFECT)

157. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

158. The design of the BIOCELL implants was defective and unreasonably dangerous, causing an unsafe, intense and dangerous inflammatory reaction, tissue damage, seromas, BIA-ALCL, and other related injuries, including death.

159. The structure, configuration, and material, as well as the method of implant, separately and together, rendered the BIOCELL implants not reasonably fit, suitable, or safe for their intended purpose.

160. The risks and dangers of the BIOCELL implants outweighed the benefits, and rendered the products unreasonably dangerous.

161. Safer alternative implants and expanders were available which did not have an unreasonable risk of harm as with the BIOCELL products and their unsafe textured surface, for example including smooth implants and textured implants manufactured by other manufacturers.

162. The risk benefit profile of the BIOCELL products was unreasonable, and the products should not have been marketed.

163. The BIOCELL products did not perform as an ordinary consumer would expect.

164. The use of the BIOCELL implants as used in Plaintiffs was foreseeable to Allergan.

165. Allergan is strictly liable for the defectively designed BIOCELL implants.

166. Allergan acted with willful and wanton disregard for the rights and health of the Plaintiffs and other patients.

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

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

FIFTH COUNT
(NEGLIGENCE)

168. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

169. Allergan had a duty to act with reasonable care, as a reasonably prudent person, in all respects.

170. Allergan's aforesaid conduct fell below the standard of care, and constitutes negligence.

171. The negligence claims are not subsumed by the New Jersey Product Liability Act to the extent the Court deems the conduct at issue not to fall within the PLA claims for manufacturing defect, design defect, or failure to warn.

172. Allergan acted with willfull and wanton disregard for the rights and health of the Plaintiffs.

173. As a proximate result of Allergan's wrongful conduct, Plaintiffs have been severely harmed, and have endured pain, suffering, disability, impairment, excessive scarring, disfigurement, increased risk of developing cancer, loss of enjoyment of life, aggravation or

activation of preexisting conditions, death in some cases, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The injuries and losses are permanent and continuing in nature.

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

SIXTH COUNT
(CONSUMER FRAUD)

174. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

175. Allergan made express and affirmative misrepresentations with regard to the risks and risk profile with the BIOCELL implants. These misrepresentations were made in non-PMA voluntary statements, as set forth herein.

176. Allergan knowingly and intentionally concealed, suppressed, and omitted material facts with regard to and relevant to the risks and risk profile with the BIOCELL implants. These misrepresentations were made in non-PMA voluntary statements, as set forth herein.

177. Allergan employed deceptive, fraudulent, misleading, and other unconscionable commercial practices in the marketing and sale of the BIOCELL implants, all in non-PMA voluntary statements, as set forth herein.

178. As a proximate result of Allergan's wrongful conduct, Plaintiffs have incurred costs for medical care and treatment, loss of wages and wage earning capacity, and other economic and non-economic damages. The injuries and losses are permanent and continuing in nature.

WHEREFORE, Plaintiffs request judgment of compensatory damages, treble damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

SEVENTH COUNT
(SURVIVORSHIP AND WRONGFUL DEATH)

179. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

180. Plaintiffs' Decedents suffered and underwent invasive evaluation and treatment, including surgeries, and the use of debilitating medications, and endured pain, suffering, disability, impairment, disfigurement, loss of enjoyment of life, medical expenses, economic damages, and death, as a proximate result of the implant of the BIOCELL implants.

181. Allergan is liable for the Decedents' suffering and death, for Plaintiffs' survivorship damages, for all damages sustained by the Decedents' estates, and all other injuries and damages flowing from Decedents' wrongful death, for the reasons set forth herein.

182. Plaintiffs request the award of all damages permitted for wrongful death and survivorship.

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, treble damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

EIGHTH COUNT
(LOSS OF CONSORTIUM)

183. Plaintiffs repeat and restate the foregoing allegations as if set forth at length herein.

184. At all times relevant, certain Plaintiffs were married. As a proximate result of the injuries and damages sustained by certain Plaintiffs, Plaintiffs' spouses have suffered the loss of care, comfort, consortium, society, services and affections from their injured spouses, and have provided valuable services for their injured spouses.

185. Allergan is liable for the loss of consortium for the reasons set forth in this Complaint.

WHEREFORE, Plaintiffs request judgment of compensatory damages, punitive damages, treble damages, attorneys fees, interest, costs, and such further relief as the Court deems equitable and just.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury of all claims set forth herein.

MAZIE SLATER KATZ & FREEMAN, LLC
Plaintiffs' Liaison Counsel

BY:_____
ADAM M. SLATER

Dated: August 31, 2020

RULE 4:5-1 CERTIFICATION

I hereby certify that to the best of my knowledge the matter in controversy is the subject of numerous other actions. On June 8, 2020 the Supreme Court designated all cases involving Allergan Biocell Textured Breast Implants as a Multicounty Litigation (MCL) and assigned this MCL to Hon. Rachelle Harz, J.S.C. in Bergen County for centralized case management.

I hereby certify that the foregoing statements made by me are true. I am aware if any of the foregoing statements made by me are willfully false, I am subject to punishment.

MAZIE SLATER KATZ & FREEMAN, LLC
Plaintiffs' Liaison Counsel

BY:_____
ADAM M. SLATER

Dated: August 31, 2020

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-005064-20

Case Caption: ALLEGING PLAINTIFF VS ALLERGAN INC
Case Initiation Date: 08/31/2020
Attorney Name: ADAM M SLATER
Firm Name: MAZIE SLATER KATZ & FREEMAN
Address: 103 EISENHOWER PKY
ROSELAND NJ 07068
Phone: 9732289898
Name of Party: PLAINTIFF : Alleging, Plaintiff
Name of Defendant's Primary Insurance Company (if known): None

Case Type: ALLERGAN BIOCELL TEXTURED BREAST IMPLANTS
Document Type: Complaint with Jury Demand
Jury Demand: YES - 6 JURORS
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

Are sexual abuse claims alleged by: Plaintiff Alleging? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO **Consumer Fraud?** NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

08/31/2020
Dated

/s/ ADAM M SLATER
Signed