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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	:	Case No. 2:19-md-02921 (BRM) (JAD) MDL NO. 2921
BARBARA PACK AND ALLEN PACK, h/w 7681 S. 1095 E. Midvale, UT 84047 Plaintiffs, v.	:	JUDGE BRIAN R. MARTINOTTI JUDGE JOSEPH A. DICKSON DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 6
Allergan plc Clonshaugh Business and Technology Park Coolock, Dublin, Ireland D17 E400 Allergan, Inc. f/k/a Inamed Corporation f/k/a McGhan Medical Corporation 5 Giralda Farms Madison, NJ 07940 Allergan USA, Inc. 5 Giralda Farms Madison, NJ 07940 Defendants.	:	Civil Action No:

Plaintiffs file this Complaint pursuant to CMO No. 6, and are to be bound by the rights,

protections, privileges, and obligations of that CMO. In accordance with CMO No. 6, Plaintiffs hereby designate the **United States District Court for the District of Utah**, as the place of remand as this case may have originally been filed there.

INTRODUCTION

Plaintiffs Barbara Pack and Allen Pack, h/w, based on information and belief, and for causes of action against the Defendants Allergan plc, Allergan, Inc. f/k/a Inamed Corporation, and Allergan USA, Inc., each of them, hereby allege as follows:

1. Plaintiffs Barbara Pack and Allen Pack, h/w, bring this action against Defendants Allergan plc, Allergan, Inc. f/k/a Inamed Corporation, and Allergan USA, Inc., (hereinafter, collectively referred to as "Defendants" or "Allergan"), in relation to the design, manufacture, marketing, labeling and distribution of McGhan and Allergan Breast Implants, the pervasive, reckless and continuous failure to comport with the Premarket Approval Application (''PMA") requirements imposed by the Food & Drug Administration ("FDA"), and failure to warn consumers of the known dangers and known adverse events.

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

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

PARTIES

4. At all times relevant hereto, Plaintiff Barbara Pack has been a resident of Midvale, Utah.

5. Plaintiff Allen Pack is the husband of Plaintiff Barbara Pack and, at all times relevant hereto, has been and remains a resident of Midvale, Utah.

6. Defendants Allergan, Inc., Allergan USA, Inc., and Allergan plc manufacture and sell BIOCELL® saline-filled and silicone-filled breast implants and tissue expanders. Allergan, Inc., formerly known as Inamed Corporation ("Inamed") (formerly known as McGhan Medical Corporation) is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware. Allergan, Inc.'s principal place of business is in New Jersey, where its US administrative offices are located. Allergan, Inc. may be served by service of process on its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

7. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business located at 5 Giralda Farms, Madison, New Jersey 07940 where Allergan's administrative offices are located.

8. Allergan plc is a publicly traded corporation whose headquarters are located at Clonshaugh Business & Technology Park, Coolock, Dublin, D17 E400, Ireland. Allergan's administrative headquarters in the United States are located 5 Giralda Farms, Madison, New Jersey 07940.

9. In March 2006, Allergan purchased substantially all of Inamed, including Inamed's outstanding common stocks, as well as its wholly-owned subsidiary, McGhan Medical

Corporation.[1]

10. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other. The combined acts and/or omissions of each Defendant resulted in injuries to the Plaintiffs. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiffs for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized, and/or ratified the conduct of each and every other Defendant.

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

12. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants conduct substantial business in this District.

13. Defendants are authorized and licensed to conduct business in the State of New Jersey and maintain and carry on systematic and continuous contacts in this judicial district, including the acts which caused or contributed to Plaintiffs' injuries.

[1] https://www.businesswire.com/news/home/20060323005237/en/Allergan-Announces-Completion-Inamed-Acquisition. Allergan has announced that it is in the process of being acquired by merger with AbbVie, Inc. The merger was expected to close in early 2020, but now has been delayed to the second quarter of 2020. *See* https://finance.yahoo.com/news/abbvie-acquire-allergan-nearly-62b-132601647.html; http://www.pmlive.com/pharma_news/abbvie_says_allergan_takeover_delayed_by_ftc_verdict_1327907

FACTUAL BACKGROUND

14. On July 24, 2019, the FDA issued a news release that announced the FDA-initiated recall of Biocell textured breast implants and Biocell tissue expanders:

> "Although the overall incidence of BIA-ALCL appears to be relatively low, once the evidence indicated that a specific manufacturer's [Allergan's] product [Biocell Textured Breast Implant] appeared to be directly linked to significant patient harm, including death, the FDA took action to alert the firm to new evidence indicating a recall is warranted to protect women's health," said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D.[2]

15. On the same day, July 24, 2019, the FDA also reported updated data: "573 unique and pathologically confirmed BIA-ALCL" cases associated with textured breast implants with 33 confirmed deaths.[3]

16. The FDA also published on July 24, 2019, for the first time, manufacturer-specific data. Allergan's Biocell implant surface device accounted for 91% of the BIA-ALCL cases (481/531) when the identity of the device manufacturer was known.[4]

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[2] United States Food & Drug Administration, FDA News Release, *FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market* (July 24, 2019). Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan.

[3] https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma.

[4] *Id. See also* https://youtu.be/YxPFayQsjUo?t=4773. In the 33 reported BIA-ALCL textured implant death cases, the manufacturer was identified by FDA in 13 cases and 12 were Allergan Biocell cases. https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma. The manufacturer and/or texture was unknown for the remaining 20 reported deaths from BIA-ALCL. *See also* Ghione, Cordeiro, et al., *Incidence of Delayed Seromas and Related Risk of Bia-ALCL in a Cohort of 3521 Breast Cancer Women with Textured Implants Prospectively Followed Long Term*, Blood (November 13, 2019) (Dr. Peter Cordeiro from Memorial Sloan Kettering Cancer implanted textured implants in 3,521 women from 1992-2017; 10 patients have been diagnosed with BIA-ALCL (1:352)), available at https://ashpublications.org/blood/article-abstract/134/Supplement_1/2842/423426. *See also* https://youtu.be/YxPFayQsjUo?t=31788 (all 10 patients (100%) received Biocell implants and Biocell tissue expanders); https://ash.confex.com/ash/2019/webprogram/Paper122572.html.

17. On September 12, 2019, the FDA published a further explanation of the July 24, 2019, recall of Allergan Biocell implants: "The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death**.**" FDA, *Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer*, https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer.

18. In commenting on the recall of Allergan's textured Breast Implants, "Dr. Mark Clemens of Houston's MD Anderson Cancer Center said Biocell's surface differs from other textured implants, producing a large number of particles that shed into the body."[5]

19. Plaintiffs plead the following facts that are more fully described in the body of the Complaint:

a. Allergan negligently manufactured Biocell textured breast implants using a manufacturing process that at times produced adulterated products with manufacturing defects caused by violations of FDA and PMA standards that support parallel state law claims.

b. Allergan manufactured Mrs. Pack's Biocell Breast Implants. They were in a defective and unreasonably dangerous condition when put to a reasonably

[5] Associated Press, AP News, *Breast implant recalled after link to more rare cancer cases* (July 24, 2019). Available at: https://www.apnews.com/509a575a35514fbea7c15beb8dedf085. (emphasis added). The presence of particles/contaminants on the surface of breast implants from a flawed manufacturing process is not unique to Allergan. In 2015, a South American breast implant manufacturer (Silimed) lost its ability to market in Europe after an inspection of the manufacturing process found that the surfaces of some devices were contaminated with particles. https://www.massdevice.com/sientra-plummets-on-u-k-breast-implant-halt/

anticipated use. They were in fact used in such a manner; and Mrs. Pack's injuries are a direct result of such defects as they existed when the implants were sold.[6]

c. The Biocell "salt loss" texturing manufacturing process at times produced non-conforming implants caused by negligent manufacturing by a variable and uncontrolled manual scrubbing texturing process, producing a large number of silicone particles and other fragments, residues and contaminants adhering to the implant surface, which particles were, at times, not adequately cleaned and removed or tested/inspected for defects due to particles. Unwanted volumes of solid silicone particles, and other fragments, residues, and adulterants were not subject to adequate quality control or validation—making the Biocell implants, at times, adulterated[7] with foreign sharp silicone particles; refractile and birefringent fragments; residues; and adulterants from the silicone implant manufacturing process that became embedded into human breast tissue when implanted.[8]

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[7] Adulterated medical devices (21 U.S.C.§ 351) are not subject to preemption. 21 C.F.R. § 808.1(d)(2)(ii) provides that, generally, § 521(a) of the Federal Food, Drug and Cosmetic Act (Act) does not preempt a state or local requirement prohibiting the manufacture of adulterated or misbranded devices.

[8] *See* Ye, et al., *Anaplastic large cell lymphoma (ALCL) and breast implants: Breaking down the evidence,* Mutation Research 762 (2014) 123–132. https://www.sciencedirect.com/science/article/pii/S138357421400043X?via%3Dihub:

> "Even if the view is taken that silicone itself is inert" "its toxic breakdown products, such as siloxane—which is an inducer of protein denaturation—and platinum and silicates which are known cellular irritants and potential inducers of fibrosis" "may nevertheless induce a foreign body response." "Each of these three compounds have been detected in significant concentrations in the fibrous capsule surrounding silicone implants and represents a significant toxicological issue for patients with silicone prostheses. Recently cytometric studies by Wolfram et al on pericapsular lymphocytes have confirmed the findings of earlier histological studies that silicone and silicone breakdown products induce, when combined with autologous proteins, an inflammatory response."

d. Allergan knew that, at times, its silicone breast implant manufacturing process produced implants with manufacturing defects from volumes of unwanted particles on the surface of the implant shell. As Allergan's Executive Director of Regulatory Affairs and designated corporate representative, Kathy Miller Carty, testified in a deposition in a federal court case in Arizona in 2017:

> Q. Like any manufacturing plant [referring to the Costa Rica plant where Allergan's breast implants are manufactured], **there are manufacturing defects like the implants that are produced**; is that right?
> A. **Sure**.
> Q. **What kind of manufacturing defects has Allergan found over the years**?
> A. Bubbles. **With respect to the shell**, it's bubbles in the shell, **particles on the shell**.

Deposition of Kathy Miller Carty at 15-17, in *Weber v. Allergan*, No. 2-12-cv-02388-SRB (D. Ariz., May 22, 2017) (emphasis added). Available at ECF 124 at p 29: https://ecf.azd.uscourts.gov/doc1/025117820833

e. Inspections of Allergan's Biocell manufacturing process by regulatory authorities (FDA and the French ANSM) found major manufacturing, quality control and post-PMA reporting and warning deficiencies in violation of FDA standards and PMA required specifications that support parallel state law claims. For example, on several occasions the FDA issued Form 483s to McGhan Medical and Allergan at McGhan/Inamed Allergan's manufacturing facilities.[9] A Form 483 is issued to

[9] For example, in October 2000 an FDA inspection issued a Form 483 and found the bioburden recovery protocol deficient at McGhan Medical's breast implant manufacturing facility in Barreal de Heredia, Costa Rica. (**Exhibit 1**). In June 2007, a Form 483 was issued to Allergan's La Aurora, Heredia, breast implant manufacturing facility for not fully validating the overall manufacturing processes for silicone-filled and saline breast implants. *FDA Establishment Inspection Report for La Aurora, Heredia,* February 23, 2009 at p. 2 of 23. ECF 115 at 98, Available at https://ecf.azd.uscourts.gov/doc1/025117683547

management at the conclusion of an FDA inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food, Drug, and Cosmetic Act and related Acts. In April/May 2015 French regulators (ANSM) inspected Allergan's Marlow, England facility and reviewed the manufacturing processes for breast implants manufactured at Allergan's La Aurora de Heredia, Costa Rica, manufacturing facility and found major deviations and non-compliance with manufacturing standards and regulations and adverse event reporting requirements.[10]

f. Allergan, by merging with McGhan Medical and Inamed, **knew** from research studies sponsored by McGhan Medical and conducted in Nashville, Tennessee and at Bowman Gray Medical School in North Carolina in the early 1990s that its "proprietary" Biocell manufacturing process to texture silicone breast implants with the "salt loss" process could result in a final product with unwanted foreign silicone particles, fragments and shedding of particles that became embedded into human tissue. Allergan (then McGhan Medical/Inamed) suspended the studies when they showed "bad" results and shelved ("deep-sixed") these animal (rabbit, pig) and human *in vivo* particulation studies. Upon information and belief, the studies and

(**Exhibit 2**).

[10] FRENCH NATIONAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS SAFETY INSPECTION DIVISION (ANSM), *Preliminary Inspection Report,* https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf (**Exhibit 3**). An April 2012 inspection of Allergan by the French ANSM found 10 deviations in Allergan's operations including deficiencies in manufacturing, quality control and post-marketing vigilance. https://ansm.sante.fr/var/ansm_site/storage/original/application/eba3d4026e13f0475a941198a4fb2ba5.pdf **(Exhibit 4).**

adverse particulation results were never reported to the FDA. The data, results and documentary proof of the these abandoned and never-reported particulation studies, however, remain available in Nashville, Tennessee and Greensboro, North Carolina. Defendants' *post*-approval PMA duties required reporting all clinical studies "not previously submitted as part of the PMA." 21 C.F.R. § 814. 84.

g. Allergan knew from internal reports of at least **18** cases of BIA-ALCL in silicone gel-filled breast implants reported to the company from 2007-2010 with **10** cases reported as Allergan textured breast implant cases.[11] Allergan violated federal law by failing to promptly review, evaluate, and investigate these medical device reports (MDRs) per 21 C.F.R. § 820.198(d), and by failing to submit these BIA-ALCL cases as MDRs within the mandatory reporting timeframes required by 21 C.F.R. § 803.50 and as required under post PMA-approval reporting requirements under 21 C.F.R. § 814.80 *et seq*. and particularly § 814.84. Upon information and belief, Allergan also failed to report, as required by law (21 C.F.R. § 814.84) at least 34 cases of BIA-ALCL reported in the medical literature in at least 18 journals.[12] Allergan also filed misleading and evasive case reports with regulatory

[11] Allergan Confidential Response to ANSM 20May2016 Request, https://ansm.sante.fr/var/ansm_site/storage/original/application/06a05a9d97a9a029508115bacee918e5.pdf. (**Exhibit 5).** Allergan provided this information to French regulators in 2016 response to a specific letter-request following an inspection of Allergan's facility in Marlow, England. https://www.ansm.sante.fr/var/ansm_site/storage/original/application/6d98eadb8dc64947ceab2979270365a5.pdf. The request was limited to silicone gel implants and did not include saline-filled implants.

[12] http://wayback.archive-it.org/7993/20170112002119/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm#appendixb

agencies that reported serious cases of lymphoma, cancer and ALCL as alternative summary reports (ASRs) and reported these serious cases in Incident Report Forms (IRFs) in the fields "All other reportable incident" and "No threat of public health."[13]

h. Based upon the FDA data reported at the March 2019 public hearing of General and Plastic Surgery and Devices Panel, Allergan never reported to the FDA MDRs for the 2007-2010 cases of BIA-ALCL that were reported to the company. The FDA has stated: "The earliest MDR reported to us [FDA] of BIA-ALCL came in 2010."[14] The first report to French regulators (ANSM) was is 2011.[15]

i. These MDR and post-PMA reporting violations preclude a preemption defense as to a parallel state-law claim for failure to warn. *See e.g.* *Stengel v. Medtronic Inc.*,

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[13] https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf. at 31-34.

[14] The earliest report to the FDA in the MAUDE database for BIA-ALCL was in 2010. http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d at 4:16:28. Likewise, reports made by ASR reporting ("Alternative Summary Reporting") referred to BIA-ALCL, cancer or lymphoma.

While Allergan received an exemption in 2007 to report certain routine complaints and product failures as an "ASR," **none** of the ASRs filed by Allergan, by our review of the data FDA released in June 2019, shows anything that could possibly be interpreted as a report of the serious cancer/lymphoma BIA-ALCL. Allergan's failure to report was despite 18 journals reporting 34 BIA-ALCL cases in the medical literature between 1997 and 2010 and at least 18 BIA-ALCL case reports made directly to Allergan.http://wayback.archive-it.org/7993/20170112002119/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm#appendixb Thus, we allege **no** reports were made by Allergan to FDA of BIA-ALCL to FDA before Mrs. Pack's implants were implanted in 2009. This violated McGhan and Allergan's PMA post-marketing duties. ASR reports, if they related to a case of BIA-ALCL and were not reported as a BIA-ALCL case and this was concealment and a violation of FDA laws and requirements.

[15] "ANSM was informed about a first case of ALCL of the breast in a woman with a PIP breast implant in November 2011." https://ansm.sante.fr/var/ansm_site/storage/original/application/7fd4f94f69f8a07befd7f1e2753187ab.pdf.

704 F.3d 1224, 1226 (9th Cir. 2013)[16]; *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343 (D. Del. 2019)(state law failure to warn claims premised on Section 388 of Restatement(Second) of Torts, which focus on a manufacturer's failure to report adverse events to the FDA, are not preempted) *Bull v. St. Jude Med., Inc.,* No. 17-1141, 2018 U.S. Dist. LEXIS 115730 (E.D. Pa. July 12, 2018); *In re Smith & Nephew Birmingham Hip Resurfacing (BUR) Hip Implant Prods. Liab. Litig.,* No. MDL No. 2775, 2019 U.S. Dist. LEXIS 131067 (D. Md. Aug. 5, 2019); *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.,* No. MDL No. 2775, 2019 U.S. Dist. LEXIS 206574 (D. Md. Nov. 26, 2019).

j. Plaintiffs therefore bring the parallel failure to warn claim against Defendants for their failure to use reasonable care to warn Mrs. Pack's plastic surgeon and the FDA (post PMA approval) of known or knowable product dangers and adverse events associated with the Biocell breast implant. This claim arises out of a longstanding duty in Utah requiring a manufacturer to warn a person's doctor of potential dangers of the product. Plaintiff's failure to warn claim parallels Defendants' duty under federal-law and the Code of Federal Regulations including 21 C.F.R. §803.50(a) (requiring a manufacturer of class III devices to file adverse event reports whenever the device may have caused or contributed to death or

[16] In *Stengel v. Medtronic, Inc.* the patient's claim specifically alleged as a violation of Arizona law a failure to warn the Food and Drug Administration (FDA) of dangers in using the device. The claim was not preempted, either expressly or impliedly, by the MDA. It was a state-law claim independent of the FDA's pre-market approval process and rested on a state-law duty that paralleled a federal-law duty.

serious injury if it recurred) and 21 C.F.R. §814.84(b)(2) (requiring a manufacturer of a class III device to provide the FDA with an account of all reports of data from any clinical investigations or studies involving the device, reports in the scientific literature concerning the device that are known or that should reasonably be known) and does not impose duties or requirements materially different from those imposed by federal law. The Utah duties precisely parallel the duties imposed by federal law and do not exist solely by virtue of the federal requirements

k. Mrs. Pack's BIA-ALCL was caused by defective, unreasonably dangerous, and adulterated textured Biocell Breast Implants.[17] There are no confirmed cases of BIA-ALCL associated with smooth breast implants. Biocell's salt loss production technique, when an implant is negligently manufactured, produces overly textured rough implants shells, with (at times) foreign and adulterated silicone particles, fragments, implant materials and residues on the implant surface that are recognized as a foreign body that triggers T-cell lymphoma and, over time, ALCL. Biocell textured implants account for the overwhelming number of BIA-ALCL cases (91%).[18]

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[17] "**Silicone particle induced inflammation is the primary cause of BIA-ALCL.**" Dennis Hammond, MD, *Presentation at 1st World Consensus Conference on BIA-ALCL* (Rome Italy, Oct. 5, 2019) (emphasis added), available at https://youtu.be/YxPFayQsjUo?t=24447 (slide presented during his presentation, "*The Micro-particulate theory and the role of innate immunity*" as part of a scientific panel addressing the etiopathogenesis of BIA-ALCL). *See infra* ¶ 102. *See also* Backovic, et al., *Silicone mammary implants – Can we turn back the time*? Experimental Gerontology Volume 42, Issue 8, August 2007 ("silicone degradation products promote protein denaturation and activate cells of both the innate and adaptive immune system, thus perpetuating a chronic pro-inflammatory response of the local tissue."). https://www.sciencedirect.com/science/article/pii/S0531556507000824?via%3Dihub.

[18] A seminal 2015 paper reported from a review of the literature and survey of 173 BIA-ALCL cases the common factors in BIA-ALCL cases "appeared to be the texturing of the silicone breast implant surface,

l. As Dr. Eric Swanson writes in Evidence-Based Cosmetic Breast Surgery (2017):

"Textured implants are not just "overrepresented" in cases of ALCL. Brody et. al [131] report *no* cases of ALCL in women treated solely with smooth implants. Similarly, Clemens [125] reports no confirmed cases of ALCL in patients treated only with smooth implants . . . **Brody [132] believes that texturing is the likely trigger,** not infection."[19]

m. Barbara Pack developed BIA-ALCL as a direct result of having defective Biocell textured implants placed in 2009 and 2015.

n. Allergan has knowingly misled the medical, scientific, surgical community and the public by advancing bogus, unsupportable, and unscientific claims that BIA-ALCL is caused by: bacteria and biofilm formation on and around textured implants; a patient's genetic predisposition; passage of time; surface implant area; and can be avoided if surgeons would just use Betadine and antibiotics in the implantation surgery using a "14 - point plan" that includes antibiotic irrigation or Betadine at the time of implantation. However, the efforts to mislead the medical community

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suggesting a site-**and material specific** chronic inflammatory cause." G. Brody et.al, *Anaplastic Large Cell Lymphoma Occurring in Women with Breast Implants: Analysis of 173 Cases, Plastic and Reconstructive Surgery* (August 2015) (emphasis added) (Allergan's Biocell implant was identified in 90% of the cases where the manufacturer was identified), available at https://journals.lww.com/plasreconsurg/Abstract/2015/03000/Anaplastic_Large_Cell_Lymphoma_Occurring_in_Women.12.aspx.

[19]At p. 97. Available at: https://books.google.com/books?id=IoptDgAAQBAJ&pg=PA96&dq=%22Biocell+implant%22&hl=en&newbks=1&newbks_redir=0&sa=X&ved=2ahUKEwj489fBq6jlAhXokOAKHbCZAWYQ6AEwAHoECAMQAg#v=onepage&q=%22Biocell%20implant%22&f=false (emphasis in bold added; italics in original).

and medical device regulators have failed. On July 24, 2019, Allergan's Biocell textured breast implants and Biocell tissue expanders were recalled worldwide by Allergan after notification from the FDA.

o. Allergan violated two PMAs (PMA 990074 and PMA 20056) applicable to Mrs. Pack's implants and post-approval FDA regulations. Although Allergan's 2002 and 2006 PMAs are not public and are not available to Plaintiffs without discovery, Courts routinely grant discovery where a manufacturing defect is pleaded with adequate facts. Here, based upon the facts that are publicly known, facts revealed by confidential Allergan documents and witnesses in connection with Plaintiffs' pre-filing investigation, facts disclosed by the FDA in a 2008 inspection of Allergan's Costa Rica breast implant manufacturing plant,[20] facts detailed by French regulatory authorities in a 2015 Allergan plant inspection,[21] and facts pleaded in this complaint, Plaintiffs aver that the applicable PMAs and federal FDA laws and specifications required Allergan (and required as to its corporate predecessors by merger) to follow FDA specified manufacturing procedures and FDA post-approval reporting regulations to disclose the risks of BIA-ALCL. Allergan was required to follow Quality System Regulations and Current Good Manufacturing Practices, validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants with excessive particles on the

[20] *See FDA Establishment Inspection Report for La Aurora, Heredia,* February 23, 2009 (**Exhibit 2**).
[21] FRENCH NATIONAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS SAFETY INSPECTION DIVISION (ANSM), *Preliminary Inspection Report* (**Exhibit 3**).

implant surface at the time of manufacture in violation of 21 U.S.C.§ 351, 21 C.F.R. § 808.1(d)(2)(ii), 21 C.F.R. §§ 820.70(c),(e)(h) and § 820.75. Instead, Allergan (and its predecessors) produced, at times, adulterated Biocell implants that had numerous unwanted particles and solid fragments of silicone on the implant surface. Allergan violated these provisions and the PMAs in numerous respects as shown in this complaint and the exhibits to this complaint. Specifically, Plaintiffs aver Allergan violated the PMAs and federal law and requirements because the PMAs and federal law required Allergan (and required its corporate predecessors by merger) to:

i. Not manufacture, at times, breast implants with degraded particles on the implant surface;

ii. follow PMA and ISO standards (e.g. 10933-1);

iii. detect, review, and dispose of impure particles and chemicals;

iv. remove and dispose of non-conforming implants;

v. prevent non-conforming implants and contaminants, fragments, particles, and impurities on the implant from reaching the public;

vi. comply with PMA post-market reporting obligations;

vii. disclose as required under *post* PMA approval requirements, adverse animal and human particulation studies that had been performed on the implants that showed the Biocell implants could have harmful solid particles on the textured implant surface that could migrate, become embedded in breast tissue and cause an unwanted adverse inflammatory giant cell foreign body reaction ;

viii. follow the manufacturing process to only "gently agitate" (brush) the implants during the salt loss texturing process to "remove all solid particles;"

ix. perform processes and testing mandated by the PMAs, Current Good Manufacturing Practices ("CGMP") and Quality System Regulations ("QSR");

x. not manufacture adulterated Biocell implants;[22]

xi. not manufacture Biocell implants in ways they can become contaminated from all foreign or injurious contaminations;

xii. not manufacture and sell as a final product implants in whole or in part of any decomposed substance; or produced, prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health;

xiii. not manufacture implants composed of any poisonous or deleterious substance which may render the contents injurious to health;

xiv. not manufacture breast implants where silicone particles, particulates, residues or harmful contaminants from the manufacturing process could remain on the implant surface after scrubbing and shipment of the final product.

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[22] *See* 21 U.S.C. § 351 (2019):

> Adulterated drugs and devices
> A drug or device shall be deemed to be adulterated—
> (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture.
> (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter [21 USCS §§ 301 *et seq.*] . . .

Section 351(h) defines an adulterated device, in part, as a device where "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable [CGMP] requirements . . .." 21 U.S.C. § 351(h). A CGMP requirement relating to manufacturing material, set forth in Section 820.70, provides:

> Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

21 C.F.R. § 808.1(d)(2)(ii) provides that, generally, Section 521(a) of the Federal Food, Drug and Cosmetic Act (Act) does not preempt a state or local requirement prohibiting the manufacture of adulterated or misbranded devices.

p. In connection with Biocell PMAs and 21 C.F.R §803(1) and § 814.20 and § 814.84 *et seq.*, Allergan had a duty to report and disclose to the FDA cases of BIA-ALCL from the medical literature, cases reported and known to Allergan and the results of clinical and laboratory studies with adverse results.

q. Defendants' violations of the federal PMAs, laws, regulations, and requirements due to negligent manufacturing in violation of federal law are not subject to federal preemption as the violations support parallel tort claims under Utah law.[23]

r. Allergan violated FDA's CGMPs and QSRs set forth in 28 C.F.R.§ 820 *et seq.* [24] See especially 21 U.S.C.§ 351, 21 C.F.R. § 808.1(d)(2)(ii), 21 C.F.R. §§ 820.70(c),(e)(h) and § 820.75.

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[23] *Gravitt v. Mentor Worldwide, LLC*, No. 17 C 5428, 2018 U.S. Dist. LEXIS 98198, at *17 (N.D. Ill. June 12, 2018):

> "The Seventh Circuit [in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010)] held that because the plaintiff's state law claim "that she was injured by [the defendant's] violations of federal law in manufacturing the device implanted in her hip ... would not impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law," the claim was not preempted. *Id*. at 553 (quoting 21 U.S.C. § 360k(a)(1))."

Money v. Johnson & Johnson, No. 15-cv-03213-LB, 2016 U.S. Dist. LEXIS 70808, at *9-11 (N.D. Cal. May 31, 2016) (holding such specific allegations of PMA violations are not preempted). *See also Bryant v. Medtronic, Inc. (In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.),* 623 F.3d 1200 (8th Cir. 2010) (no preemption where plaintiffs alleged defendants "violated a federal requirement specific to the FDA's PMA approval of this Class III device." *Accord Sumpter v. Allergan Inc.*, No. 4:17-CV-2289 RLW, 2018 U.S. Dist. LEXIS 154467, 2018 WL 4335519, at *2 (E.D. Mo. Sept. 11, 2018).

[24] Plaintiffs aver that where, as here, a complaint alleges *both* that a device was not manufactured in accordance with the requirements of the PMAs *and* in violation of Current Good Manufacturing Practices and Quality System Regulations, the failure to follow the CGMPs and QSRs *also* provides a basis for liability as violations of federal law that are parallel state law claims. *See Mendez v. Shah*, 94 F. Supp. 3d 633 (D.N.J. 2015); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466 (W.D. Pa. 2012); *Warren v. Howmedica Osteonics Corp.*, No. 4:10 CV 1346 DDN, 2011 U.S. Dist. LEXIS 32643, at *9 n.2 (E.D. Mo. Mar. 29, 2011). In addition —because we allege the implants were "adulterated" by foreign, decomposed and injurious unwanted silicone and particles— federal law specifically incorporates CGMPs. 21 U.S.C. § 351.

s. Allergan's violations of the PMAs and violations of FDA requirements set forth in the QSRs and CGMPs caused Mrs. Pack's BIA-ALCL.

HISTORY OF ALLERGAN'S BIOCELL TEXTURED BREAST IMPLANTS

20. The history of Allergan's Biocell textured breast implants is important for an understanding of the Plaintiffs' non-preempted failure to warn and manufacturing defect claims and the medical and scientific basis of the historic worldwide recall of Allergan's Biocell textured breast implants in July 2019.

21. The Biocell history is central to an understanding of the direct causal link between Allergan's: post-approval failure to file AERs (adverse event reports), MDRs (medical device reports); post-approval failure to file and report adverse laboratory and clinical studies; negligent manufacturing of adulterated Biocell implants and the injuries of Barbara Pack from BIA-ALCL.

22. In 1987 McGhan Medical Corporation introduced a breast implant with a textured surface named "Biocell" and began marketing the Biocell textured breast implant in 1988.[25] [26] [27] Upon information and belief, McGhan Medical placed the Biocell implant on the market in 1988 with no, or legally insufficient, animal, human, or biocompatibility testing of the Biocell textured implant final product. Notably, Allergan failed to provide regulatory authorities in France with

[25] https://www.ncbi.nlm.nih.gov/books/NBK44794/ ("A textured (Biocell) shell was announced in 1987").
[26] A. Mathur (ed.), NANOTECHNOLOGY IN CANCER at 75- 76 (2017). Available [Google Books] at: https://books.google.com/books?id=81vBBwAAQBAJ&pg=PA76&lpg=PA76&dq=1987+mCghan+Biocell&source=bl&ots=UrcVI74nuC&sig=ACfU3U1pAJIMHSvQRZbcGD_NKqxxxNRWjA&hl=en&sa=X&ved=2ahUKEwjf9Z76orjlAhUBjq0KHQmIBwoQ6AEwCHoECAkQAQ#v=onepage&q=1987%20mCghan%20Biocell&f=false.
[27] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P990074.

animal, human, or biocompatibility testing for the Biocell *textured* implant *as manufactured*; leading to Biocell implants being withdrawn from the market in France and Europe. [28]

23. McGhan Medical Corporation was founded in 1974[29] by Donald McGhan, a former employee of Dow Corning.[30] McGhan's implants were sold in the United States and worldwide under the McGhan brand name.[31]

[28] In June 2016, ANSM notified breast implant manufacturers that they would be required to prove biocompatibility by providing in vivo testing data on the finished product and specific to the textured surface. https://www.fda.gov/media/80685/download; https://ansm.sante.fr/var/ansm_site/storage/original/application/aa533f4eacc8b36bd6504894235f7f29.pdf Allergan failed to provide the testing data and lost its "CE" mark that allowed Allergan to sell its products in Europe. https://translate.google.com/translate?sl=auto&tl=en&u=https%3A%2F%2Fwww.ansm.sante.fr%2FS-informer%2FPoints-d-information-Points-d-information%2FLe-marquage-CE-des-implants-mammaires-textures-de-la-marque-Allergan-Microcell-et-Biocell-n-a-pas-ete-renouvele-par-l-organisme-notifie-GMED-Point-d-information

[29] The history of the company is detailed in a law review article: W. Brown, *Grandfathering Can Seriously Damage Your Wealth: Due Diligence in Mergers and Acquisitions of Medical Device Companies,* 36 GONZAGA L. REV. 315, 319-320 n. 22 (2000/2001), including:

> McGhan Medical Corporation was incorporated in 1974, for the express purpose of marketing silicone breast implants. In June 1977, 3M acquired the assets of McGhan and transferred them to a new subsidiary, also known as McGhan Medical Corp. (McGhan 2) In 1980, McGhan 2 was merged into 3M, and operated as a department in 3M's surgical products division. *Id.* In August 1984, 3M sold its breast implant business to a group of investors including the founders of the original McGhan Medical Corp. They named the new company McGhan Medical Corp. (McGhan 3). *Id.* The following year, McGhan 3 was merged into a new company called Inamed Corporation.

Available at: https://pdfs.semanticscholar.org/71c8/b038bcf4781fa0dda43f978893f71329c927.pdf.

[30] Reuters, *The troubled history of PIP's implants man in America* (Han. 10, 2012). Available at : https://www.reuters.com/article/us-implants/exclusive-the-troubled-history-of-pips-implants-man-in-america-idUSTRE8090XI20120111.

[31] Institute of Medicine (US) Committee on the Safety of Silicone Breast Implants; Bondurant S, Ernster V, Herdman R, editors. Washington (DC): National Academies Press (US); 1999. Available at: https://www.ncbi.nlm.nih.gov/books/NBK44794/.

24. The McGhan trade name was used to market Biocell textured implants[32] until the name was changed in 2007 to "Natrelle Silicone-Filled Breast Implants."[33]

25. McGhan Medical Corporation began marketing textured breast implants in 1987/1988 as a perceived means of reducing capsular contracture and competing with polyurethane foam-textured breast implants that had become increasingly popular.[34]

26. In 1988, in response to growing safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices.

27. In 1989, the FDA published a notice of intent to require submissions of a premarket approval application ("PMA") or completion of product development protocols ("PDPs') for these devices.

28. In April 1991, the FDA issued a final rule calling for submission of premarket approval applications (PMAs) on silicone gel-filled breast implant devices.

29. In 1991, McGhan, a predecessor corporation to Inamed and Allergan, Inc., applied for premarket approval for various styles of implants. The FDA denied approval of the application for use of such devices for the augmentation of healthy female breasts, but also determined there was a public health need for the devices to be available for reconstruction patients.

30. In April 1992, FDA concluded that none of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support approval. Thus, in the United States, silicone gel-filled breast implants were only available to women for reconstruction procedures

[32] http://garylross.com/pdf-guides/inamed-mcghan-implant-catalogue.pdf.
[33] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056S003.
[34] Mathur, *supra*, at 75.

through entry into a clinical study. However, saline-filled breast implants remained available for augmentation and reconstruction during this time via 510(k) approval.

31. In 1999, the FDA issued a final rule requiring PMAs for these devices to be filed with the FDA, or PDPs to be completed, within ninety (90) days. Thus, an approved PMA or PDP was then required to market a saline-filled breast implant.

32. In September 2000, McGhan received approval to begin clinical studies (referred to as the Pivotal or Core study) of the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants. These implants had Biocell textured shells.

33. Two additional clinical studies, Continued Access and Continued Access Reconstruction/Revision (CARE) were to provide further information to the FDA.

34. The FDA entered into an agreement with McGhan setting forth the requirements for McGhan to conduct clinical trials of the silicone implant devices for use in reconstruction patients. Under the agreement, the FDA required that any clinical trial protocols be approved by the FDA and local Institutional Review Boards. The FDA also required McGhan to take all reasonable steps to ensure that it received informed consent from all patients prior to implantation of any evidence on a form consistent with that which had previously been approved by the FDA, and McGhan was to make sure all products were labeled consistent with the agreement and the terms of the approved protocols.

35. McGhan was also required to submit data from the trials in accordance with an agreed schedule and take reasonable steps to ensure that participating physicians complied with the protocols. Further, McGhan was required to cooperate with the FDA's review of the application and monitoring of the clinical trials.

36. The FDA also retained the power to terminate the study at any time if the data showed that continuation of the study was not necessary to, or in the interest of, the public health.

37. In March 1998, the FDA approved McGhan's study protocol, which was submitted pursuant to the 1992 agreement, subject to the FDA's inspection of McGhan's manufacturing facilities. In the same letter indicating approval, the FDA stated that McGhan's facility in Arklow, Ireland could export silicone gel-filled mammary prostheses into the United States.

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

39. In addition to the adjunct study involving reconstruction patients, McGhan also applied for an investigational device exemption ("IDE") for use of the same devices for breast augmentation. The breast augmentation clinical trial was referred to as the "CORE" study and was approved by the FDA in 1998.

40. As the studies progressed, the FDA continued its oversight and considered a large volume of material submitted about the CORE and adjunct studies submitted by McGhan each year. The submissions in both included manufacturing, chemical, physical, toxicological, and clinical information. McGhan noted that while the adjunct study was not being conducted under an IDE, the submissions it made relative thereto were structured to follow FDA guidelines for IDE clinical study annual reports.

41. Pursuant to FDA action in the second half of 1999, the FDA required any manufacturer wishing to continue to market saline-filled implants in the U.S. to file an application for pre-market approval of such products by November 17, 1999.

42. On November 16, 1999, Inamed filed a PMA for the "McGhan Medical RTV Saline-Filled Breast Implant" which was referred to an FDA Advisory Panel on general plastic surgery for review. This product utilized the Biocell lost-salt technique.

43. According to McGhan Medical Corporation's PMA Application number P990074, which sought approval for the RTV Saline-Filled Mammary Implant, "[s]aline filled breast implants are preamendment devices and have been on the market since 1965. McGhan Medical began marketing the RTV saline-filled mammary prostheses in 1988. A total of 704,802 devices were sold during the period 1988 [through] 1999 in over 50 countries."

44. The Advisory Panel met in open session on March 1-3, 2000 to consider the applications. On May 10, 2000, the FDA announced that it had approved the application for PMA of four styles of McGhan saline-filled breast implants for augmentation in women age 18 and older and for reconstruction in women of any age. These products were previously available in the U.S. marketplace as 510(k)-cleared devices.

45. As conditions of the 2000 approval, the FDA required McGhan to conduct multiple post-approval studies to characterize the long-term performance and safety of the devices.

46. The Summary of Safety and Effectiveness Data ("SSED") and Directions for Use ("DFU") did not contain any mention of BIA-ALCL, or anything related to this particular risk of lymphoma.

47. In December of 2002, Allergan sought (and received in November of 2006) PMA approval for its second generation of BIOCELL® textured breast implants (then known as Inamed). The SSED and DFU for this PMA likewise contained no mention of BIA-ALCL or risk of lymphoma.

48. To texturize the surface of the silicone shell breast implant, McGhan's Biocell implant used a specific manufacturing process known as the "salt loss technique."[35]

49. The "salt loss technique" for texturizing the surface of the Biocell silicone shell breast implant involves putting solid particles of cubic salt (sodium chloride) over the surface of the implant during the manufacturing of the implant shell, such that the cubic/angular salt particles are embedded into the surface of the implant, followed by a final layer of silicone. The final silicone layer is washed and scrubbed off in an effort to remove all solid particles.[36] As Dr. Dennis Hammond, a world renowned plastic surgeon,[37] who has published in the medical literature on BIA-ALCL and particles,[38] explained at the 1st World Consensus Conference on BIA-ALCL in Rome, Italy on October 5, 2019:

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[35] Mathur, *supra*, at 77-78.

[36] *Id.* at 77; Australian Government, Department of Health, Therapeutic Good Administration, *Biomaterials & Engineering Laboratory Report, Project: Surface Topography Device: Non- active mammary implants* (September 2019) at 20, 43. Available at: https://www.tga.gov.au/sites/default/files/biomaterials-and-engineering-laboratory-report-non-active-mammary- implants.pdf. Last visited October 24, 2019; C. Kaoutzanis et al. *The Evolution of Breast Implants*, Seminars in Plastic Surgery 2019; 33(04): "Biocell (Allergan), on the other hand, is an aggressive open-pore textured silicone surface. It is created by using a "loss-salt" technique, which involves formation of a layer of salt crystals with a thin overcoat of silicone that is then cured in a laminar flow oven." Available at: https://www.researchgate.net/publication/336628199_The_Evolution_of_Breast_Implants.

[37] https://www.mastersinbreastsurgery.com/masters-in-breast-surgery-iii.

[38] Hallab, Smerko, Hammond, *The Inflammatory Effects of Breast Implant Particulate Shedding: Comparison With Orthopedic Implants,* Aesthetic Surgery Journal Vol 39(S1) S36–S48 (Jan. 30, 2019). Available at: https://pdfs.semanticscholar.org/7635/841c2edd2b45000c04641befa345a46028e7.pdf?_ga=2.2342962.326928717.1572881512-793102741.1572881512.

> It is well established that implant debris causes local inflammation … The take-home message for BIs is 2-fold: (1) increased implant debris will result in increased pathogenic inflammation over time. Conversely, less particulate debris will result in less inflammation and improved performance. And (2), a subset of patients susceptible or predisposed to BIA-ALCL or hypersensitivity-type adaptive immune responses will be more vulnerable to implant debris than the general population and utilizing implants that minimize this response may be paramount in these patients.

"Because of my past relationships [including with Allergan], I know a lot about textures. So, the way textures are made is you peel a shell off of a mandrel that's still got a little bit of tackiness to it. The way that Mentor does this is they take a piece of polyurethane foam and they imprint into to it. There's a way you can put salt crystals or sugar crystals on it, and you let those dry and wash them away. That's one way to texture. **But the big distinguisher is what happens next with Biocell.** Because what they do is, they take this mandrel that's now got the salt crystals in it and they dip it **one last time** in the silicone elastomer and they let it dry. So, every salt crystal, if you will, is encased in a layer of silicone. **And then when these come off the assembly line there are actually workers that with scrub brushes tear the last layer of silicone off and it looks as you can see here in this diagram. That is a particle laden environment.** "[39]

50. McGhan Medical did not develop or invent the "salt loss" texturing process. Upon information and belief, McGhan purchased, licensed, or otherwise acquired the rights to use the

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See also, MT. Brown et al., *A Different Perspective on Breast Implant Surface Texturization and Anaplastic Large Cell Lymphoma (ALCL),* Aesthetic Surgery Journal, Volume 39, Issue 1, January 2019 ("It may be that the fragmentation of silicone produced by some textured implants is the initiating agent"). Available at: https://academic.oup.com/asj/article-abstract/39/1/56/4962476?redirectedFrom=fulltext.

[39] https://youtu.be/YxPFayQsjUo?t=23765. (emphasis added). *See* ¶ 102 *infra*.

Biocell process invention from two residents of Santa Barbara, California, Joel Quaid and William Dubrul.

51. The Allergan/McGhan/Inamed salt loss texturing process for the outer surface of the Biocell silicone implant shell was generally described in a patent filed by Joel Quaid[40] on May 2, 1988, (US patent 4,889,744[41]) that was later assigned to McGhan Medical Corporation, then Inamed Corporation and then Allergan, Inc[42]:

> "It is with the application of the **final layer of silicone elastomer,** that the present invention departs from the existing procedures for forming prostheses. After the mandrel is raised out of the dispersion with what is to be the **final layer adhering thereto**, this layer is allowed to stabilize. That is, it is held until the final coating no longer flows freely. This occurs as some of the solvent evaporates from the final coating, raising its viscosity. Once the layer has stabilized, **granulated solid particles** [salt crystals] **are applied evenly over the entire surface.** Currently the solid particles are applied manually by sprinkling them over the surface while the mandrel is manipulated. However, it is envisioned that a machine operating like a bead blaster or sand blaster could be used to deliver a steady stream of solid particles at an adequate velocity to the coating on the mandrel. Alternatively, it is envisioned that adequate methods of solid particle application can be developed based on machines that pour the solid particles or based on dipping the coated mandrel into a body of the solid particles or exposing it to a suspension of the solid particles … This final layer, with the solid particles embedded therein, is then allowed to volatilize. **After volatilization, the entire silicone elastomer shell structure is vulcanized in an oven at elevated temperatures.** The temperature of the oven is preferably kept between about 200° F. and about 350° F. for a vulcanization time preferably between about 20 minutes and about 1 hour, 40 minutes. Upon removal from the oven, the mandrel/shell assembly is placed in a solvent for the solid particles and the solid particles allowed to dissolve. When the solid particles have dissolved**,** the assembly is removed from the solvent and the solvent

[40] On information and belief, Joel Quaid was an engineer in Santa Barbara, California who worked for McGhan at the time he designed /patented the implant surface design and manufacturing process that would be used in Biocell implants.

[41] Method for Making Open-Cell, Silicone Elastomer Medical Implant, Available at: https://patentimages.storage.googleapis.com/a2/22/59/ecf35d81b82350/US4889744.pdf.

[42] https://patents.google.com/patent/US4889744A/en#legalEvents. There was litigation between Quaid and McGhan over the patent rights to the Biocell implants. *See Medical Products Development, Inc. v. McGhan Medical Corporation,* CV-99-00053 JSL (CWx). This lawsuit was resolved when Quaid's company, Medical Products Development, assigned the Biocell patents to McGhan Medical in October 2002. https://www.sec.gov/Archives/edgar/data/109831/000091205702012689/a2073866zex-10_30.htm.

> evaporated. The shell can then be stripped from the mandrel. At this point, it is preferable to place the shell in a solvent for the solid particles and **gently agitate it** [the shell] **to ensure dissolution of all the solid particles.** When the shell is removed from the solvent, the solvent is evaporated.
>
> The process described above produces a shell 16 like that shown in FIGS. 3 and 4. The shell has a thin outer wall 18 made of silicone elastomer with an opening 20 therein at the point where support member 14 entered mandrel 12. In addition, the outer surface of the shell is covered with open cells where solid particles used to be before being dissolved. FIGS. 5 and 6 provide magnified views of the process whereby these open cells are formed in the surface of the shell. In FIG. 5, solid particles 24 are shown embedded across the surface of the shell. In FIG. 6, the solid particles have been dissolved, leaving behind open spaces in the surface of the shell. When applied, some of the solid particles are partially exposed so that they can be acted upon by the solvent. These exposed solid particles also provide a way for the solvent to reach those solid particles beneath the surface to dissolve them in turn**.** The result can be an interconnected structure of cells, some of which are open to the surface, in the outer layer of the shell." (emphasis added).

52. Quaid's patent makes clear that the intended and described manufacturing process for making the textured implant surface relies on embedding solid particles [later revealed as sharp cubic salt crystals in other patents/articles/product descriptions[43]] and then, after baking/curing the implant shell in an oven and placing it in a solvent, **gently agitating the surface silicone** to **ensure dissolution of all of the solid particles.**"[44]

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[43] *Id.* Allergan itself called the cubic salt particles (covering with a silicone layer) created in the Biocell "salt loss" process as producing particles that were "angular," "sharp," with "sharp corners". On October 30, 2008 Allergan, Inc. filed a new patent, Soft Prothesis Shell Texturing Method, US Patent No. 8,313,527." This patent was approved as US Patent 8,313,527 on November 20, 2012. https://patents.google.com/patent/US8313527B2/en. In this patent Allergan described a manufacturing process based upon a change from cubic salt crystals to round salt crystals, sating: "**the prior art [Biocell**] involved] "using conventional cubic salt crystals." This . . .relatively rough surface is partly the result of **the angular salt crystals** used in the formation process. "As mentioned above, **the properties of [the patent—]an implant shell having a texture formed with round salt crystals are statistically superior to those formed using cubic salt crystals.** This is believed to be due to a reduction in stress concentrations, which may be seen at the **sharp corners formed using cubic salt crystals** . . . In contrast to regular crystalline sodium chloride as seen against a scale in FIG. 5, the rounded salt crystals have been appropriately processed to **smooth any sharp or non-rounded edges that are typically found on standard sodium chloride crystals** (sometimes, termed "cubic salt crystals").

[44] *Id.*

DETAILS OF ALLERGAN'S DEFECTIVE "SALT LOSS" MANUFACTURING DEVIATIONS FOR BIOCELL IMPLANTS REVEALED BY FRENCH AUTHORITIES IN 2015

53. The details of the proprietary manufacturing process for Allergan's BIOCELL® breast implant 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 (**Exhibit 3**).[45]

54. In this ANSM report, based upon an inspection from April 27, 2015—May 1, 2015, ANSM [the French equivalent of the US FDA] examined, *inter alia*, the "salt loss" manufacturing processing and records from Allergan's Costa Rican manufacturing facility that at that time manufactured all of Allergan's breast implants worldwide.[46]

55. Allergan's manufacturing process for texturing breast surfaces was described in detail by the French authorities as follows:

> "Manufacturing process :
> 2.1 Dispersion mixing;
> 2.2 Shell dipping;
> 2.3 Shell curing;
> 2.4 Shell texturation;
> Tack coat:
> Immersion in salt;
> **Overcoating** [with a final silicone layer] in std dispersion;
> Oven cure;
> Soaking in warm water;
> **Scrubbing** (to reveal the textured surface);

[45] https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf

[46] *Id*. at 6 ("ALLERGAN Costa Rica carries out the production operations (component preparation and assembling, sterilization, packaging and final product release) of all the BIs [breast implants] marketed by ALLERGAN throughout the world."

2.5 Control of shell thickness;
2.6 Control of absence of salt residues (not mentioned in ALLERGAN validation file nor specifications);
2.7 Control of absence of Xylene residues (not mentioned in ALLERGAN validation file nor specifications);
2.8 Control of surface topography (not mentioned in ALLERGAN validation file nor specifications);
2.9 Patch vulcanization;
2.10 Gel mixing;
2.11 Gel curing."[47]

56. Plaintiffs aver that Mrs. Pack's Biocell breast implants were manufactured according to the above-described scrubbing/abrading salt loss "proprietary" technique whereby workers in an manual and variable uncontrolled process would scrub off a final cured layer of silicone in a scrubbing room using different brushes and unvalidated methods to "reveal" (release) sharp cubic salt fragments embedded in the implant surface thereby leaving, at times, overly textured implants with foreign degraded and loosened fragments of silicone particles, implant materials, particles, fragments and residues — adulterations—on the implant surface due to over-aggressive scrubbing, lack of quality control and lack of testing and validation as required by FDA and PMA requirements.[48]

57. The French authorities (ANSM) conducted their inspection because of "interests" in "materiovigilance" because of cases of ALCL associated with "BIs [breast implants] of ALLERGAN brands" including, at that time (April, May, 2015) 195 cases of ALCL diagnosed

[47] *Id*. at 15-16 (emphasis added).
[48] Biocell implants were manufactured in Costa Rica beginning in 2000. https://www.sec.gov/Archives/edgar/data/109831/000091205702012689/a2073866z10-k.htm. Inamed also manufactured breast implants in Santa Barbara, CA and in Arklow, Ireland; however, the manufacturing processes were the same. Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) *Preliminary Inspection Report of Allergan Ltd Marlow*, note 12, *supra*, **Exhibit 3** at 6 ("ALLERGAN Arklow supports the above request by a validation program intended to demonstrate that those medical devices shall be manufactured with the same equipment and according to the same processes between Costa Rica site and Arklow site").

worldwide, among which 135 cases were breast implants associated with breast implants manufactured by Allergan.[49]

58. The French authorities (ANSM) noted in their inspection report that in preclinical and clinical data provided by Allergan, "Solid state tumors can form in rodents in which **solid materials** with an excessive surface area have been implanted for long periods of time."[50]

59. The French authorities (ANSM) found, in their inspection of Allergan's manufacturing procedures, a number of "critical" and "major" "deviations" in Allergan's manufacturing and MDR reporting processes with respect to "legal references" and "standards" applicable to medical devices."[51] These deviations violated Allergan's PMAs, and controlling federal specifications, standards and CGMPs thus supporting parallel state law claims.

60. The French inspection documented a "MAJOR" deviation (D7) from standards and legal requirements in connection with Allergan's salt loss manufacturing technique for the Biocell implants:

> "ALLERGAN Ltd Marlow, as the legal manufacturer of BIs marketed in Europe, does not take all the necessary actions to keep under control the residues that may be contained in those BIs, which may compromise their biocompatibility and consequently their compliance with the essential requirements applicable to medical devices (MDD Annex I item 7.2, Annex II items 3.2 b and 3.2 e), insofar :
>
> 1. The water temperature, during the soaking step of the BIs integrated to the texturation, is never reported in the batch records (DHR);
>
> 2. **The control of the manufactured BIs is limited to a visual inspection and some control points, the results of which may impact the safety of the BIs, are neither**

[49] Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) *Preliminary Inspection Report of Allergan Ltd Marlow*, note 12 *supra* at 7.
[50] *Id.* (emphasis added).
[51] *Id.* at 10.

integrated in the validation records of the manufacturing processes, nor in routine production control, particularly regarding the controls of:

Xylene residues, in accordance to specifications that should be established; Surface topography, in accordance to specifications that should also be established.

3. The control of texturing salt residues after the soaking step, within justified and documented limits, is not evidenced in a validation file regarding the microtextured BIs (MICROCELLTM);

4. The control of texturing salt residues after the soaking step, regarding the textured BIs (BIOCELLTM), 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."[52]

61. The French inspection further documented another "MAJOR" deviation (D11) from standards and legal requirements in connection with:

" **the implementation of actions within the scope of BIs production, particularly in terms of residue controls (salt, Xylene, D4/D5 short molecules, others...) and surface topography, associated with adequate specifications**, considering especially that:

- 195 cases of ALCL are diagnosed worldwide to date on patients bearing BIs, among which 130 cases concern patients bearing BIs manufactured by ALLERGAN, with 90 cases confirmed (including 66 cases involving BIOCELLTM) 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 (ISO 14971 item 6.2 b)."[53]

62. The French inspection further documented a deviation (D12) from ISO Standards because Allergan's biocompatibility testing was limited to components of the breast implants as

[52] *Id.* at 16 (emphasis added).
[53] *Id.* at 20 (emphasis added).

opposed to biocompatibility testing on the final product - the implant after it was manufactured and ready for sale:

> "The biocompatibility and preclinical data presented by ALLERGAN Ltd Marlow during the inspection are not sufficient to guarantee the biocompatibility of its BIs marketed in Europe (MDD Annex I item 7.2), insofar:
>
> 1. The 'Biocompatibility review of gel filled mammary implants manufactured by ALLERGAN' and 'Gap analysis for biocompatibility assessment of ALLERGAN Medical breast products testing: An expert opinion's reports, which document the Cytotoxicity (ISO 10993-5), Systemic toxicity (ISO 10993-11), Immunotoxicity (ISO 10993-11), Mutagenicity (ISO 10993-3), Chronic toxicity (ISO 10993-3), Carcinogenicity (ISO 10993-3), Degradation products (ISO 10993-13) and Chemical characterization ISO 10993-18) :
>
> - mention that most of these preclinical trials have not been conducted on the sterilized BIs as finished products ready for sale, but on raw materials or manufacturing intermediates, which does not allow to take into account the risks associated to the manufacturing processes;
>
> - do not provide additional preclinical data regarding the risks of cancer, lymphomas and ALCL, compared to the data mentioned in its previous reports since 2007;
>
> - do not assess the residues of salts and Xylene, neither short molecules such as D4 [Octamethylcyclotetrasiloxane] D5 [Decamethylcyclopentasiloxane] etc., in the part devoted to the chemical characterization of materials.
>
> 2. The in vitro preclinical study on immune cells in contact with BIOCELLTM texture particles does not take into account the chemical characterization of these particles."[54]

63. The French regulators summarized Allergan's regulatory violations:

> "The above accumulated findings represent a major risk regarding the materiovigilance, and safety of the breast implants marketed in Europe by ALLERGAN Ltd Marlow, considering particularly that:
>
> - the knowledge and control of residues that may be present in those medical devices are documented neither in the design data (D12), nor in production

[54] *Id.* at 21.

data (D7 Major) nor in the materiovigilance post-market (PMS) data (D11 Major), and

- the breast implants history records are never reviewed nor challenged while processing the complaint and materiovigilance cases (D8 Critical, R2 Major)."[55]

64. In response to the French authority's (ANSM) report, Allergan filed a formal response in June 2015 (**Exhibit 6**) and effectively conceded that it had not monitored or reported cases with respect to surface (smooth versus textured) and that there were major manufacturing failures/"deviations" such that "corrective actions" as to deficiency 7 (D7) would be made:

> "D7.1 Water Temperature during soaking: Update router and work instructions to record soak tank water temperature.
> D7.2 Controls of xylene residuals: Perform xylene residual analysis and incorporate xylene residual monitoring for every dispersion lot and evaluate routine monitoring frequency after a year.
> D7.3 As a short term corrective action, establish an alert limit on xylene residuals based on historical data analysis
> D7.4 Assess existing xylene specifications after significant body of data is collected from xylene monitoring program and as applicable apply new specification limits
> D7.5 Complete the pFMEA 04653 in accordance with AMED 002 and any additional control measures will be implemented as the results from the pFMEA's outcome.
> D7.6 Surface topography: Implement a monitoring process for pore size, pore depth, and pore density and establish process control limits using the data from TR—1103, Characterization of Surface Morphology: BIOCELL Gel-filled Breast Implants and Tissue Expanders to gain additional information on these characteristics
> D7.7 As a short term corrective action, based on the data from the monitoring program of surface topography (Corrective action D7.6), evaluate and determine if an internal alert limit can be established.
> D7.8 Assess all data collected from the monitoring program and all data from current surface morphology processes and the determine what additional controls and specifications can be applied.
> D7.9 Control of texturing sodium chloride residual: Perform an evaluation to demonstrate that the NaCl residue is <0.155 g / Shell for the texturing application process after soaking."[56]

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[55] *Id*. at 26.

[56] https://ansm.sante.fr/var/ansm_site/storage/original/application/f251f06469a78097b648ec58117c0258.pdf at 24-25.

Plaintiffs aver Allergan's concessions in connection with the French inspection are fully applicable to negligent manufacturing claims brought by Plaintiffs and establish violations of Allergan's PMAs, FDA requirements, and the Quality System Regulations and Current Good Manufacturing Practices identified in this Compliant.

65. After receiving Allergan's Response to the preliminary report, ANSM issued a final report **Exhibit 7**) accepting Allergan's concessionary corrections to the manufacturing process (D7) but found other Allergan's responses "unsatisfactory" as to:

- deficiency 4 (D4) -Allergan did not provide a methodology for post market reports as to adverse incidents broken down by surface (smooth or textured) that was "particularly important to update and consolidate the clinical data;"

- deficiency 11 (D11) - Allergan "did not submit a complete documentation demonstrating its analysis of the cases of cancer, lymphomas and ALCL involving some of its marketed Bis, of the resulting issues, challenges and stakes that may be identified and of an investigation plan mentioning, for example: . . the implementation of actions within the scope of Bis production, particularly in terms of residue controls (salt, Xylene, 04/05 short molecules, others...) and surface topography, associated with adequate specifications, considering especially that - 195 cases of ALCL are diagnosed worldwide to date on patients bearing Bis, among which 130 cases concern patients bearing Bis manufactured by ALLERGAN, with 90 cases confirmed (including 66 cases involving BIOCELLTM 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 (ISO 14971 item 6.2 b).[57]

66. Plaintiffs aver that the deficiencies identified by the French authorities in Allergan's manufacturing process (at the Costa Rica facility) and in connection with the lack of compliance with standards and regulations are completely applicable to the manufacturing processes that

[57] *Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)* Final Inspection Summary Report (May 29, 2015).

occurred in this case (for Mrs. Pack's 2009 and 2015 implants) and are proof of a manufacturing defect and proof that Allergan's manufacturing of the Biocell implants was at times in violation of the PMAs, and federal laws, specifications, standards, requirements CGMPs and thereby constituted negligence and an unreasonably dangerous breast implants that directly caused Barbara Pack's BIA-ALCL due to adulterated and negligently mis-manufactured Biocell textured breast implants.

67. Plaintiffs further aver that the variable and uncontrolled "scrubbing" of the implant during the manufacturing process "to reveal the textured surface"[58] of the Biocell breast implant after a final layer of silicone is applied and after curing was done by **manual scrubbing/brushing** by various workers who **abrade** the external surface of the implant with a brush.[59] Upon information and belief, the intended and as-designed process under the PMAs, however, was to "gently agitate" the shell to "ensure" that "all solid particles are removed." Allergan violated the PMAs and CGMPs because its process was capable of producing implants that are adulterated at times because the process is highly variable and without consistency as it depends on the brushing (with different types of brushes at different times)[60] and an individual scrubbing technique of individual workers where the final result is not controlled by validated processes and adequate inspection controls.[61] Allergan violated the PMAs, federal law, specifications and requirements

[58] **Exhibit 3** (ANSM Preliminary Report) at 15.
[59] Confidential Witness 1 (CW 1). A former Allergan employee with first-hand knowledge of the manufacturing process at Allergan's La Aurora de Herendia, Costa Rica, manufacturing facility. Dr. Dennis Hammond also described Allergan's manufacturing process for the Biocell surface in detail based upon first-hand knowledge and observation of the manufacturing process.
[60] Confidential Witness 1 (CW 1), a former Allergan employee with first-hand knowledge of the manufacturing process.
[61] *Id.*

(including CGMPs) when workers negligently manufactured certain implants and lots by overly aggressive brushing, failure to remove all solid particles, inconsistent manual brushing by low paid workers and lack of sufficient quality control measures, thereby producing, in certain instances, unreasonably dangerous implant products with adulterated, foreign and decomposed solid fragment silicone particles/remnants on the implant surface, including Barbara Pack's implants.[62]

68. The manufacturing process and potential for product defects due to the variable and unvalidated salt loss technique used in the making of the Biocell breast implant is similar to Quaid's US patent 4,889,744 patent and a series of follow-up patients ultimately assigned to Allergan in October 2000 for Biocell textured breast implants that describe how Allergan utilized the salt loss technique by relying upon abrading of the shell of the Biocell implant silicone shell by manual brushing after a final layer of silicone was applied over salt particles before curing with intent to ensure removal of all solid particles.

69. Plaintiffs allege the Biocell manufacturing process involves placing a tack coat of silicone over the implant; immersing the implant in salt; overcoating with a final layer of silicone; curing the implant in the oven; soaking in warm water and then manually scrubbing the implant with brushes to reveal the textured surface. This process produces unwanted fragmented silicone

[62] **Exhibit 7**, ANSM, *Final Inspection Summary Report* at 12 (May 29, 2015) (Allergan did "not assess the residues of salts and Xylene, neither short molecules such as D4, D5 [silicone molecules] etc, in the part devoted to the chemical characterization of materials. 2. The in vitro preclinical study on immune cells in contact with BIOCELL TM texture particles does not take into account the chemical characterization of these particles." . . . "The control of the manufactured BIs is limited to a visual inspection and some control points, the results of which may impact the safety of the BIs, are neither integrated in the validation records of the manufacturing processes, nor in routine production control, particularly regarding the controls of Xylene residues, in accordance to specifications that should be established ; Surface topography, in accordance to specifications that should also be established.").

particles and contaminants —refractile or birefringent residues[63] (e.g., salt crystals, silica[64]), xylene, and cyclosiloxane impurities, siloxane molecules, e.g., D4 and D5.[65]

70. Plaintiffs aver that the deficiencies in Allergan's manufacturing process and the lack of compliance with federal standards and regulations directly caused Barbara Pack's BIA-ALCL due to adulterated and negligently manufactured Biocell textured breast implants.

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[63] *See e.g.* Santos-Briz, et.al., *Granulomatous reaction to silicone in axillary lymph nodes. A case report with cytologic findings*, Acta Cytol. 1999 Nov-Dec;43(6):1163-5. (reporting silicone lymphadenopathy in patient with breast implants and "**a granulomatous reaction to birefringent material** with predominance of foreign body giant cells in a lymphoid background.")(emphasis added). https://www.karger.com/Article/Pdf/331373; Rosen's Breast Pathology at 50, 56 (2009)(noting fine particles or crystals of birefringent material in silicone granulomas in breast tissue capsule).

[64] *See* K.W. Dunn, et al., *Breast Implant Material: Sense and Safety, British Journal of Plastic Surgery* (1992) (The tissue reaction. . .is maximum to fumed silica, which is present in the envelope of the implants." The authors noted that the implant shell consists of 30% silicone dioxide (silica) as a filler, that silicone and silica are physically, chemically and immunologically distinct, that silicone dioxide is chemically fused to silicone polymer in the elastomer shell, "[h]owever suggestions have been made as to how silica may be liberated from its bond to silicone, for example by macrophage phagocytosis. . ." The authors go on to say that "free silica" "is a potent stimulus to inflammation" and that if there is any "risk" "linking breast augmentation to human carcinogenesis" "the time from implantation to presentation is likely to be great, as seen in other foreign body associated tumors (e.g. asbestosis and schistosomiasis)." https://www.jprasurg.com/article/0007-1226(92)90060-B/pdf

[65] *Cf.* Particulate contamination and cyclosiloxane impurities on the textured implant surface were found in the manufacturing process of another textured implant manufacturer (Silimed). The Netherlands, Ministry of Health, *Risk analysis of particulate contamination on Silimed silicone-based breast implants* at 8 (2015)(" In addition to the particulate contamination, the RMS report describes **relatively high levels of cyclosiloxane impurities that were found in 3 of the 3 evaluated Silimed textured SBI.**"). https://www.rivm.nl/bibliotheek/rapporten/2015-0202.pdf (emphasis added).

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ALLERGAN FILES A PATENT IN 2008 FOR IMPLANT TEXTURING THAT REVEALS MANUFACTURING DETAILS AND CLAIMS SUPERIORITY OVER THE "PRIOR ART" OF THE BIOCELL IMPLANT TEXTURING PROCESS

71. On October 30, 2008 Allergan, Inc. filed a new patent, Soft Prothesis Shell Texturing Method, US Patent No. 8,313,527."[66] This patent was approved as US Patent 8,313,527 on November 20, 2012.

72. Allergan's 8,313,527 patent describes a "superior" implant shell compared to the "prior art" — directly referring to the Biocell implant described in the Quaid patent as manufactured by Allergan. The new patent described a manufacturing process based upon a change from cubic salt crystals to round salt crystals:

> "FIG. 4 is a magnified view of a sample of rounded salt crystals used in the implant texturing process of the present invention;"
> "FIG. 5 is a magnified view of a sample of cubic salt crystals used in conventional implant texturing processes of the prior art:"

[66] https://patents.google.com/patent/US8313527B2/en

Fig. 4

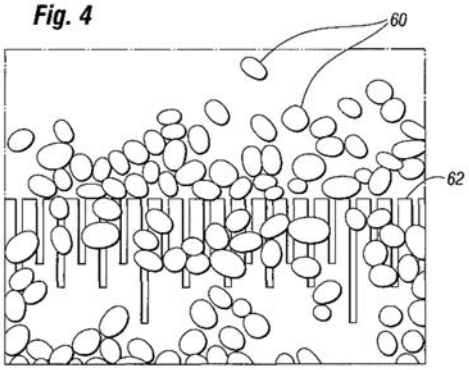
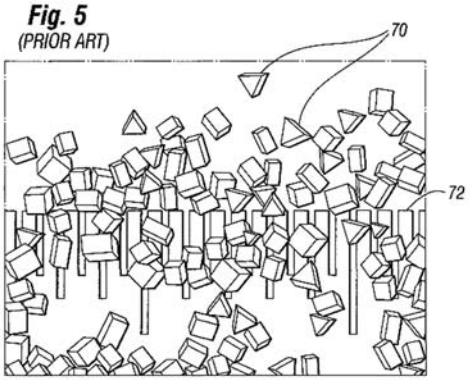


Fig. 5
(PRIOR ART)



"FIGS. 6A and 6B illustrate in magnified cross-section and plan view, respectively, an implant shell 80 of the prior art:

Fig. 6A
(PRIOR ART)

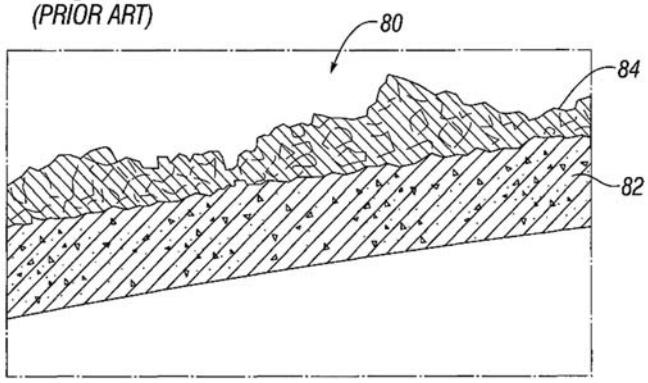
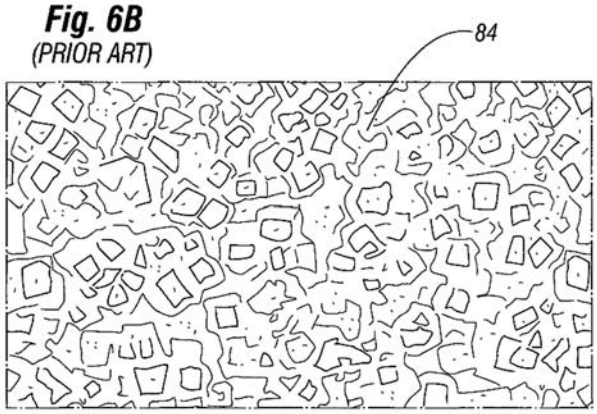


Fig. 6B
(PRIOR ART)



"The present invention diverges from previous processes in the make-up of the salt crystals used in the dispersion 22. Namely, as seen in FIG. 4, rounded salt crystals 60 are shown over a reference scale 62. In contrast to regular crystalline sodium chloride 70, as seen against a scale 72 in FIG. 5, the rounded salt crystals 60 have been appropriately processed to smooth any sharp or non-rounded edges that are typically found on standard sodium chloride crystals 70 (sometimes, termed "cubic salt crystals)."

"FIGS. 6A and 6B illustrate in magnified cross-section and plan view, respectively, an implant shell 80 of the prior art having texturing formed using conventional cubic salt crystals. The shell 80 includes an inner wall 82 and an outer textured surface 84. This textured surface 84 is formed by applying cubic salt crystals and then dissolving those crystals to leave an open-celled porous surface. The relatively rough surface 84 is partly the result of the angular salt crystals used in the formation process. The particular texture illustrated is sold under the tradename BIOCELL® surface texture by Allergan, Inc. of Irvine, Calif.

> "To compare the different shells, standard tensile strength specimens were cut from the shells and subjected to stress tests. The comparison shell was a standard commercial textured shell of the prior art sold under the tradename INAMED® BIOCELL® Saline- or Silicone-Filled Breast Implants, by Allergan, Inc. of Irvine, Calif. More specifically, random BIOCELL® shells formed using the process described with reference to FIGS. 6A and 6B were used for comparison. Sixty specimens from this group were cut using an H2 die and tested for tensile strength. Table I below illustrates the results."

> "As mentioned above, the properties of an implant shell having a texture formed with round salt crystals are statistically superior to those formed using cubic salt crystals. This is believed to be due to a reduction in stress concentrations, which may be seen at the sharp corners formed using cubic salt crystals."

> "The breast implant of claim 1 wherein the ultimate break force of the flexible shell is more than 5% greater than the ultimate break force of said identical flexible shell made using the same process and same materials except for angular particles instead of round particles."

> "The present invention diverges from previous processes in the make-up of the salt crystals used in the dispersion 22. Namely, as seen in FIG. 4, rounded salt crystals 60 are shown over a reference scale 62. In contrast to regular crystalline sodium chloride 70, as seen against a scale 72 in FIG. 5, the rounded salt crystals 60 have been appropriately processed to smooth any sharp or non-rounded edges that are typically found on standard sodium chloride crystals 70 (sometimes, termed "cubic salt crystals")."

73. Plaintiffs aver that Allergan's patent 8,313,527 is inculpatory evidence that Allergan's "prior art" — the Biocell textured surface using cubic/angular salt crystals — produced, by Allergan's own admission, solid sharp-edged angular particles with rough "dividing walls" in the open pores with more "angular discontinuities":

> "Although not shown in great detail, the pores or openings in the open-celled surface [using sound salt crystals] 104 have smoother dividing walls and fewer angular discontinuities than the pores or openings in conventionally manufactured shells [Biocell] that are otherwise identical but use angular salt crystals rather than rounded salt crystals. As will be shown, this difference surprisingly leads to statistically significant changes in overall shell strength."

74. Plaintiffs aver that Allergan patent 8,313,527 presented a changed manufacturing process because Allergan knew, at least by 2008 (date of filing of US patent 8,313,527), that its

Biocell implants were prone, at times, to have sharp-edged solid particles (salt encased by silicone) particles left on the implant surface in the manufacturing process for Biocell implants by over-abrasion and lack of infection and quality controls. The process created certain non-conforming implants, including the Biocell implants implanted into Mrs. Pack in 2009 and 2015, that were defective, dangerous and inferior in design and manufacture when solid sharp particles were left on the implant surface by negligent manufacturing and over- texturizing.

ALLERGAN KNEW THE MANUAL SALT SCRUBBING PROCESS WAS VARIABLE, INCONSISTENT AND, AT TIMES, PRODUCED DEFECTIVE IMPLANTS

75. The variable manual salt crystal hand scrubbing process used to make Biocell implants was known by Allergan managers and employees in Costa Rica and in California to be a "bad mix" that produced nonstandard outcomes and, at times, negligently manufactured implants with particles on the surface of the implant.[67]

76. Allergan's Costa Rica management at the La Aurora de Herendia facility alerted Allergan's upper management in the United States, Ronald H. Lentsch and Raymond H. Diradoorian, concerning the problems with the manual hand-scrubbing process and recommended changing to a sand blasting process.[68] The proposal to change the manufacturing process was not approved, however, because Diradoorian, Allergan's Executive Vice President of Global Technical Operations, did not want to make the necessary capital expenditure to improve the

[67] Confidential Witness 2 (CW2), a former Allergan employee with first-hand knowledge of the manufacturing process. *See also* ¶ 15(iv) *supra* (testimony of Allergan corporate representative manufacturing defects in implants with particles on the surface of an intact shell).
[68] CW2.

product and process" [69] The decision to keep producing Biocell implants with the manual salt loss process in order to save money was made despite Allergan's awareness of an increasing number of BIA-ALCL cases associated with Biocell textured implants both reported to the company and in reports in the medical literature.

77. In 2011 the FDA reviewed data from Allergan's post-approval "Device Failure Studies" that Allergan performed between November 2006, when the implants were approved for sale, and June 2009.[70] Of the 2,665 devices that were returned and evaluated by Allergan, only "53.6 percent" of the "devices were found to be "Intact and Functional," with no openings or other failure characteristics. Thus, despite Allergan's alleged quality control processes, nearly half of the devices that were returned were defective or failed in some way. "Device surface observations with **defects**" were noted in 3.4% of the cases and 26 devices (1 percent) had "**manufacturing defects**" with openings in the shell.[71]

ALLERGAN KNEW THE BIOCELL MANUFACTURING PROCESS WAS DEFECTIVE AND PRODUCED UNWANTED ADULTERATED SILICONE PARTICLES THAT BECAME EMBEDDED IN BREAST TISSUE

78. Allergan, by merging with McGhan Medical and Inamed, knew from research studies sponsored in the early 1990's that its proprietary Biocell textured surface for silicone breast implants made with the "salt loss" process produced (at times in the final product) unwanted foreign silicone and debris particles on the surface of the implant shell whereby

[69] *Id.*
[70] https://www.fda.gov/media/80685/download
[71] *Id.* (emphasis added).

fragments and shedding of particles migrated and embedded into animal and human tissue.[72] These studies were conducted in Nashville, Tennessee and at Bowman Gray Medical School in North Carolina in 1991 and 1992.[73] Allergan (then McGhan Medical/Inamed) prematurely and with scienter suspended the studies when they showed "bad" results and shelved ("deep-sixed") these animal (rabbit and pig) and human *in vivo* particulation studies. One shelved study was titled, "A Histological Evaluation of Capsular Silicone Particulation and Migration with Time Using Textured Surface Implants." Another study was titled, "Histologic and Tonometric Analysis of Novel Surface Textures of Breast Implants in Pigs." Upon information and belief, these studies and adverse particulation results were never reported to the FDA in violation of federal law and PMA post-approval requirements, particularly 21 C.F.R. §§ 803, 814.20 and §814.84. The data, results and documentary proof of the these abandoned and never-reported particulation studies, however, remain available in Nashville, Tennessee and Greensboro, North Carolina.

79. The sponsor of the study, McGhan Medical, had the researchers conduct both a silicone particulation study in animals and a clinical study for silicone particulation *in vivo* in patients (interim report).[74] This information was provided to the sponsor (McGhan Medical).[75] The

[72] Confidential Witness ("CW3") a physician with first-hand knowledge of this testing and these studies), personal communication to the counsel for Plaintiff Lizabeth Paulette Parr (Case No. 1:20-cv-00005, E.D. Mo.), October 14, 2019.
[73] Personal communications to the counsel for Plaintiff Lizabeth Paulette Parr (Case No. 1:20-cv-00005, E.D. Mo.) from Confidential Witness ("CW4"), a physician with first-hand knowledge, October 17-21, 2019.
[74] Confidential Witness ("CW5") a health care professional in Nashville, Tennessee with first- hand knowledge of this testing and these studies), personal communication to the counsel for Plaintiff Lizabeth Paulette Parr (Case No. 1:20-cv-00005, E.D. Mo.), October 17, 2019.
[75] *Id.*

studies' results, however were "bad" and the studies were stopped (with no publication) because they showed that silicone particles from the Biocell implant became embedded in tissue.[76]

80. The suspended Biocell particulation studies conducted by McGhan Medical were never disclosed or reported to the medical/scientific community or to the public until the filing of this Complaint. Upon information and belief, Plaintiffs aver that Defendants violated: post-approval legal duties; federal law; the Biocell saline implant 510(k); the 2000 and 2006 PMAs; and 21 C.F.R. §803, 21 C.F.R. § 814.84 by failing to disclose the adverse events and clinical and laboratory studies to FDA.

81. Barbara Pack and hundreds (at this point) of other women would never have developed BIA-ALCL had Defendants not violated their PMAs, C.F.Rs., and MDR, AER and post-approval duties and reporting obligations under federal law (which violations are parallel duties under Utah negligence and product liability law for failing to warn third persons (i.e. the FDA and plastic surgeons) of unreasonably dangerous adulterations in the product.

82. The acts and omissions of McGhan Medical, in stopping and suppressing the animal and *in vivo* human particulation studies on the Biocell implant surface were reckless, intentional, oppressive and contrary to all FDA laws, standards, regulations and tort law duties under state law. By virtue of the consolidation and merger of McGhan Medical into Inamed and then into Allergan,

[76] Personal communication from CW3 to counsel for Plaintiff Lizabeth Paulette Parr (Case No. 1:20-cv-00005, E.D. Mo.), October 14, 2019. *See* note 79 *supra*. Pleading the facts learned from these confidential witnesses does not waive the attorney work product privilege and expects to independently prove these facts from discovery from Allergan and by subpoenas to the institutions and entities that conducted the research. *See* *In re St. Paul Travelers Sec. Litig. II*, No. 04-4697 (JRT/FLN), 2007 U.S. Dist. LEXIS 34527 (D. Minn. May 10, 2007).

Allergan must accept successor liability for McGhan Medical's egregious suppression of studies that showed its manufacturing process was prone to adulteration.

83. Plaintiffs aver the particulation studies/research followed the FDA's notice to breast implant manufacturers in 1991 that they would be subject to PMAs. In 1988 FDA reclassified breast implant into Class III, higher-risk products needing premarket approval (PMA), and in 1989 called for manufacturers to provide data demonstrating the devices were safe and effective.

ALLERGAN KNEW OF THE SERIOUS RISK OF BIA-ALCL BUT FAILED TO ISSUE REQUIRED REPORTS AND WARNINGS TO THE FDA

84. As medical device manufacturers McGhan, Inamed and Allergan had a continuing post-510(k) and post-PMA duty to monitor the medical literature and make timely reports to FDA of any clinical studies or adverse drug experiences in connection with its breast implant products. 21 C.F.R. §§ 803, 814.84. This duty to report and warn the FDA supports the recognized state tort claim under Utah law based on the underlying state-law duty to warn about the dangers or risks of a product.

85. The duty to monitor the medical and scientific literature is vitally important especially for new or rare diseases. The tragic experience of the teratogenic drug thalidomide (introduced in Germany 1956) and used as a sedative and for morning sickness in pregnant women provides the best example. In December 1961 an Australian obstetrician, William McBride wrote a letter to British medical journal The Lancet and described "multiple severe abnormalities"

(absence of limbs) in babies whose mothers had been prescribed thalidomide for morning sickness.[77]

86. McBride's letter, consisting of merely five sentences, caused the manufacturer to immediately withdraw all preparations of thalidomide from the market and led to a worldwide ban on the drug. Fortunately, thalidomide was not allowed in the U.S. market because Dr. Frances Kesley at FDA refused approval out of safety concerns.[78]

87. In August 1997, two physicians in California, John Keech and Brevator Creech published a similar sentinel case report/letter in the leading plastic surgery journal, Plastic and Reconstructive Surgery titled, *Anaplastic T-Cell Lymphoma in Proximity to a Saline Filled Breast Implant.* Bilateral McGhan Medical Corporation Style 168 (Biocell) implants were placed into a 42-year-old woman in 1991 and an "identical implant" was also implanted in 1995 when the left side deflated. A right breast mass appeared and in 1996 she was diagnosed with anaplastic large cell lymphoma.

88. At the time of Keech and Creech's 1997 case report of ALCL in connection with McGhan's Biocell Style 168 Biocell implants, McGhan Medical/Inamed Corporation was under a legal duty to report this case from the medical literature to the FDA. McGhan's 510K conditions of approval (and plain legal duty under 21 C.F.R. § 803 and 814.84) required McGhan to report and notify this case of ALCL to the FDA. The breach of Defendants' post-approval (but pre-sale) duty to warn the FDA proximately caused Mrs. Pack's injuries from the BIA-ALCL caused by her

[77] https://www.bmj.com/content/362/bmj.k3415.full.
[78] https://www.theglobeandmail.com/news/national/canadian-doctor-averted-disaster-by-keeping-thalidomide-out-of-the-us/article21721337/.

Biocell implants implanted in 2009 and 2015. Unlike the thalidomide experience, Allergan's violations of FDA requirements caused a defective and deadly product to remain on the market for more than 22 years.

89. In 2003, for example, Sahoo, Rosen *et al.* published a case report and review of the literature in The Archives of Pathology and Laboratory Medicine, *Anaplastic Large Cell Lymphoma Arising in a Silicone Breast Implant Capsule: A Case Report and Review of the Literature.*[79] The authors reported that a silicone gel-filled implant placed in the left breast 1991 resulted in ALCL in the left breast diagnosed in March 2000. Notably, pathology of the left breast capsule showed "Empty spaces containing unstained **refractile material consistent with silicone particles** (black arrows) are often in close proximity to the tumor cells."[80]

90. In 2008 Newman et al., reported a case of ALCL diagnosed in 2003 in a woman who had received "McGhan 500 cc silicone gel implants" in 1989. The authors noted, "[p]athology revealed amorphous debris, crystals and histocytes."[81]

91. On January 2011, the FDA released a report on BIA-ALCL, listing as its primary finding the following: "[b]ased on the published case studies and epidemiological research, the FDA believes that there is a possible association between breast implants and ALCL." The FDA's report stated 34 cases of BIA-ALCL had been reported in 18 published articles in the medical literature prior to 2010.[82] Upon information and belief, Defendants reported *none* of

[79] https://www.archivesofpathology.org/doi/full/10.1043/0003-9985%282003%29127%3Ce115%3AALCLAI%3E2.0.CO%3B2
[80] *Id.*
[81] Newman et al., *Primary breast lymphoma in a patient with silicone breast implants: a case report and review of the literature,* Journal of Plastic, Reconstructive & Aesthetic Surgery (2008) 61. https://www.jprasurg.com/article/S1748-6815(07)00216-1/pdf
[82] http://wayback.archive-

these BIA-ALCL cases to FDA prior to 2010 and the FDA's first MDR report from any manufacturer of BIA-ALCL was not until 2010.

92. In addition to the failure to monitor the scientific literature and failure to report the many cases of BIA-ALCL reported in the medical and scientific literature, Allergan, McGhan and Inamed also breached their post-marketing duties to report BIA-ALCL based upon actual complaint and case reports that were received by the company but not reported to FDA. By 2010 Allergan, according to a confidential document provided to French regulators in 2015, had received complaint/case reports of 18 cases of BIA-ALCL for silicone gel-filled implants from 2007-2010.[83] This number does not include saline implants.

93. Plaintiff's review of the MAUDE database shows Allergan first reported an ALCL case to the FDA in 2010 (a death from ALCL that had been reported to Allergan by a health care professional.")[84]

94. Allergan's management and persons within the company were well aware that BIA-ALCL was being reported in the literature and were also well aware that the company had received case reports of ALCL associated with its implants, particularly its Biocell textured implant.

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it.org/7993/20170112002119/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm#appendixb ("In a thorough review of scientific literature published from January 1997 through May 2010, the FDA identified 34 unique cases of ALCL in women with breast implants throughout the world.).

[83] https://ansm.sante.fr/var/ansm_site/storage/original/application/06a05a9d97a9a029508115bacee918e5.pdf. **(Exhibit 5).**

[84] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=1735706&pc=FWM

95. Prior to Mrs. Pack's first implant surgery, Allergan knew of the risk of ALCL associated with its product and should have warned and notified the FDA based upon reports in the medical literature and pursuant to Allergan's post-PMA duty to monitor the medical literature.

96. Allergan's breach of its legally required medical device reporting post-510(k) and post-PMA approval (MDR) duties were further detailed by the French ANSM's inspection of Allergan in 2015. This inspection found Allergan's materiovigilance and reporting of adverse events seriously deficient, characterized as a "critical" — the most serious deviation:

D8 Critical

The management of the individual complaints and MV cases by ALLERGAN Ltd Marlow is not satisfactory, which compromises the proper processing and notification of the serious incidents occurred in France to ANSM, regarding particularly the cases of Cancers-Lymphoma-ALCL (MDD Annex II item 3.1, claimed ISO 13485 standard items 7.2.3, 8.2.1, 8.4 and 8.5, Meddev 2.12/1 points 5.1.7 et 5.3), in terms of :

1. Assessment of the gravity and causality of the incidents regarding the BIs involved, insofar

- The Incident Report Forms (IRFs) issued by ALLERGAN
  - rank those serious cases in the fields 'All other reportable incident' and 'No threat of public health' (points 3, 7, 12, 14, 15, 19, 27);
  - do not always take into account the conclusions of the physician notifiers and anatomopathological reports, when available, in terms of causality of some cases regarding the BIs involved (point 12);
- database does not always:
  - clearly mention the seriousness (point 11) and causality (points 20, 24) of some cases regarding the BIs involved;
  - take into account the conclusions of the physician notifiers and anatomopathological reports, when available, in terms of causality of some cases regarding the BIs involved (point 12);
- ALLERGAN Ltd Marlow does not always request to notifiers:
  - for returning the BIs (in order to proceed to their analysis and expertise) and for the identification of their batch number, so that the causality of the concerned cases regarding the BIs involved cannot be assessed (point 18);
  - the reasons why some BIs are not returned, which compromises again the assessment of the causality of the concerned cases regarding those BIs,

considering particularly that some notifiers are physicians involved in clinical trials (point 26);

- The processing of cases that do not involve an ALLERGAN BI in place at the time of the diagnosis of the patient, even if the BI concerned has been worn by the patient for only few months and implanted to replace an ALLERGAN BI worn for several years by this same patient, is such that ALLERGAN excludes the causality and risk assessment related to the ALLERGAN BI (point 16).[85]

BARBARA PACK'S BIOCELL IMPLANTS WERE NEGLIGENTLY MANUFACTURED IN THE "SALT LOSS" TEXTURING PROCESS

97. Plaintiffs aver that the use of salt crystals, in tandem with the uncontrolled Allergan Biocell manufacturing process with variable scrub brushing by individual workers, created variant products and the potential for non-conforming adulterated implants such as those implanted in Barbara Pack—implants with an excessive amount of foreign, adulterated, sharp solid silicone particles/fragments/contaminants. The variable final scrubbing whereby the implant shells are manually "**abraded after curing to remove the salt"** "produces a surface that is very complex with randomly-arranged, **cubic** indentations covered with ruptured silicone domes **and torn silicone fragments**."[86]

98. The operative defect in Allergan's negligent manufacturing process for textured Biocell implants —variable roughness and at times volumes of scrubbed particles from the silicone elastomer shell created by the uncontrolled actions of workers scrubbing and abrading the implant shell—was known and reasonably knowable to Defendants. While the McGhan, Inamed, and

[85] https://ansm.sante.fr/var/ansm_site/storage/original/application/18e9bb9ab07166f3c70e9919d237e03f.pdf at 17, 31-34.

[86] Australian Government, Department of Health, Therapeutic Good Administration, Biomaterials & Engineering Laboratory Report, Project: Surface Topography Device: Non- active mammary implants (September 2019) at 20, 43. Available at: https://www.tga.gov.au/sites/default/files/biomaterials-and-engineering-laboratory-report-non-active-mammary-implants.pdf.

Allergan Biocell textured breast implants relied upon the "salt loss technique" whereby solid salt particles were embedded; coated with a final overcoat of silicone elastomer; and were then supposed to be removed by a process abrading the surface, other manufacturers relied upon different *proprietary* texturing techniques and openly questioned whether Allergan's manufacturing method was routinely safe and prone to manufacturing defects.[87]

99. McGhan/Inamed/Allergan competitor Mentor, for example, produced its Siltex textured breast implant using a stamp texturing process:

"In fact over the last decades, known 'as micro/macrotexturization', several surface modifications to increase roughness have emerged such as Siltex texturing, a patterned surface created as a negative contact imprint off of a texturing foam, and the Biocell surface, a more aggressive open-pore textured surface created with a lost salt technique in which the entire elastomer shell is placed on a bed of finely graded salt with light pressure."[88]

100. Other competitors in the textured breast implant business took aim at the Biocell "salt loss technique" manufacturing process and noted the "salt loss technique" carried the potential and "detrimental" risk that not all the particles would be dissolved or abraded away.[89]

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[87] United States Food and Drug Administration, FDA Executive Summary Breast Implant Special Topics Prepared for the Meeting of the General and Plastic Surgery Devices Advisory Panel March 25 and 26, 2019. Available at: https://www.fda.gov/media/122956/download. ("Each breast implant company utilizes a proprietary manufacturing process to create the textured surface.").

[88] Munhoz, et al., Nanotechnology, nanosurfaces and silicone gel breast implants: current aspects, CASE REPORTS IN PLASTIC SURGERY AND HAND SURGERY, 2017 VOL. 4, NO. 1, 99–113, at 102. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5727455/pdf/icrp-4-1407658.pdf

[89] Method of manufacture of enhanced surface implant, US Patent No. 5,525,275 (filed Jul.27,1993). Available at: https://patentimages.storage.googleapis.com/10/db/7b/c3aeb33481c1b3/US5525275.pdf

101. In a 1993 US patent application, breast implant maker PMT Corporation in Minnesota pinpointed the potential for manufacturing defects in the Biocell implant:

> "In U.S. Pat. No. 4,889,744, issued to Quaid, a method for making a medical implant with an open cell textured surface is disclosed. The implant has an open cell texture produced by applying soluble particles (e.g., salt, sugar, etc.) to an uncured layer of silicone dispersion. The silicone layer is then fully cured. Subsequent to curing, the silicone layer is then placed in a suitable solvent so that the solid particles are dissolved from the surface of the shell. This method creates open cells on the surface of the implantable body. This prior art device is depicted in FIG. 5. **The open cell structure manufacturing technique is believed to pose three potential problems. First, introduction of a foreign or non-silicone particle to the surface of the uncured silicone can affect the properties of the silicone during the curing process or over the life of the implant. The open cell structure also creates *potential* silicone fragments which can easily become detached from the open cell structure or cell wall as can be readily seen by the physical shape of the cells in FIG. 5.** [90] **Finally, use of a soluble particle requires that the particle be fully dissolved prior to implant. If the particle is not fully dissolved or the particle becomes encapsulated by the silicone, such particles may be released from the surface after implantation. This may be detrimental."**[91]

90

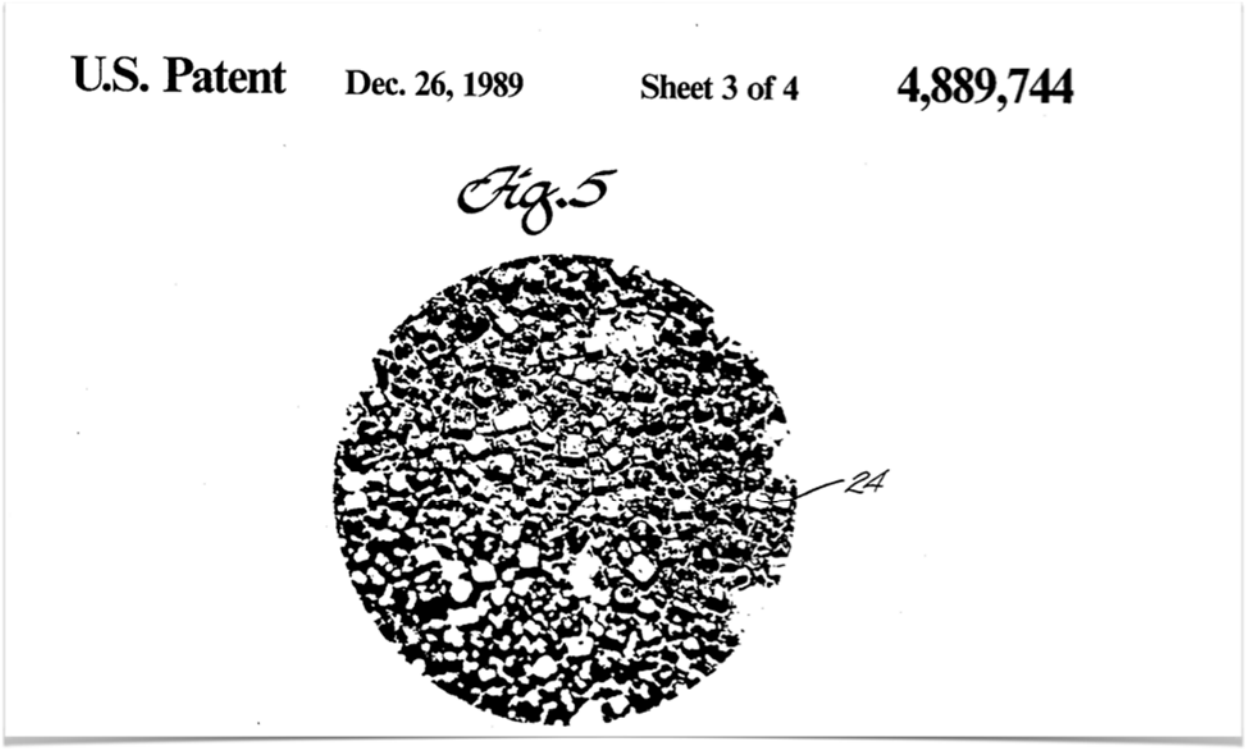
U.S. Patent Dec. 26, 1989 Sheet 3 of 4 4,889,744

Fig. 5

24

91 *Id.* (emphasis added).

102. In US Patent application US2019/0142574A1 published in May 2019, breast implant manufacturer, Establishment Labs, S.A., maker of the Motiva implant sold in South America (and now seeking approval for sale in The United States) further identified the variable nature of Allergan's salt loss manufacturing technique and the potential for producing defective implants with remnant particles:

> A further concern with regard to implant manufacturing is consistency. Implants often vary in terms of biocompatibility from manufacturer to manufacturer, implant model to model, and often from individual implant to implant. Such variation can lead to unpredictability in clinical outcomes of implantation surgeries, costly and painful diagnostic procedures, and subsequent surgeries in order to fix problematic implants. For example, one known method of manufacturing [i.e. the Allergan salt loss process] implant surfaces includes bombarding the surface with particles of salt or other solids, and then washing away the particles. Implants produced by this method, however, may exhibit variations in surface texture from one implant to the next, due to variations in individual salt or other particles and in the bombardment process. **Further, the implant may also include remnants of particles that do not fully wash away, causing additional adverse effects on surrounding tissues**. **Such manufacturing processes provide little to no control over surface properties, not to mention a lack of reproducibility.**[92]

103. Articles in the medical literature have also addressed the potential for a manufacturing product defect in cases of "aggressive" and "overaggressive texturing" [as opposed to Allergan's described requirement of "gentle" agitation] with the Biocell textured implant manufacturing process.[93]

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[92] Medical implants and methods of preparation thereof, US Patent Application No. US20190142574A1 (May 19, 2019)(emphasis added). Available at: https://patentimages.storage.googleapis.com/b5/4f/cd/370dd6b6634064/US20190142574A1.pdf

[93] *See e.g.,* Huemer, et al., *Motiva Ergonomix Round SilkSurface Silicone Breast Implants: Outcome Analysis of 100 Primary Breast Augmentations over 3 Years and Technical Considerations,* PLASTIC AND RECONSTRUCTIVE SURGERY at 832e, 838e (June 2018) https://journals.lww.com/plasreconsurg/fulltext/10.1097/PRS.0000000000004367:

104. Allergan's Biocell implant was intended to be manufactured by "gently agitating" the surface after a final layer of silicone had to be scrubbed off to reveal the salt crystals (a euphemism for scrubbing/abrading) to "**ensure**" that "**all solid particles**" were removed from the implant. In fact, solid silicone fragments and particles from Allergan's Biocell "macrotextured implants" were at times manufactured with solid particles and implant materials/residues left on the implant surface. These particles have recently been identified in the medical literature as being responsible for "chronic inflammation and the activation of T-lymphocytes.":

> **Particulate coming from peaks of textured implants creates extra foreign bodies, giving a chronic immunologic inflammatory reaction with tissue growth,** the periprosthetic capsule. Although implant producers have coped with rupture and bleeding by implant core structure modification (cohesive gel, triple shell, etc.), **particulation is not addressed at all with the macrotextured surfaces still routinely used.** Silicone particles when captured by macrophages ignite a complex mechanism that leads to chronic inflammation and activation of T-lymphocytes.[94]

> Breast implant surfaces have conventionally been characterized as either smooth or textured. Textured surfaces can be induced by projecting salt, sugar, or other particles onto the implant shell. Lately, several **studies have linked aggressive texturing with secondary adverse effects** such as late seroma, double-capsule formation, and capsular contracture.
>
> **Although overaggressive, salt-based texturing was recently linked to secondary adverse events** such as late seroma and double-capsule formation, a suspected decrease in pore size of Allergan's Biocell (Allergan, Inc., Dublin, Ireland) surface over the past decade is speculated to correlate with increased implant nonadhesions and dislocations." (emphasis added; citation references omitted).

Available at: https://www.researchgate.net/publication/325443104_Motiva_Ergonomix_Round_SilkSurface_Silicone_Breast_Implants_Outcome_Analysis_of_100_Primary_Breast_Augmentations_over_3_Years_and_Technical_Considerations (emphasis added).

[94]Munhoz, *supra,* at 107.

105. 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.*"[95] The authors explained their study as follows:

> "Texturing of breast implants is done to decrease the risk of associated complications. **Each manufacturer utilizes unique and at times proprietary techniques to texture the surface of their implants. Little is known about the integrity of this surface structure texturing or the propensity for the surfaces to shed particulate matter.** This study aimed to determine the extent of surface particulate shedding from 3 textured implants approved by the US Food and Drug Administration (FDA), which are manufactured by Allergan, Mentor, and Sientra."[96]

106. In this study, the authors examined new Allergan Biocell textured implants provided as they came from the Allergan factory. With sterile gloves and in a sterile laboratory, the researchers were able to view the Biocell textured "salt loss" surface as it had been manufactured under scanning electron microscopy (SEM). What they found were **solid particles**

[95] 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

[96] *Id.* at 179.

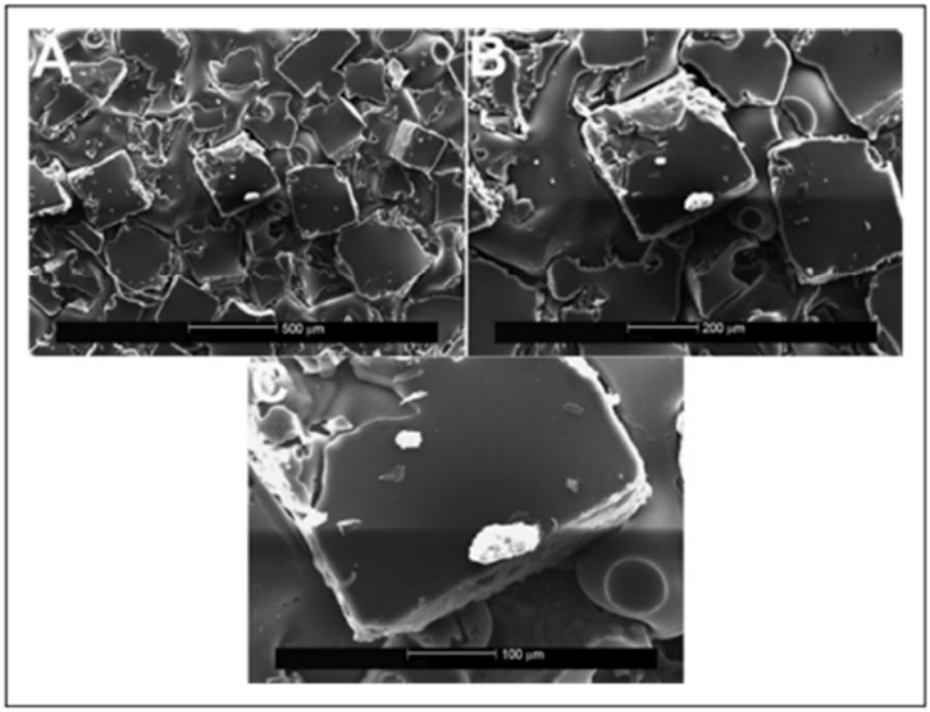


Figure 3. Ethylene vinyl acetate copolymer after spallation of the Allergan Natrelle Biocell implant, shown on scanning electron microscopy (A, ×50; B, ×100; C, ×250). The white flecks of material indicate shed particles of silicone from the surface topography.

of silicone—"white flecks"—on *some* surfaces of the Natrelle [Allegan Biocell] implant that the researchers concluded were **"shed particles of silicone**:"

107. In 2009, Barr et al. performed electron microscopy on the Biocell implant surface that showed the torn/fragmented Biocell surface caused by the "unique" abrading salt loss

manufacturing process with a "not **cleanly** pushed out surface" (Figures 9 & 10[97]):

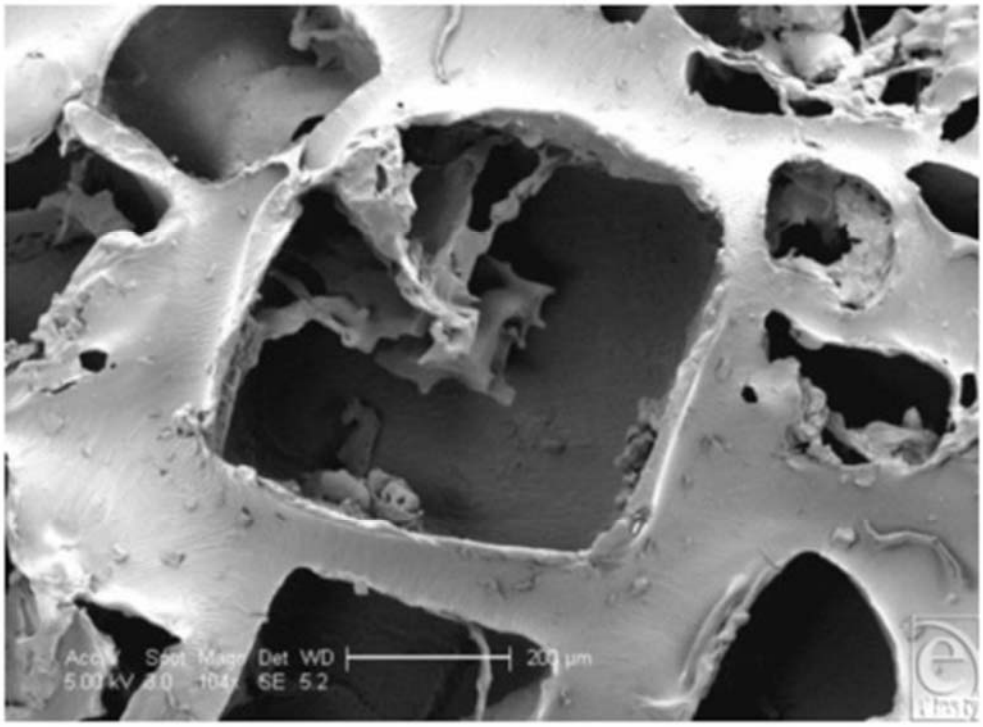
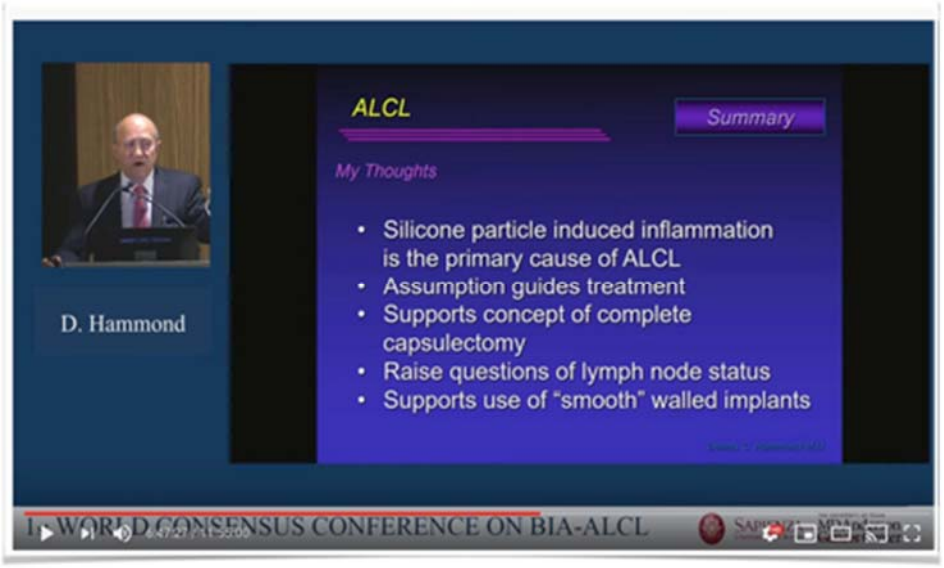


Figure 10

Allergan Biocell (Santa Barbara, Calif) in scanning electron microscopy at 104× magnification with a 200-µm scale bar and 25-µm representations of an average human fibroblast. This image looks further into one of the Biocell implant surface pits and demonstrates the irregularity of its dimensions compared to the surrounding pits. It also shows that this surface feature has its own internal topography and that it is not a cleanly punched-out feature within the surface of this silicone implant.

[97] Barr et al., *Current Implant Surface Technology: An Examination of Their Nanostructure and Their Influence on Fibroblast Alignment and Biocompatibility*, Eplasty., 2009 at 11-12. Available at: https://www.researchgate.net/publication/26674569_Current_Implant_Surface_Technology_An_Examination_of_Their_Nanostructure_and_Their_Influence_on_Fibroblast_Alignment_and_Biocompatibility (emphasis added).

108. Dr. Dennis Hammond, a plastic surgeon and researcher with numerous articles in the peer-reviewed medical literature on breast implants,[98] succinctly presented the mechanism of Allergan's negligent and variable manufacturing process at the 1st World Consensus Conference on BIA-ALCL in October 2019[99] to explain that "**silicone particle induced inflammation is the primary cause of ALCL**."[100] In a thorough explication supported by medical literature; scientific/medical research; data and findings from Dr. Hammond's surgery and experience in treating BIA-ALCL patients in his plastic surgery practice; and testing pathology and tissue samples from Dr. Hammond's BIA-ALCL patient cases;[101] Dr. Hammond presented his published research findings *and* the critical details to support his conclusion that silicone particles from



Allergan's manufacturing process caused BIA-ALCL:

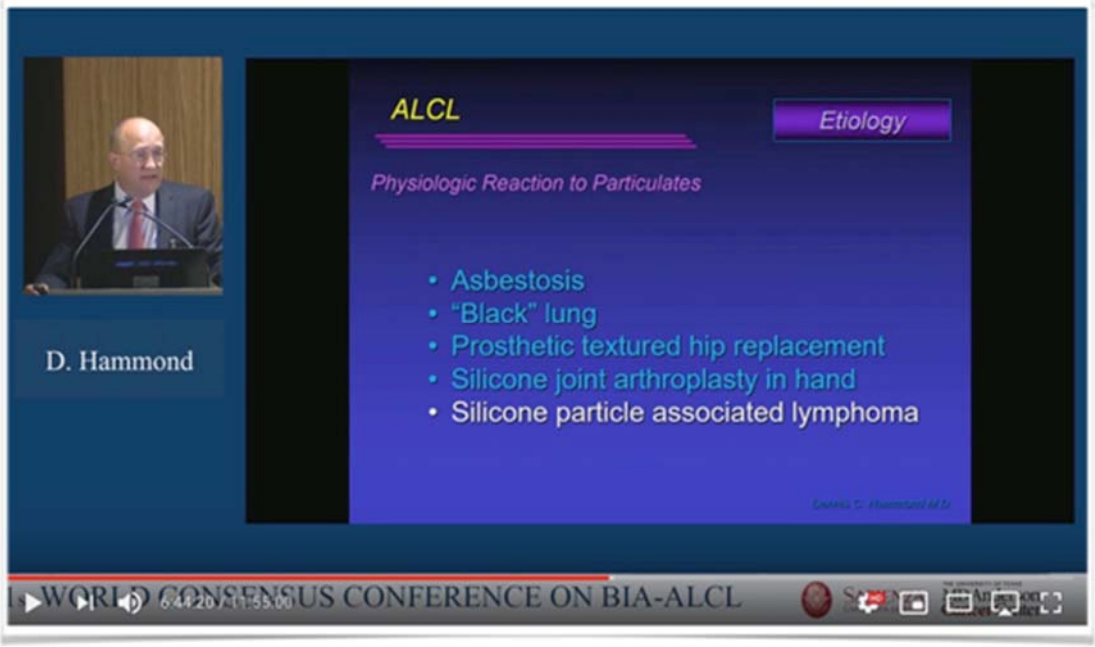
[98] https://scholar.google.com/scholar?hl=en&as_sdt=0%2C43&q=Dennis+Hammond+implants&btnG=

[99] https://youtu.be/YxPFayQsjUo?t=23460 —https://youtu.be/YxPFayQsjUo?t=24582

[100] https://youtu.be/YxPFayQsjUo?t=24447 (emphasis added).

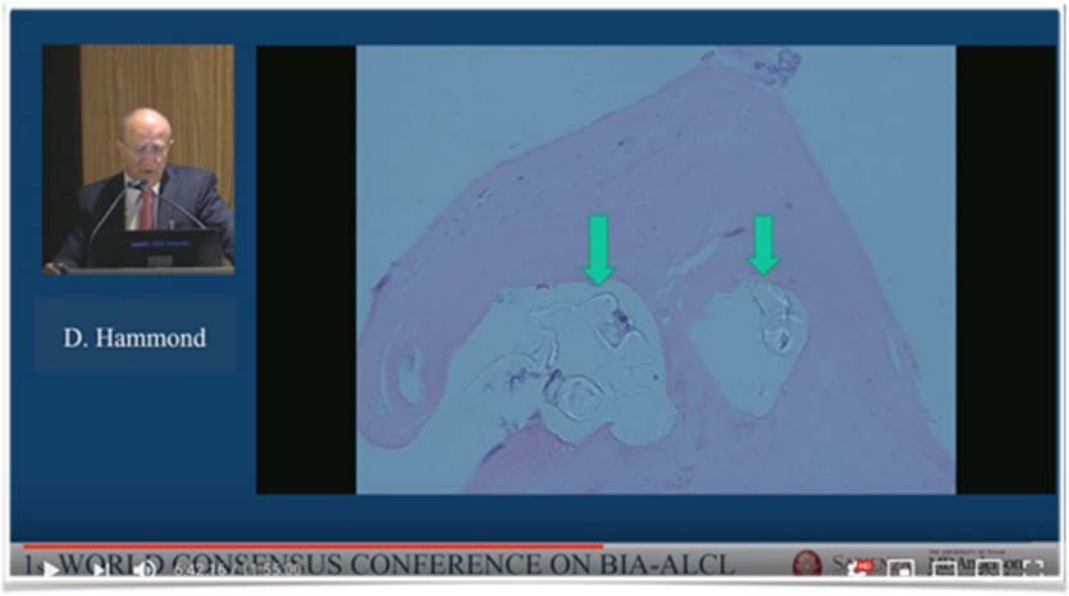
[101] https://youtu.be/YxPFayQsjUo?t=24200.

i. Allergan's "cavitation and abrasion" manufacturing process for the Biocell implant surface ("cavitation with abrasion") can create solid silicone particles when workers abrade the implant shell creating "refractile **foreign** material;"[102]



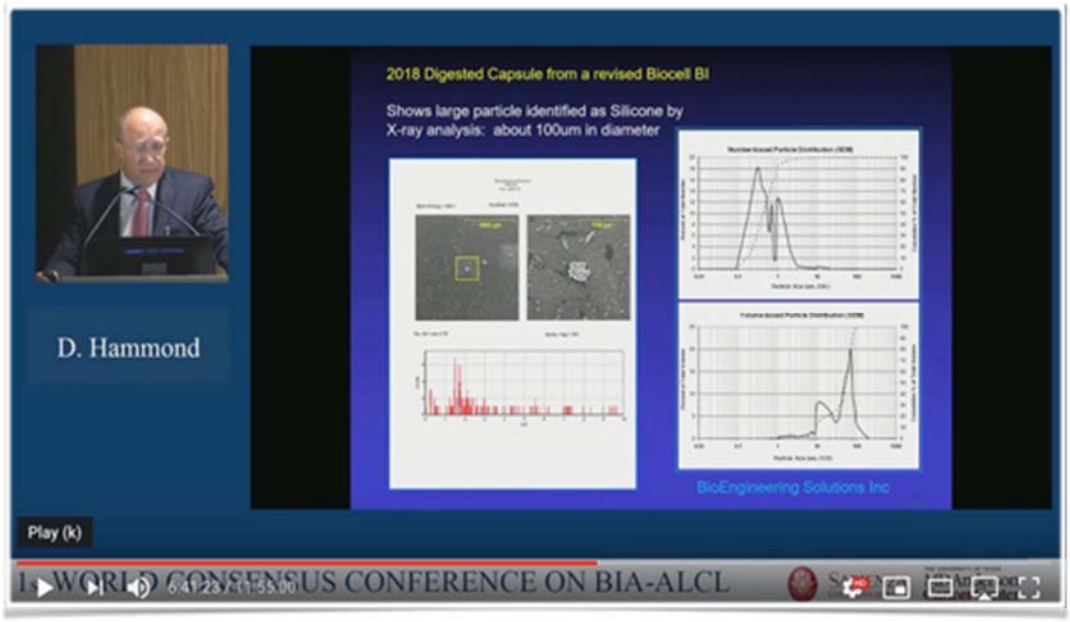
[102] https://youtu.be/YxPFayQsjUo?t=23568

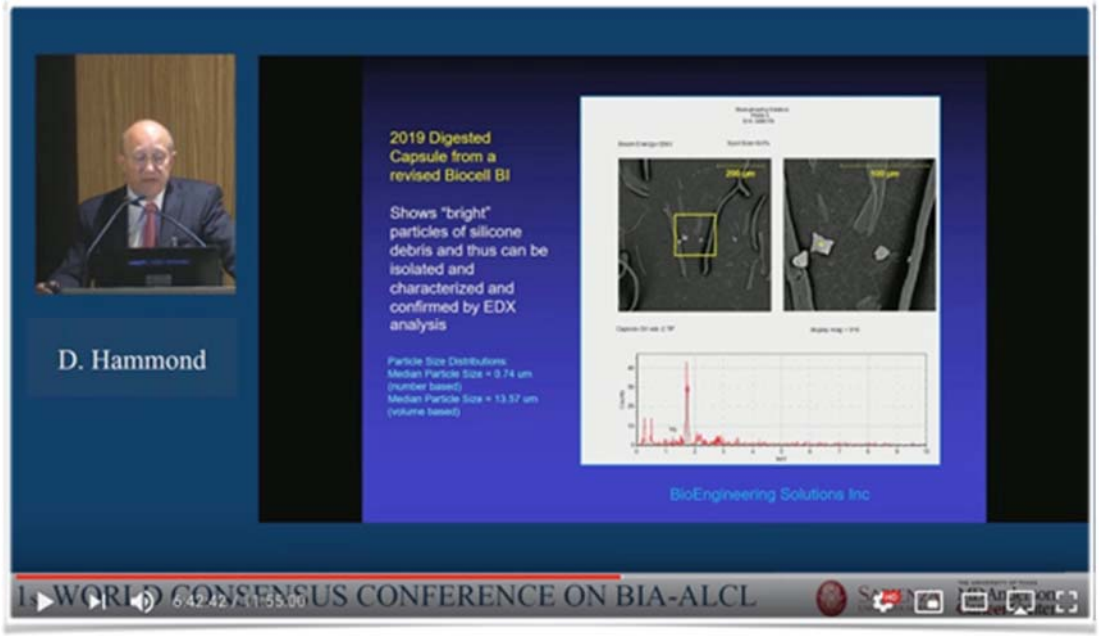
ii. Research and testing done at Rush University in Chicago on tissue from his BIA-ALCL patients (published in the literature) showed, in graphic detail, the presence of volumes of foreign silicone particles in the breast tissue capsules of his patients;[103]



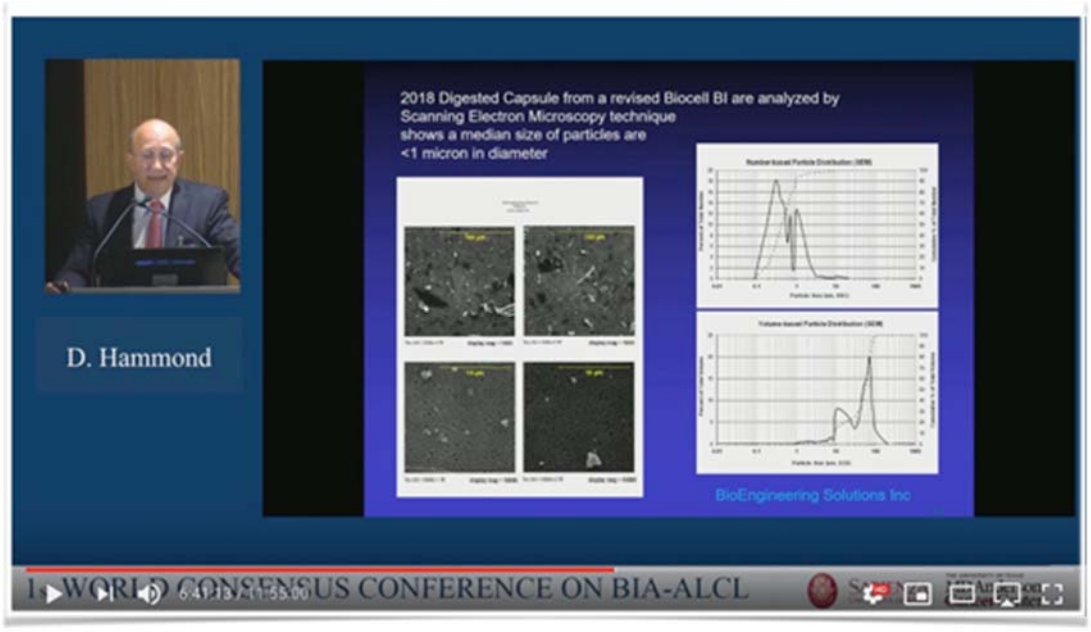
[103] https://youtu.be/YxPFayQsjUo?t=24019.

iii. Tissue from BIA-ALCL patients (breast capsules) was microscopically examined and the results confirmed various sizes and amounts of silicone particles in the breast capsules;[104]

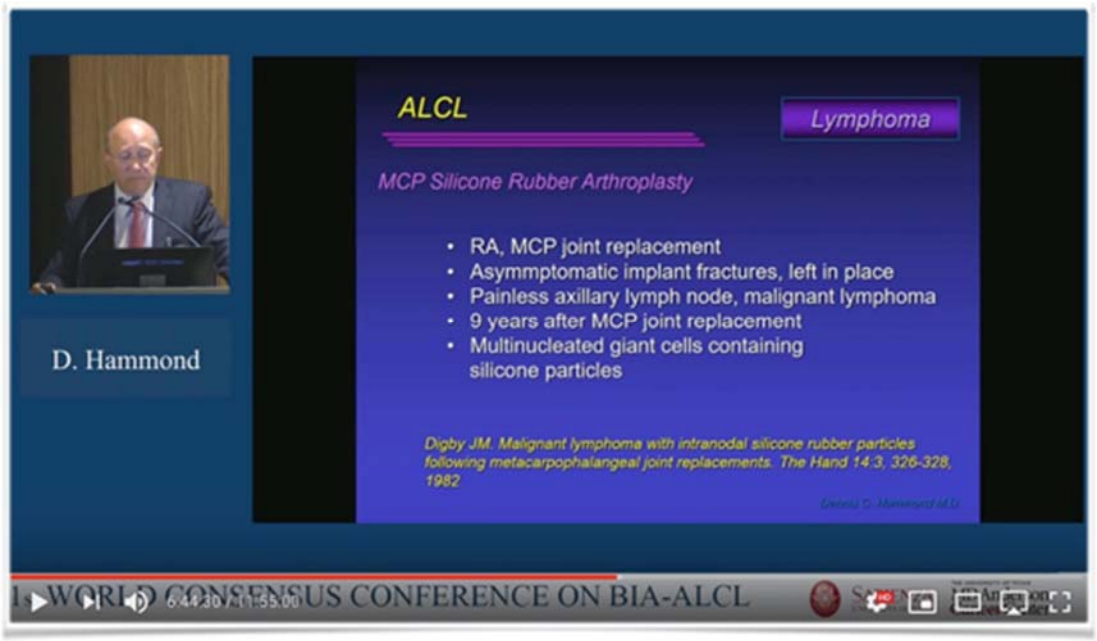




[104] https://youtu.be/YxPFayQsjUo?t=24070



iv. From the orthopedic literature (particles in hips and silicone particles in the wrist) Dr. Hammond explained there is support in the medical literature that silicone particles are associated with lymphoma and capable of causing lymphoma and BIA-ALCL:



v. Hammond also explained that, in the small number of reported non-Biocell cases of BIA-ALCL in textured implant where the "salt loss" technique was not used (e.g., Mentor Siltex using an negative imprint polyurethane foam process), silicone particles or fragments from the implant surface are also a likely cause of BIA-ALCL due to a crease, fold or tear in the imprinted textured surface causing silicone fragments to tear off. https://youtu.be/YxPFayQsjUo?t=23986.

109. Allergan *knew* that particles or contaminants on the surface its Biocell implant should not be implanted into the patient and that surgeons should not use any implants with "particulate contamination." Allergan also knew that PMA and FDA requirements, including the prohibition of "adulterated" products and requirements under 21 C.F.R. § 820.70(h) to remove manufacturing material, would be violated where volumes of foreign and decomposed particles were left on the implant surface. In its instructions to surgeons (Directions for Use INAMED® Silicone-Filled Breast Implants Smooth & Biocell Texture[105] and Directions for Use NATRELLE® Silicone-Filled Breast Implants Smooth & Biocell Texture[106]), Allergan instructed surgeons to examine the implant and not use any implant with "**particulate contamination**:"

> "Examination of Silicone Gel-Filled Breast Implants
>
> **Prior to use, examine the breast implant for evidence of any particulate contamination**, damage, or loss of shell integrity. If satisfactory, return the breast implant to the inner thermoform tray and cover it with the lid until implanted to prevent contact with airborne contaminants.

[105] https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020056c.pdf.
[106] https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/labeling/natrelleus/410implants/natrelle-410-dfu-l3717rev04.pdf.

> **DO NOT implant any device that may appear to have particulate contamination**, damage, or loss of shell integrity. A sterile back-up implant must be readily available at the time of surgery."

110. Plaintiffs aver Allergan's hand-finished small batch artisan process produced implants that were not manufactured in the same way every time.[107] Allergan's negligent manufacturing process for the Biocell implants produced, at times, unwanted "particulate contamination" on the implants including those received by Barbara Pack. This "particulate contamination" violated Allergan's PMAs, FDA regulations, and parallel state law and directly caused Mrs. Pack's injuries.

ALLERGAN PROMOTED A FALSE AND MISLEADING NARRATIVE TO HIDE AND DIVERT ATTENTION FROM THE TRUTH: THAT BIOCELL IMPLANTS ARE THE CAUSATIVE "TRIGGER" OF BIA-ALCL

111. Allergan, in an effort to draw attention away from the company's defective and adulterated Biocell textured breast implants, engaged in a prolonged and concerted plan and effort to actively mislead regulators and the scientific and medical community that a multifactorial *infectious* process—rather than its device and particle contamination— is the likely cause of BIA-ALCL. Allergan raised a string of "red herrings," including: biofilm; poor surgical technique (in not using the Adams "14-point plan"); larger implant surface in macro-textured implants; and genetic predisposition.

[107] As FDA's website explains to manufacturers with regard to PMA compliance with the controlling ISO 1033-1 standard: "If the materials, manufacturing processes, and intended use are not identical to those in legally marketed device(s), or if manufacturing information is not available for a comparator device, additional biocompatibility information should be provided." FDA, PMA Special Considerations, https://www.fda.gov/medical-devices/premarket-approval-pma/pma-special-considerations. *See also* 21 C.F.R. § 820.70(h).

112. Allergan's public claims, especially to medical device regulators, are based upon self-serving, trumped up, and co-opted Allergan-funded "research." Plaintiffs aver, and show in this Complaint, that Allergan's multifactorial infectious process claims are no more than "junk science" promoted by Allergan as a public relations campaign to persuade regulators and plastic surgeons into believing the problem stems from surgeon technique, instead of from the product itself. The "research" presented by Allergan to medical device regulators in France and the United States (FDA and ANSM) was false and misleading on all counts. These facts are relevant to Plaintiff's claim for punitive damages.

ALLERGAN'S CONFLICTED RESEARCH

113. Allergan's biofilm and surgical technique (the "14-point plan") provides purported explanations to medical device regulators (FDA and ANSM) as to the etiology of BIA-ALCL. The 14-point-plan was composed almost entirely on Allergan-funded research by Allergan physician consultants. While industry-funded research, standing alone, is not necessarily a reason to reject scientific research findings, close industry connections should be disclosed to regulators and carefully scrutinized to assure the results presented are not tainted and are scientifically reliable, especially where, as here for example, Allergan paid nearly five million dollars ($4,973,340) to 46% of the speakers at the 2017 meeting of the American Society for Aesthetic Plastic Surgery.[108]

[108] Gray, R, Tanna, N, Kasabian, AK., *Conflict of interest at plastic surgery conferences: is it significant?* Plast Reconstr Surg. 2019;144:308e–313e.(" The significant difference in payments to speakers at conferences compared with the average plastic surgeon suggests that biomedical companies may have influence over some of the conference content."). Available at: https://insights.ovid.com/pubmed?pmid=31348372. *See also* E. Swanson, *The Food and Drug Administration Bans Biocell Textured Breast Implants, Lessons for Plastic Surgeons*, Annals of Plastic

114. Dr. William Adams, the lead author of the 2013 "14-point plan" was a long-time paid consultant for Allergan[109] who had served as a paid investigator for Allergan in breast clinical trials, an "educational advisor" for Allergan and an investigator for Allergan on IDE trials.[110] Adams served as the spokesman for a public relations effort that included a press release,[111] videos on Internet websites,[112] and an article[113] to trivialize the risks of BIA-ALCL from textured implants by promoting a false narrative that the risk of dying from a textured implant was 1:2,500,000.[114]

Surgery published online (November 9, 2019)("Speakers at plastic surgery meetings ae often heavily compensated by industry. Allergan is the top contributor, paying $4,973,340 to 46% of the speakers at the 2017 meeting of the American Society of Aesthetic Plastic Surgery and US $ 1, 598,901 to 34% of the speakers at the 2017 meeting of the American Society of Plastic Surgeons. At the 2018 meeting of the American Society of Aesthetic Plastic Surgery, none of the panelists called for the banning of textured devices.")
https://journals.lww.com/annalsplasticsurgery/Citation/publishahead/The_Food_and_Drug_Administration_Bans_Biocell.96844.aspx#pdf-link

[109] https://projects.propublica.org/d4d-archive/payments/9839248;
https://pdfs.semanticscholar.org/8499/40f52da384b7fae5b4803d06f9973a7cb38a.pdf.

[110] https://journals.lww.com/plasreconsurg/Citation/2013/01000/Discussion___Simultaneous_Augmentation_Mastopexy_A.27.aspx; https://www.plasticsurgery.theclinics.com/article/S0094-1298(08)00091-6/abstract; https://insights.ovid.com/pubmed?pmid=28841597.("Dr. Adams is an investigator for Mentor and Allergan Cohesive Gel IDE studies and a consultant to Allergan.").
Of note, **6 of the authors of the Adams et al., "14 point plan" article are Allergan consultants**. E. Swanson, Surgery Volume 80,Number 5,May 2018. ("Lista has abandoned textured devices out of concern for BIA-ALCL risk. Hall-Findlay,8 Hidalgo and
Weinstein, and I believe that macrotextured implants should no longer be offered to our patients. What is the commonality that links the opposition? Unlike the authors, 6 of whom are Allergan consultants, none of us is burdened by a financial conflict of interest.").

[111] https://www.prnewswire.com/news-releases/asj-study-puts-the-risk-of-death-from-breast-implant-associated-anaplastic-large-cell-lymphoma-into-plain-perspective-for-patients-300508556.html.

[112] https://twitter.com/dallasplasticmd/status/897859561255776256;
https://www.youtube.com/watch?v=-vohQv_bvNo;

[113] Adams, et al., *What's Your Micromort? A Patient-Oriented Analysis of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL),* Aesthet Surg J 2017; 37(8):887-8: https://academic.oup.com/asj/article/37/8/887/3979712

[114] *Id.* In this article and videos, Adams compared the risk of BIA-ALCL with daily activities such as driving a car or flying an airplane using "micromort" calculations. One micromort represents a 1:1,000,000 chance of death. Adams suggested that patients should be told that, for example, that the risk of traveling 8

This was part of Allergan's campaign of denial that began in 2011 when the FDA announced a "possible association" between breast implants and BIA-ALCL.

115. In 2011 Allergan downplayed the BIA-ALCL concerns in a statement by Allergan spokesperson Caroline Van Hove, who served on Allergan's "Global Operating & International Leadership Teams."[115] Ms. Hove, as Allergan's spokesperson, claimed: "a woman is more likely to be struck by lightning than get this condition."[116] Allergan's paid consultant Dr. Adams repeated this claim in 2015 in a book chapter: "a patient is 2 times more likely to be hit by an asteroid than to develop ALCL."[117] The same claim was advanced in an article critiquing the seminal paper by Dr. Garry Brody that linked ALCL to textured implants: "It [BIA-ALCL] is extremely rare; a cosmetic implant patient is twice as likely to be struck by an asteroid as to develop

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hours by car carries a 40× higher risk (*i.e.*, 16 micromorts) than the lifetime risk of two textured implants (0.4 micromorts) (1:2,500,000). FDA's data shows (as of July 2019) 573 confirmed BIA-ALCL cases with 33 deaths— a risk of death of 5.8%. Applying that risk rate to the risk rate of BIA-ALCL from Biocell implants (1:2207) the risk of death for a patient with Biocell is 1:38,321— a far cry from Adams 'risk of 1:2,500,000 (.4 micromort).

[115] https://siennabio.com/company/management/caroline-van-hove/

[116] Kim LaCapria, *FDA, Breast Implants May be Linked to are Cancer, Inquisitir* (Jan. 26, 2011) https://www.inquisitr.com/96723/breast-implants-cancer-risk/.

[117] W.P. Adams et al., *The Process of Breast Augmentation With Special Focus on Patient Education, Patient Selection, and Implant Selection* at 414, chapter in B. Bengston, Breast Augmentation: an Issue of Clinics in Plastic Surgery (October, 2015). https://books.google.com/books?id=KdWZCwAAQBAJ&pg=PA414&lpg=PA414&dq=william+adams+asteroid+breast+alcl&source=bl&ots=hI7U_uVngt&sig=ACfU3U3Opt2qXVtOcIxnmP27MDtcth_t_A&hl=en&sa=X&ved=2ahUKEwiT7avArJDmAhUDX60KHUdsCgAQ6AEwBnoECAsQAQ#v=onepage&q=william%20ad

implant-associated ALCL."[118] In 2019 Allergan, however, acknowledged to the FDA that its own studies showed a risk of 1:3000.[119]

116. Likewise, Dr. Anand Deva, whose 2013 and 2017 co-authored papers served as a mainstay of Allergan's multifactorial infectious process arguments, was a paid consultant to Allergan. In 2013, for example, in a paper Dr. Deva co-authored, it was disclosed that "A.K. Deva is a consultant to Allergan, Mentor (J&J) and KCI. He has previously coordinated industry sponsored research for these companies relating to biofilms and breast prostheses." Another paper in 2018 stated; "Professor Deva is research coordinator and consultant to Allergan." A 2019 paper states: "Professor Anand K. Deva is a consultant, research coordinator, educator for Allergan."

117. In a presentation to French (ANSM) medical device regulators in February 2019, Allergan's representative at the French hearing, Allergan Medical Director Dr. Jason Hammer, represented to the French Committee that the Adams/Deva "14-point plan" and use of a "no-touch technique" would prevent BIA-ALCL stating: "when an enhanced surgical technique is used, like the 14 point plan mentioned earlier, **it can effectively mitigate BIA-ALCL**" citing Dr. Adam's 2017 " study" of 42,000 implants.[120]

118. Allergan, in a presentation to the FDA in March 2019 by Dr. Stephanie Brown, a plastic surgeon and the Vice President of Clinical Development for devices at Allergan, repeated

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[118] W.P. Adams, *Discussion: Anaplastic Large Cell Lymphoma Occurring in Women with Breast Implants: Analysis of 173 Cases*, Plastic and Reconstructive Surgery at 711(March 2015). https://journals.lww.com/plasreconsurg/Citation/2015/03000/Discussion__Anaplastic_Large_Cell_Lymphoma.15.aspx

[119] *See* footnote 131 *infra* and accompanying text.

[120] https://youtu.be/H2zmIBWGYuI?t=14900 (emphasis added).

the claim that "biofilm" was the "leading hypothesis" for the cause of BIA-ALCL[121] Dr. Brown stated that: during the implant surgery bacteria may be introduced; then the higher surface area of textured implants contributes to bacterial accumulation and biofilm and long-term inflammation, leading to BIA-ALCL in genetically predisposed patients.[122] Dr. Brown also stated that "clusters" of BIA-ALCL cases, such as in Australia, "may speak to" "potential genetic or surgical technique components."[123] Dr. Brown sought to explain the high incidence of BIA-ALCL cases reported in

[121] *Id.* at 49; video at: http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d (at 1:32:12).

[122] https://www.fda.gov/media/123744/download; at 52; video at http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d (1:32:14).

[123] Allergan's "clusters" explanation (premised on a theory of poor surgical technique if a physician or practice group has several BIA-ALCL cases) also has no scientific support and has been soundly rejected as a theory for BIA-ALCL etiology. *See e.g.* Jones et al, *Breast implant associated anaplastic large cell lymphoma (BIA-ALCL): an overview of presentation and pathogenesis and guidelines for pathological diagnosis and management,* Histopathology (June 5, 2019) ("It is important to note that no clustering of BIA-ALCL cases to particular units has been described, so this association with bacterial infection does not implicate a relationship with surgical practice, but rather it has been suggested that genetic host factors are likely to play a role in susceptibility. . ."). Available at: https://onlinelibrary.wiley.com/doi/pdf/10.1111/his.13932. *See also* M. Clemens, Presentation at Rome conference: https://youtu.be/YxPFayQsjUo?t=5841 (refuting cluster theory).

Allergan's CA/CARE study (1/3000)[124] by saying they "may represent the effects of [surgical] procedure, patient genetic predisposition, and/or environmental factors."[125]

119. Dr. Brown's FDA presentation then turned to the Adams "14-point plan," citing the Adams et al., "14-point plan" paper[126] as "evidence" that BIA-ALCL mitigation (by surgical technique) can be effective:[127]

> Evidence suggests that BIA-ALCL mitigation can be effective. To mitigate an introduction of bacteria in the surgical environment and subsequent biofilm formation on higher surface area implants, an enhanced 14-point aseptic protocol has been proposed. Of the 14 points, enhancements include changing gloves between implant sites, soaking the implant in antiseptic solution, and the use of minimal touch technique. When these and other steps were taken, researchers reported zero cases of BIA-ALCL

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[124] P. McGuire, et al., *Risk Factor Analysis for Capsular Contracture, Malposition, and Late Seroma in Subjects Receiving Natrelle 410 Form-Stable Silicone Breast Implants,* Plast Reconstr Surg. 2017 Jan;139(1):1-9. https://www.ncbi.nlm.nih.gov/pcfubmed/27627058. Dr. Brown cited the incidence as 1/3000. Dr. Mark Clemens cited the same paper and cited the risk at **1/2207** (17,656 ÷ 8): https://www.fda.gov/media/123022/download at 11. One FDA panelist asked, what is the denominator? Clemens reported the most reliable risk estimate in patients implanted with Biocell 410 devices, which stands at a 1:2200 lifetime risk according to the 2017 McGuire paper *supplemented by 4 additional cases of BIA-ALCL diagnosed after publication.* Webcast. General and Plastic Surgery Devices Panel Meeting. Day 1. http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d. McGuire, an Allergan consultant has now abandoned Biocell 410 implants. Swanson, *Plastic Surgeons Defend Textured Breast Implants at 2019 U.S. Food and Drug Administration Hearing: Why It Is Time to Reconsider, Plastic and Reconstructive Surgery – Global Open*: August 2019 – Volume 7 - Issue 8. Available at: https://journals.lww.com/prsgo/Fulltext/2019/08000/Plastic_Surgeons_Defend_Textured_Breast_Implants.25.aspx. Swanson states "The denominator and numerator are clear – 17,656 women, 8 cases of BIA-ALCL (and likely to increase over time)." *Id.*

[125] https://www.fda.gov/media/123744/download at 52; video at http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d at 1:33:37.

[126] https://journals.lww.com/plasreconsurg/Abstract/2013/11000/The_Role_of_Bacterial_Biofilms_in.51.aspx. *See also* W. Adams, et al.(with Anand Deva as a co-author), *Macrotextured Breast Implants with Defined Steps to Minimize Bacterial Contamination around the Device: Experience in 42,000 Implants,* Plast Reconstr Surg. 2017 Sep;140(3):427-431 (available at: https://insights.ovid.com/pubmed?pmid=28841597.

[127] https://www.fda.gov/media/123015/download at 52; video at http://fda.yorkcast.com/webcast/Play/a6baa43b37004ecab288779ac3a263bd1d at 1:33:58.

> in 42,000 Biocell implants with a mean follow-up of 11.7 years. These data underscore the value of continued communication on the importance of aseptic technique." [128]

120. In both of Allergan's presentations to FDA in March 2019 and to the French ANSM in February 2019, Allergan's physician-spokespersons (Drs. Hammer and Brown) inexplicably failed to even mention particles, contaminants or leachables from the silicone elastomer in Biocell implants as a possible (in fact, likely) causative or contributing factor to BIA-ALCL. Allergan's "crickets" approach to particles from its Biocell implant surface when addressing the FDA and ANSM was calculated deception and misrepresentation by omission given: Allergan's knowledge since the late 1980's that the Biocell textured implant produced foreign-body reactions with giant cells histiocytes and inflammatory cells with silicone particles in the capsule interface; numerous articles in the medical literature identified silicone particles on the surface of as-manufactured Biocell textured implants (especially the microscopy studies)[129]; and numerous articles in the medical literature discussing silicone particles and foreign implant materials on the implant surface as a potential cause of BIA-ALCL.[130]

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[128] https://www.fda.gov/media/123744/download at 52, last visited October 24, 2019.

[129] *See* ¶¶ 103-107, *supra*; ¶¶ 191-200 *infra*.

[130] *See e.g.*, S. Ghali, *An update on BIA-ALCL* , The PMFA Journal, (June/July 2019) Available at: https://www.thepmfajournal.com/features/post/an-update-on-bia-alcl. Last visited November 2, 2019 (emphasis added):

> "The first case was reported in 1997 by Keech and Creech [1] and in the last 10 years, there has been an exponential rise of cases, culminating in the 2016 classification of BIA-ALCL as a unique disease entity by the World Health Organization [2]. **Suggested theories of the cause of BIA-ALCL include textured implant particulate,** chronic allergic inflammation, and / or response to a biofilm."

See also Hallab et al., *The Inflammatory Effects of Breast Implant Particulate Shedding: Comparison With Orthopedic Implants,* Aesthetic Surgery Journal, Volume 39, Issue Supplement_1, March 2019. Available at:

121. Plaintiffs aver that Allergan sponsored and paid for "research" principally by paying large sums of money to Dr. William Adams and Dr. Anand Deva, to actively promote unscientific alternative theories for the cause of BIA-ALCL—alternative to the cause being the implants themselves as-manufactured with variant levels of silicone and foreign implant materials and particles.[131]

ALLERGAN'S JUNK SCIENCE

122. The statements made by Allergan to the FDA and ANSM are "junk science" on all counts. Allergan knew that these regulatory hearings would the affect future sales of Allergan's Biocell medical devices. To ward off a ban or recall, Allergan sought to defend the Biocell implants based upon the research papers written by Allergan's paid consultants —Dr. Deva and Dr. Adams. The claims and conclusions in their 2013 and 2017 papers were the "evidence" Allergan presented to FDA and ANSM.

123. There is no reliable scientific basis for any of the infection theory claims made by Allergan and its consultants (Deva and Adams) as to biofilm, surgical technique (the 14-point plan), implant surface area or the alleged role of genetic predisposition as to the primary cause of BIA-ALCL.[132]

https://academic.oup.com/asj/article/39/Supplement_1/S36/5304922. Last visited November 2, 2019.

[131] At neither the FDA or ANSM hearings in February or March 2019 did Allergan disclose that Drs. Deva and Adams were Allergan consultants. The 2013 and 2017 papers, however, did disclose that Drs. Adams and Deva were Allergan consultants.

[132] Notably, the only papers in the medical literature to advance the infectious process/surgical technique/biofilm theory are papers written/ co-authored by Allergan consultants.

124. All of Allergan's medical claims are not scientifically reliable and were advanced to protect profits and direct attention away from the defective Allergan implants—the Biocell textured implant fraught with adulterated and contaminated silicone particles and foreign implant materials on the surface of the implant at the time of sale.

BIOFILM, SURGICAL TECHNIQUE, IMPLANT SURFACE & "14 POINT PLAN"

125. Rather than face the stark fact that 91% of the manufacturer-known BIA-ALCL cases, according to FDA, are Allergan Biocell textured implants, Allergan continued to promulgate a multifactorial causation theory premised on an *infectious* origin as the precipitating cause of ALCL. Allergan's presentations to regulators asserted the etiology could be explained by:

- failure to follow the "14 -point plan" in implant surgery to prevent bacterial *infection* (the Adams protocol) causes bacteria (**surgical procedure**);
- the bacteria then create **biofilm**;
- such biofilm accumulates on the "larger" **surface area** of deeply textured "macrotextured" implants (i.e. Biocell implants) that, because of their larger surface area, have a larger biofilm field;
- thereby producing a **chronic inflammatory process**;
- the chronic inflammatory then causes the **activation of T cells** and cell mutations;
- particularly in **genetically predisposed patients**; and then,
- **[Voilà]**—the patient gets (rarely) the lymphoma/cancer known as BIA-ALC.

That is what Allergan told the FDA and ANSM in February and March 2019 citing, for the most part, *only* the research papers of Allergan consultants.[133]

126. But then, at the 1st World *Consensus* Conference on BIA-ALCL (Rome, Italy; October 2019) numerous physicians, scientists, and researchers from 23 countries completely debunked and disproved each and every part of the "Allergan" unscientific narrative: No—said

[133] Allergan presentation to FDA General and Plastic Surgery Devices Panel, March 25, 2019 by Dr. Stephanie Brown, https://www.fda.gov/media/123744/download at 49-54.

the assembled experts—the infection bacteria/biofilm/surface area theory of BIA-ALCL causation had no basis in science or precedent; nor did the notion that operative technique with the "14 point plan" could be effective in mitigating or preventing ALCL. Likewise, the genetic argument mistook cause for effect.

127. These issues become important for Mrs. Pack's case because, as established by facts pleaded in this Complaint, it was the device itself (negligently made in a variable manufacturing process that caused, at times, adulterated implants with volumes of silicone and foreign implant material particles to trigger a foreign body/inflammatory reaction leading to T cell activation and lymphoma) that caused Mrs. Pack's injuries.

128. A complete deconstruction and refutation of the Allergan's false "junk science" narrative occurred at a meeting of the world's foremost scientists and physicians researching BIA-ALCL at the 1st World Consensus Conference on BIA-ALCL and may be summarized as follows:

i. Dr. Suzanne Turner, a world-leading authority on lymphoma and ALCL, corrected the multifactorial infection theory (advanced by Allergan and plastic surgeons Deva and Adams) by explaining that there was no scientific basis to support the theory that bacterial infection in the implant surgery (the gravamen of the infection/surface area/biofilm theory and 14 point plan) could support a process of inflammation leading to lymphoma, saying: "**there's actually no precedent of a bacteria driving a T-cell lymphoma.**"[134] Dr. Mark Magnusson, a plastic surgeon and professor in Australia, who is also a member of Allergan's "expert advisory group" echoed this key scientific point: "Although bacterial

[134] https://youtu.be/YxPFayQsjUo?t=24758 (emphasis added).

and viral agents are linked to the development of other lymphoid malignancies, **there are no bacteria directly linked to the etiology of any form of T-cell lymphoma."** [135]

ii. MD Anderson associate professor of plastic surgery Dr. Mark Clemens, in his comments opening the conference, noted that while scientists in 2016 "brought up the idea" that infection and bacterial contamination (Ralstonia pickettii) and biofilm could cause BIA-ALCL, *by 2019* it "has fallen out of favor" and "was **no longer the driver"** of BIA-ALCL (emphasis added).

iii. In refuting the biofilm theory of BIA-ALCL etiology, Dr. Clemens, at https://youtu.be/YxPFayQsjUo?t=5707, referred to a paper and collaborative research done at MD Anderson and Washington University in St. Louis: *Insights into the Microbiome of Breast Implants and Periprosthetic Tissue in Breast Implant-Associated Anaplastic Large Cell Lymphoma*, Nature (July 2019) https://www.nature.com/articles/s41598-019-46535-8. Dr. Clemens explained that research at MD Anderson and Washington University in Saint Louis showed **no difference** in the microbiome of BIA-ALCL patients and other breast implant patients: "Microbiome of BIA-ALCL Similar to Normals; No district microbiome." https://youtu.be/YxPFayQsjUo?t=5707 (emphasis in original). Dr. Clemens, at https://youtu.be/YxPFayQsjUo?t=5731, debunked the theory that ALCL is caused by biofilm and can be prevented if surgeons use a specific anti-infective surgical technique—the so-called "14 point plan" advanced by Dr. Deva, an Australian plastic

[135] M. Magnusson, *Commentary on: Comparative Analysis of Cytokines of Tumor Cell Lines, Malignant and Benign Effusions Around Breast Implants*, Aesthetic Surgery Journal (on-line ahead of print, November 15, 2019). https://academic.oup.com/asj/advance-article-abstract/doi/10.1093/asj/sjz267/5625867

surgeon and Adams in their 2013 paper *The Role of Bacterial Biofilms in Device-Associated Infection*, Plast Reconstr Surg. 2013 Nov;132(5):1319-28 and followed up in a 2017 paper written by Adams and Deva and six other Allergan consultants. Dr. Clemens, in a power point slide showing the 2013 and 2017 Deva/Adams and Adams papers and a picture of Betadine, explained: "actually we looked at—Can [surgical] technique predict for ALCL?" and concluded: "**No operative strategy has been shown to decrease the risk of ALCL.**" https://youtu.be/YxPFayQsjUo?t=5801.

iv. Dr. Fabio Santanelli di Pompeo, is a professor of plastic surgery at Sapienza University of Rome.[136] Dr. Santanelli described the biofilm and 14-point plan theories for the etiopathogenesis of BIA-ALCL as a "myth" and showed, to make his point, a slide with a picture of Swiss cheese filled with holes.[137] Dr. Santanelli described the "protagonists" of the biofilm and 14-point plan theories for the etiopathogenesis of BIA-ALCL as "two Mr. no ones—one coming from Australia [Dr. Deva] and one from the United States [Dr. Adams]."[138] Dr. Santanelli's take down of the biofilm and 14-point plan theories cited the MD Anderson/Washington University St. Louis paper in *Nature*, *Insights into the Microbiome of Breast Implants and Periprosthetic Tissue in Breast Implant-Associated Anaplastic Large Cell Lymphoma*, Nature (July 2019)[139] as proof that refuted the biofilm

[136] https://youtu.be/YxPFayQsjUo?t=6314
[137] https://youtu.be/YxPFayQsjUo?t=7061
[138] *Id.*
[139] https://youtu.be/YxPFayQsjUo?t=7254

theory such that it had to be "abandoned" because the research showed that "BIA-ALCL patients do not show a distinct microbiome."[140]

ALLERGAN'S ACTS SUBSEQUENT TO MRS. PACK'S SURGERIES ARE ADMISSIBLE AS "AGGRAVATING EVIDENCE" RELEVANT TO THE AMOUNT OF PUNITIVE DAMAGES THAT SHOULD BE ASSESSED IN THIS CASE

129. Plaintiffs aver that Allergan acted with scienter and engaged in a conscious and intentional plan to advance and promote co-opted "junk science" research and advanced a false public relations campaign in an effort to keep its Biocell implants on the market. Allergan made numerous false, misleading, and incomplete statements to medical device regulators (FDA, ANSM) and to the public in an attempt to continue to sell defective textured implants and explain away the unique and alarming numbers on the incidence of Biocell BIA-ALCL cases.

130. Allergan outrageously and knowingly sought to hide and minimize the truth: that the Biocell textured implant—the device itself—was causing BIA-ALCL. These acts and efforts reflect Allergan's motive and reckless indifference to the rights of others and entitles Plaintiffs (and the State of Utah) to punitive damages in such sum as will serve to punish Allergan and to deter defendant and others from like conduct.[141]

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[140] *Id. See also* E. Swanson, *Plastic Surgeons Defend Textured Breast Implants at 2019 U.S. Food and Drug Administration Hearing: Why It Is Time to Reconsider,* Plast Reconstr Surg Glob Open. 2019 Aug; 7(8): e2410("There is no reliable evidence that the 14 points eliminate BIA-ALCL risk."). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6756678/#R49. See also E. Swanson, *A 1-Point Plan to Eliminate Breast-Implant Associated Anaplastic Large Cell Lymphoma, Annals of Plastic Surgery,* Volume 80,Number 5,May 2018.

[141] By virtue of the consolidation and merger of McGhan Medical into Inamed and then into Allergan, Allergan must accept successor liability for punitive damages for McGhan Medical's knowledge that showed its manufacturing process was prone to adulteration.

131. Plaintiffs aver that under Utah law Allergan's subsequent/post-injury aggravating acts and omissions are relevant evidence to show Allergan's state of mind on the issue of the amount of punitive damages that should be assessed against Allergan for the Biocell-BIA-ALCL debacle.

132. Further evidence of Allergan's motive and reckless indifference and intent to downplay the role of Biocell implants in causing BIA-ALCL was provided in a securities fraud class action case against Allergan based upon Allergan's public statements regarding Biocell implants and BIA-ALCL, *In re Allergan PLS Sec. Litig*., 2019 U.S. Dist. LEXIS 162510 (S.D.N.Y. Sep. 20, 2019).

133. In an order entered September 20, 2019, denying in part and granting in part Allergan's motion to dismiss the complaint that alleged Allergan made false public statements with scienter about Allergan's Biocell impacts and BIA-ALCL (thereby causing investors to lose money in the stock market, federal judge C.J. McMahon stated: "Plaintiff also alleges that Defendants did not tell the whole truth about Allergan's breast implant products. **Here, they stand on firm ground**."[142]

134. Additional aggravating evidence, albeit circumstantial, is relevant to the quantum of punitive damages was revealed in the securities class action case:

> Confidential Witness 1 ("CW1"), a senior project manager for Allergan who was based at the Company's Santa Barbara from June 2010 to November 2014 (Id. ¶ 29), alleges that Allergan started to change the texture and manufacturing technique of its textured implants "sometime during the last year of [her] employment" (Id. ¶ 74). "While CW1 was not told by the Company that these suggested changes were related to the link between textured implants and the development of ALCL, it was shortly thereafter that

[142] *In re Allergan PLS Sec. Litig.*, 2019 U.S. Dist. LEXIS 162, at *3 (S.D.N.Y. Sep. 20, 2019) (emphasis added).

studies began to be published alerting to this precise link."[143]

….

"**The CAC [class action complaint] adequately alleges strong circumstantial evidence of fraudulent intent or recklessness.** As pleaded, the Company and its senior executives were well aware of the growing body of evidence suggesting that Allergan's implants were more closely associated with ALCL than others—indeed, they furnished various statements about the issue during the Class Period. Yet Defendants failed to update their allegedly stale disclosure that "reports [*74] H [*sic*] have suggested a possible association between" ALCL and breast implants, which included "negative reports from regulatory authorities in Europe related to a breast implant manufacturer that is not affiliated with the Company." (Connolly Decl. Exs. 14, 20, 29.) **As alleged, Defendants knew or recklessly disregarded that their positive statements commenting on a "possible association" between breast implants and ALCL, while technically true, downplayed the specific risk that might be associated with Allergan's products**.

This strong inference of scienter is particularly compelling when juxtaposed with the mounting media reports on BIA-ALCL—especially the New York Times's May 2017 article titled, "A Shocking Diagnosis: Breast Implants 'Gave Me Cancer.'" That report specifically observed that Allergan's implants "seem to be associated with more cases than other types, possibly because they are more deeply textured and have more surface area to stick to." (See Denise Grady, A Shocking Diagnosis: Breast Implants 'Gave Me Cancer', N.Y. Times (May 14, 2017), https://www.nytimes.com/2017/05/14/healthibreast-implants-cancer.html (cited in CAC ¶ 93).) Even after they were publicly confronted with [*75] this allegation, **Defendants failed to update their risk disclosures**.

Accepting the allegations as true and drawing all inferences in Plaintiffs favor, Defendants knew or, at minimum, were reckless about the potentially misleading nature of their public statements. **Plaintiff has plausibly pleaded scienter**.[144]

[143] *Id.* at *38.

[144] *Id.* at *73 (emphasis added).

ALLERGAN & THE FDA: ALLERGAN VIOLATED MEDICAL DEVICE LAWS, FDA REGULATIONS AND PARALLEL STATE LAWS

135. In 2009 Allergan's Natrelle Style 120 silicone-filled breast implants with a Biocell textured shell were implanted into Mrs. Pack (the "2009 Biocell Implants").

136. In 2015, her 2009 Biocell Implants were replaced with new Allergan Natrelle Style 120 silicone-filled breast implants with a Biocell textured shell ("the 2015 Biocell Implants").

137. The 2009 and 2015 Biocell Implants were unreasonably dangerous and defective as they were manufactured in violation of Allergan's two PMAs, federal medical device laws, FDA standards and regulations, including failures to warn — all actionable as parallel state law claims.

138. The 2009 and 2015 Biocell Implants, due to violations of the PMAs, applicable CFRs and by virtue of their adulteration, proximately and directly caused Barbara Pack's BIA-ALCL.

139. As a condition of Defendant's PMA, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Defendants were required to submit written report information concerning any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that was attributable to the device and had not been addressed by the devices' labeling or (b) had been addressed by the device's labeling, but occurred with unexpected severity or frequency. 21 C.F.R. § 814.82(a)(9).

140. According to the PMA P020056 approval order, Defendants were required to report to the FDA information from any source that reasonably suggests that a device marketed by the Defendant may have caused or contributed to a death or serious injury; or has malfunctioned and

such device or similar device marketed by the manufacturer or importer would be likely cause or contribute to a death or serious injury if the malfunction were to reoccur. (*See* Exhibit 8 PMA P020056 Approval Order.) This continuing duty to report included reporting any clinical or laboratory studies or reports in the scientific literature concerning the device not previously submitted as part of the PMA.

141. Defendants' failure to comply with the post-approval requirements constitutes a ground for withdrawal of PMAs P990074, P040046 and P020056 and the commercial distribution of a device that is not in compliance with conditions of the PMA is a violation of the FFDCA.

142. At all times relevant, and pursuant to 21 C.F.R. § 7.40(a), a PMA applicant manufacturer may voluntarily recall its product to carry out its responsibility to protect the public health and well-being from products that present a risk of injury or gross deception.

143. While Allergan received premarket approval (PMA) from the FDA on May 10, 2000 for the McGhan saline filled Biocell textured implants and on November 17, 2006 for Natrelle silicone gel-filled Biocell textured implants (PMA P020056), those PMA approvals do not insulate Allergan from tort liability from parallel state law claims in this case because the Biocell implants were at various times adulterated by negligent manufacturing and Allergan violated *post*-approval duties to report adverse events, clinical and laboratory studies and reports in the scientific literature. Allergan violated PMA requirements by negligent manufacturing and failure to follow medical device laws, FDA regulations and the PMAs.[145] Moreover, because the

[145] It is unclear (as the PMAs, SSEDs and publicly available FDA documents do not reveal) whether the FDA was ever provided testing data on the Biocell textured surface implant as-manufactured or whether the FDA even considered the safety or effectiveness of the Biocell surface. If the FDA did not consider or evaluate the risks of particles on the Biocell surface or the risks of BIA-ALCL there is no PMA preemption.

FDA had no reports of BIA-ALCL until 2010, the PMAs in 2000 and 2006 did not consider any risk of BIA-ALCL and thus no failure to warn claim is preempted.

144. Allergan was required to describe its Biocell manufacturing process to the FDA as part of its application for pre-market approval filed in December 2002.[146] 21 C.F.R. 814.20(b)(3)(ii) provides:

> (ii) *Device description.* An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device.

145. Section 520(f) of the Food Drug & Cosmetic Act (the "Act") gives the FDA authority to prescribe regulations requiring that the methods, facilities, and controls used for the manufacture, packing, storage, and installation of medical devices conform to good manufacturing practices.[147]

146. In 1997, the FDA promulgated the Quality System Regulations. [148] Under the QSRs, medical device manufacturers were required to "establish and maintain a quality system

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See Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); In re Medtronic, Inc., 465 F. Supp. 2d 886, 896 (D. Minn. 2006); In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig., No. MDL 01-1396, 2004 U.S. Dist. LEXIS 148, 2004 WL 45503, at *11 (D. Minn. Jan. 5, 2004) (if the FDA was not aware of a particular risk at the time it approved a device, then a failure-to-warn claim premised on that risk not be preempted.); Riegel v. Medtronic, Inc., 552 U.S. 312, 333 n.1 (2008) ("The Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only after the device receives premarket approval." (Ginsburg, J. dissenting).

[146] https://www.fda.gov/medical-devices/premarket-approval-pma/pma-quality-system.

[147] *See* 21 U.S.C. § 360j(f).

[148] *See* 21 C.F.R. § 820.1

that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of" the QSRs.[149]

147. Failure to comply with the QSRs renders a device "adulterated" under the Act.[150] The QSRs, therefore, become very material to a claim, as made here, of a product that is "adulterated" in the uncontrolled manufacturing process. Allergan, for example, violated federal law, the QSRs and specifications required under its PMA in 2000 when the FDA issued Form 483s to Allergan. A Form 483 is issued to management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food, Drug, and Cosmetic Act and related Acts.

148. Allergan is therefore subject to parallel state tort law liability because Allergan was legally required under federal law (and the PMAs) to follow the QSRs as set forth in 21 C.F.R. §820, including, without limitation:

> 21 C.F.R. § 820.70
>
> Production and Process controls
> (a) General. 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. Where process controls are needed, they shall include:
> (1) Documented instructions, standard operating procedures (SOP's), 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

[149] 21 C.F.R. § 820.5. This system is known as the Quality Management System ("QMS").
[150] The implants were "adulterated" by foreign, decomposed and injurious unwanted silicone particles and federal law specifically incorporates CGMPs. 21 U.S.C. § 351.

(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.
(b) Production and process changes. Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40.
. . .
(h) Manufacturing material. **Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.** (emphasis added).[151]

Sec. 820.86 Acceptance status

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

Sec. 820.90 Non-conforming Product

(a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented

Sec. 820.140 Handling.
Each manufacturer shall establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

Sec. 820(g)

[151] Emphasis added. A violation of this CGMP is not pre-empted. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 437 (6th Cir. 2010).

> (g) Design validation. 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 validation 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.

149. Allergan was also required to follow ISO Standards, particularly ISO 10933-1[152] and ISO 14067.[153]

150. Allergan violated FDA regulations and the PMAs, violated the above regulations set forth in the QSRs, and violated ISO Standards, particularly ISO 10933-1[154] and ISO 14067. Allergan failed to exercise reasonable care in its manufacturing, quality control and quality assurance processes.[155] The failures and violations of the PMAs, federal law and parallel state laws are set forth above and in the "Counts" of this Complaint *infra.*

151. Allergan violated FDA regulations and post-PMA requirements by violating 28 C.F.R. §§ 803, 814.84 by not disclosing the human health risks of silicone particulation and not reporting (post-approval) the numerous cases of BIA-ALCL that Allergan received prior to Mrs. Pack receiving her implants. These risks were never addressed by Allergan in its FDA PMA filings and post-market reports before Mrs. Pack received her Biocell implants; were never considered by

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[152]ISO 10993 – Part 1, Biological evaluation of medical devices – Part 1: Evaluation and testing," International Organization for Standardization (ISO).
[153]ISO 14067, "Implants For Surgery - Specific Requirements For Mammary Implants."
[154]ISO 10993 – Part 1, Biological evaluation of medical devices – Part 1: Evaluation and testing," International Organization for Standardization (ISO).
[155]*See* *Brooks v. Mentor Worldwide, LLC,* No. 19-2088-KHV, 2019 U.S. Dist. LEXIS 161820, at *17-18 (D. Kan. Sep. 23, 2019) (explaining that such state-law claims against a Class III PMA approved breast implants can survive preemption if sufficient facts are pleaded under *Twombly* and *Iqbal*).

the FDA in connection with the PMAs; and were not addressed in Allergan's PMAs[156] [157]or in post-market reports to the FDA.

152. After obtaining premarket approval, manufacturers of Class III devices are subject to an ongoing obligation to comply with Medical Device Reporting ("MDR") requirements. 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a). Most significantly, MDR requires manufacturers to file adverse event reports. Specifically, 21 C.F.R. § 803.10 provides that manufacturers must:

> (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.
>
> (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:
> (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or
> (ii) A reportable event for which we made a written request.
>
> (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

Allergan violated these federal requirements that are parallel to state law.

153. Manufacturers must also prepare and submit periodic reports to the FDA that, data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant" and all "[r]eports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant." 21 C.F.R. § 814.84(b)(2)).

154. Manufacturers must also "establish and maintain procedures for receiving, reviewing, and evaluating complaints," which includes a requirement to "review, evaluate, and

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[156] *See* Munhoz, *supra*.
[157] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P020056.

investigate" "[a]ny complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications" and "to determine whether the complaint represents an event which is required to be reported to FDA." 21 CFR § 820.198.

155. Since 1996, the FDA has made adverse event reports publicly available through an online database called Manufacturer and User Facility Device Experience ("MAUDE").[158] Today, MAUDE contains over 4 million medical-device adverse-event reports dating back to 1991, including voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE is heavily cited and relied upon in the medical literature, and "medical experts trust [MAUDE] to identify problems that could put patients in jeopardy."

156. The FDA explains the requirement to file adverse event reports as follows:

> Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.
> ***
> Manufacturers: Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
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> ***
> Device User Facilities: A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not

[158] *See* U.S. FDA, MAUDE — Manufacturer and User Facility Device Experience, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

a physician's office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.[159]

157. Allergan violated requirements applicable to Allergan *after* the PMAs were approved, including, but not limited to:

a. Reporting to the FDA information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur [21 CFR §803.50];

b. Monitoring the product and reporting to the FDA any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 CFR §814.84];

c. Submitting a PMA supplement for any listed or material changes to the product [21 CFR §814.39];

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

e. Establishing and maintaining procedures for validating the device design, including testing of production units under actual or stimulated use conditions, and creation of a risk plan and conduction of risk analyses [21 CFR §820.30(g)]. Defendants failed to test and inspect finished Biocell devices under actual or simulated use conditions;

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

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

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

[159] *Id.*

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

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

158. Mrs. Pack's diagnosis of BIA-ALCL was due to Allergan's negligent variable and uncontrolled process of manually abrading and brushing the shell implant surface by overly-aggressive scrubbing "to reveal the implant surface" in an inconsistent and untrained manual labor process. This resulted, at times, in the manufacture and sale of adulterated implants with foreign, loose, and fragmented silicone particles, contaminants and residues on the implant—a result that was not intended by the manufacturer, violated FDA PMA, CGMPs, and QSRs. Biocell implants with particles from the shell constitute a dangerous, adulterated and negligently manufactured product under both federal and (parallel) Utah law.

ALLERGAN BIOCELL TEXTURED IMPLANTS CAUSED BARBARA PACK'S BIA-ALCL

159. After being diagnosed with breast cancer Mrs. Pack had a bilateral mastectomy.

160. In 2009, Mrs. Pack underwent breast reconstruction surgery at which point Allergan's Natrelle Style 120 silicone-filled breast implants with a Biocell textured shell were implanted into her body (the "2009 Biocell Implants").

161. In 2015, Mrs. Pack developed a seroma in her right breast accompanied with intense itching. Her plastic surgeon recommended the implant be replaced. On August 25, 2015, the 2009 Biocell Implant in her right breast was removed and a new Allergan Natrelle Style 120 silicone-filled breast implant with a Biocell textured shell ("the 2015 Biocell Implant") was

implanted. At the time he made these recommendations, Mrs. Pack's plastic surgeon was unaware of the risk of BIA-ALCL with the use of Biocell implants.

162. In 2018, Mrs. Pack again noticed swelling in her right breast. On June 15, 2018 the fluid was aspirated and the flow cytometry showed abnormal cells.

163. On June 22, 2018, Mrs. Pack underwent explant surgery and capsulectomy and was diagnosed with BIA-ALCL in the right breast.

164. At the time the 2009 and 2015 Biocell Implants were placed into Mrs. Pack's body, she was not advised, nor did she have any independent knowledge the Defendants' implants product were associated with and/or known to cause BIA-ALCL.

165. Mrs. Pack was not advised, and had no independent knowledge that:

i. A significant risk of ALCL existed; or

ii. A significant risk of BIA-ALCL existed; or

iii. She might need future surgery to remove the implants based upon contracting ALCL and/or BIA-ALCL; or

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

i. The textured surface that Allergan used— the Biocell surface — contained silicone particles, shredded silicone fragments, encapsulated sharp salt crystals or other compounds or chemicals that were toxic to the human body.

166. If Mrs. Pack had been advised that implantation was associated with even the slightest risk of developing ALCL and/or BIA-ALCL she would not have proceeded with implantation of the Products.

167. Had the FDA been notified of BIA-ALCL cases and reports as required by Defendants' post PMA reporting requirements, the medical community would have been made

aware of the existence of the true frequency, severity and significance of BIA-ALCL caused by Allergan's Biocell textured Breast Implants. Medical professionals and providers, including those who advised and served Mrs. Pack, would not have advised patients, including Mrs. Pack, to proceed with implantation of the Biocell textured implants.

168. Defendants, through their misrepresentations and omissions including their refusal or reckless failures to disclose or report defects and significant events as required by federal law and by state law, which does not impose duties or requirements materially different from those imposed by federal law concealed from Mrs. Pack and her healthcare providers the significant risks associated with the implants.

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

170. At all times material hereto, Defendants knew or should have known that their textured, silicone-filled breast implants were inherently dangerous with respect to known or knowable risk of BIA-ALCL.

171. At all times material hereto, Defendants misrepresented and omitted facts concerning the safety of Allergan's Biocell Breast Implants.

172. Defendants' misrepresentations included knowingly withholding material information about the known or knowable risks of the implants and BIA-ALCL from the public, including Mrs. Pack, concerning the safety of the products.

173. At all times material hereto, Defendants knew or should have known and recklessly disregarded and/or omitted the fact that Allergan's Biocell Breast Implants cause BIA-ALCL.

174. Notwithstanding the foregoing, Defendants continued to aggressively market Allergan's Biocell Breast Implants to consumers, including Mrs. Pack, without disclosing and/or omitting the known or knowable risks involved with use of the implants.

175. Defendants knew Allergan's Biocell Breast Implants were defective and unreasonably dangerous, as set forth herein, but continued to manufacture, market, distribute and sell Biocell textured implants so as to maximize sales and profits at the expense of the health and safety of the public, including Mrs. Pack, in conscious and/or negligent disregard of the foreseeable harm caused by the Products.

176. Defendants intentionally concealed and/or recklessly failed to disclose to the FDA, the public, including Mrs. Pack, the potentially life-threatening effects of the implants in order to ensure continued and increased sales.

177. Defendants' intentional and/or reckless failure to disclose information deprived Mrs. Pack of necessary information to enable her to weigh the true risks of using Allergan's silicone-filled breast implants against its benefits.

178. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Mrs. Pack, she suffered severe and permanent physical injuries. Mrs. Pack endured substantial pain and suffering and had to undergo extensive medical and surgical procedures. Mrs. Pack was forced to incur significant expenses for medical care and treatment as a direct and proximate result of Mrs. Pack's injuries due to Allergan's Biocell implants. Mrs. Pack lost past earnings and suffered a loss of earning capacity. Mrs. Pack suffered substantial economic loss, and was otherwise physically, emotionally and economically injured. Mrs. Pack's injuries and damages were permanent.

179. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Mrs. Pack, and was wanton and reckless, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

180. Plaintiffs aver that Allergan's Biocell textured implants with their rough surface were the direct and proximate cause of Mrs. Pack's BIA-ALCL.

181. There is well-supported, reliable, and peer-reviewed medical literature to support expert medical opinions that the *probable* cause of BIA-ALCL is texturized implants with particulates and implant materials, adulterants and contaminates from the implant shell left on the product at the time of sale causing chronic inflammation, peri-implant lymphoma and BIA-ALCL. As noted above, at the 2019 1st World Consensus Conference on BIA-ALCL in Rome, Italy Dr. Dennis Hammond addressed the etiology of BIA-ALCL with a comprehensive review of the literature, case reports, studies and his own research published in a peer-reviewed article to support his expert opinion that "silicone particle induced inflammation is the primary cause of ALCL."[160]

182. Allergan, prior to Mrs. Pack's breast surgeries, was clearly on notice of an association between BIA-ALCL and breast implants from internal company reports and complaints of BIA-ALCL and by the numerous published reports in the medical literature.

183. In 2011, the FDA noted its adverse event reporting systems contained 17 reports of ALCL in women with breast implants and that cases were being identified through the FDA's contact with other regulatory authorities, scientific experts, and breast implant manufacturers for

[160] *See* ¶ 102 *supra*.

a total of approximately 60 case reports of ALCL in women with breast implants worldwide. The FDA also noted the reports were more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell.[161]

184. As case reports of BIA-ALCL continued to mount related to Biocell textured implants, medical device regulators finally took action in 2018-2019:[162]

- Egypt restricted textured implants in July 2018.
- Allergan's GMED CE Mark was not renewed in December 2018 resulting in loss of sales in t in Europe, Israel and South Africa.
- Brazil suspended Allergan's Biocell in December 2018.
- Colombia suspended Allergan's Biocell in February 2019.
- France ANSM advisory hearings in February 2019
- FDA advisory hearing in March 2019
- France suspended macrotextured implants on April 2, 2019.
- FDA states Allergan's Biocell "did not meet the banning standard" on May 2, 2019.
- Canada restricted Allergan Biocell implants on May 28, 2019
- Australia banned textured implants on July 11, 2019.
- FDA requested a voluntary recall of Allergan Biocell implants on July 24, 2019
- Allergan recalled Biocell implants worldwide on the same day—July 24, 2019.

185. All confirmed cases of BIA-ALCL are associated with textured breast implants.[163]

186. Despite actual knowledge on the part of the Defendants of an association between breast implants and ALCL dating back to at least 1997, including actual internal case reports from 2007-2010**,** Defendants purposefully failed to comply with their clearly-established post-market surveillance obligations and in doing so have exposed many hundreds of thousands of women to

[161] *Id.*
[162] M. Clemens, presentation at 1st World Consensus Conference on BIA-ALCL. https://youtu.be/YxPFayQsjUo?t=4683
[163] *See* footnote 2, *supra*.

life-altering and avoidable cancer, surgery to replace the implants including capsulectomies and the damage to the breasts, plus financial losses, hospitalization, and medical expenses.

187. This causal link between BIA-ALCL and highly textured surface breast implants and particles or implant materials is buttressed by numerous earlier case reports and studies in the medical literature. A leading article[164] summarized this relationship in 2015:

> The general mechanisms leading to the development of breast implant associated ALCL remain obscure, but hypotheses can be made based on similar scenarios. First, **we may surmise that an immune reaction to silicone or other substances used in manufacturing process . . . might cause T cell infiltration with later clonal expansion of T lymphocytes** ."
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> "Based on these observations, we may conclude that capsular fibrosis is not merely the result of a foreign-body reaction, while **silicone itself or its particles, or particles combined with autologous proteins, may trigger a specific antigen-driven local Th1/Th17 immune response** [138]. The initiation of a chronic inflammatory response in the fibrous capsule and draining lymph nodes with lymphocyte infiltration (Fig. 3), along with the production of specific cytokines, **should be considered as a possible cause of indirect stimulation of malignant clones** [132]. Moreover, **removal of the implant and accompanying tumor may switch off the T cell expansion trigge**r, thus explaining the good prognosis of breast implant associated ALCL.[165]

See also See e.g. Jones et al, *Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL): an overview of presentation and pathogenesis and guidelines for pathological diagnosis and management,* Histopathology at 2-3(June 5, 2019)[166]:

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[164] *See also* Bizjak M, Selmi C, Praprotnik S, et al. *Silicone implants and lymphoma: the role of inflammation*. J Autoimmun. 201 at 68.

[165] That the scientific community, as of the time of the filing of this complaint, has not *definitively* settled on the etiology of BIA-ALCL does not mean that a probable ("more likely than not") cause cannot be identified and support by competent expert proof especially where, as here, numerous leading medical and scientific experts support particle contamination from the implant surface as the most probable etiology for BIA-ALCL. *See e.g.* D, Hammond (¶41); J. Brody (¶ 111); G. Brody (¶ 112); and ¶¶ 15viii.

[166] https://onlinelibrary.wiley.com/doi/epdf/10.1111/his.13932?r3_referer=wol

> The cause of BIA-ALCL is not established; however, it has been proposed that lymphomagenesis may be driven by chronic inflammatory reaction induced by capsule contents or surface **and there is some evidence to support this.** . . Silicone leachable and particles have also been implicated as the chronic inflammatory stimulus in BIA-ALCL and, interestingly, other prostheses containing silicone also have been associated with peri-implant lymphoma.[167]

188. In 2019, researchers at Weill Cornell Medical College in New York conducted a causation study based upon an *ex vivo* biomimetic, 3-dimensional breast model to study the effects of implant shells on patient-derived BIA-ALCL cells. The researchers found that BIA-ALCL cells thrive in the presence of implant shell materials and significantly increase BIA-ALCL cell

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[167] *See e.g.* Hallab, Smerko,Hammond, *The Inflammatory Effects of Breast Implant Particulate Shedding: Comparison With Orthopedic Implants,* Aesthetic Surgery Journal Vol 39(S1) S36–S48 (Jan. 30, 2019). Available at: Vol 39(S1) S36–S48. Available at: https://pdfs.semanticscholar.org/7635/841c2edd2b45000c04641befa345a46028e7.pdf?_ga=2.2342962.326928717.1572881512-793102741.1572881512.

See also *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151 (E.D. La. 1997) (court held that expert testimony that foreign particles from silicone elastomer in penile implants caused tissue reaction, foreign body granulomas, macrophages and migration to lymph nodes was admissible under *Daubert* and could support general causation for plaintiff's autoimmune disease claim). In *Pick*, the court excluded expert testimony on specific causation that the particular plaintiff's autoimmune disease was caused by the penile prosthesis and deferred ruling on summary judgment on the issue of general causation, stating: "With respect to general causation, the Court assumes, without deciding, that the admissible evidence after the *Daubert* analysis is sufficient to survive summary judgment. The evidence as to specific causation, however, is not." The Fifth Circuit affirmed this ruling in a *per curiam* opinion. *Pick v. Am. Med. Sys., Inc.*, 198 F.3d 241 (5th Cir. 1999). By contrast, specific causation is indisputable in this case.

In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig., 127 F. Supp. 3d 1306, 1343 (N.D. Ga. 2015) (summary judgment denied, and expert testimony held admissible under *Daubert* that particles from surface of hip implant leached out of device causing harm. This ruling was affirmed in *Christiansen v. Wright Med. Tech., Inc.*, 851 F.3d 1203 (11th Cir. 2017)(affirming $2.1M jury verdict).

In re Silicone Gel Breast Implants Prod. Liab. Litig., 318 F. Supp. 2d 879, 922 (C.D. Cal. 2004) (court found plaintiff's expert opinions admissible as against a *Daubert* challenge and supported general causation in a polyurethane breast implant case products liability case where the plaintiff alleged PUF (polyurethane foam) on the implant shell surface degraded into carcinogenic chemicals. The court granted summary judgment on specific causation).

proliferation when compared with no implant shell.[168] The authors concluded: "These findings contribute to the implication of breast implant materials in the development of BIA-ALCL."

189. The presence of foreign solid silicone particles in tissue capsules in contact with the Biocell textured surface was known to Allergan (McGhan Medical) as early as 1989. A McGhan Medical-sponsored rabbit capsular contracture study was "[p]resented at the Annual Meeting of the American Society of Plastic Surgeons in San Francisco (October 25-November 3, 1989)." [169] The paper was published in July 1992 in Plastic and Reconstructive Surgery. The authors reported that under the microscope (scanning electron microscope) the tissue capsules from the New Zealand White rabbit showed "foreign- reaction with giant cell histiocytes" and

[168] Wright, et.al. *Exploring the Effect of Implant Shell on Patient-derived Breast Implant–associated Anaplastic Large Cell Lymphoma Cells in Ex Vivo Biomimetic Breast Tissue, Plastic and Reconstructive Surgery,* August 2019 - Volume 7 - Issue 8S-1 - p 21-22. https://journals.lww.com/prsgo/pages/articleviewer.aspx?year=2019&issue=08001&article=00031&type=Fulltext&Ppt=Article%7Cprsgo:2019:08001:00031%7C%7C

[169] Barone et al., *The Biochemical and Histopathologic Effects of Surface Texturing in Tissue Implantation and Expansion,* Plastic and Reconstructive Surgery (July 1992).

"silicone particles were observed within [mononuclear] inflammatory cells in the capsule interface in the Biocell-surfaced specimens."[170]

[170] *Id.* at p. 84. "The mononuclear cell reaction in and around the silicone implant capsule consists largely of T-Cells." P. Rosen, Rosen's Breast Pathology at 59 (2009).

Silicone gel leaking from breasts— causing silicone-induced granulomas (silicone-induced granuloma of the breast capsule or "SIGBIC)—is materially different from the silicone particles from textured implants precisely because of the presence of monoclonal inflammatory cells found in BIA-ALCL (as shown above in tissue capsules from the Biocell implant) . *See* E. de Faria Castro Fleury, et al. *Silicone-induced granuloma of breast implant capsule (SIGBIC): similarities and differences with anaplastic large cell lymphoma (ALCL) and their differential diagnosis,* Breast Cancer (Dove Med Press). 2017; 9: 133–140. Published online 2017 Mar 10 ("As seen above, the pathophysiology of ALCL is very similar to that of SIGBIC, where **the only difference would be monoclonal neoplasia induced by activation of T lymphocytes**." (emphasis added). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5513491/. In addition, the sharp and fragmented particles from the Biocell surface (scrubbed remnants of the hardened silicone elastomer are materially different from the silicone globules from silicone gel found in SIGBIC. *See also Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1161 (E.D. La. 1997)(discussing difference between silicone shell (elastomer) and silicone gel).

190. In 1993, "solid silicone fragments" in textured breast implants were found histologically by Kasper: *Histologic features of breast capsules reflect surface configuration and composition of silicone bag implants.* Am Clin Pathology (1993) 655-9:[171]

> In contrast to the regular capsules bordering smooth surfaced implants, capsules around textured implants have an irregular inner surface festooned with small knob-like projections **with trapped irregular solid silicone elastomer fragments. Irregular fragments of solid silicone elastomer often were trapped within the collagenous knob-like protrusions. . .** Thus, certain differences in capsular micro anatomy can be used to differentiate between capsules adjacent to textured versus smooth-surfaced implants. In addition to variation in capsular surface morphology, **a number of foreign materials are observed** either within or adjacent to the capsules, **depending on implant type used**. Many of the **foreign substances** can be identified histologically. (emphasis added).

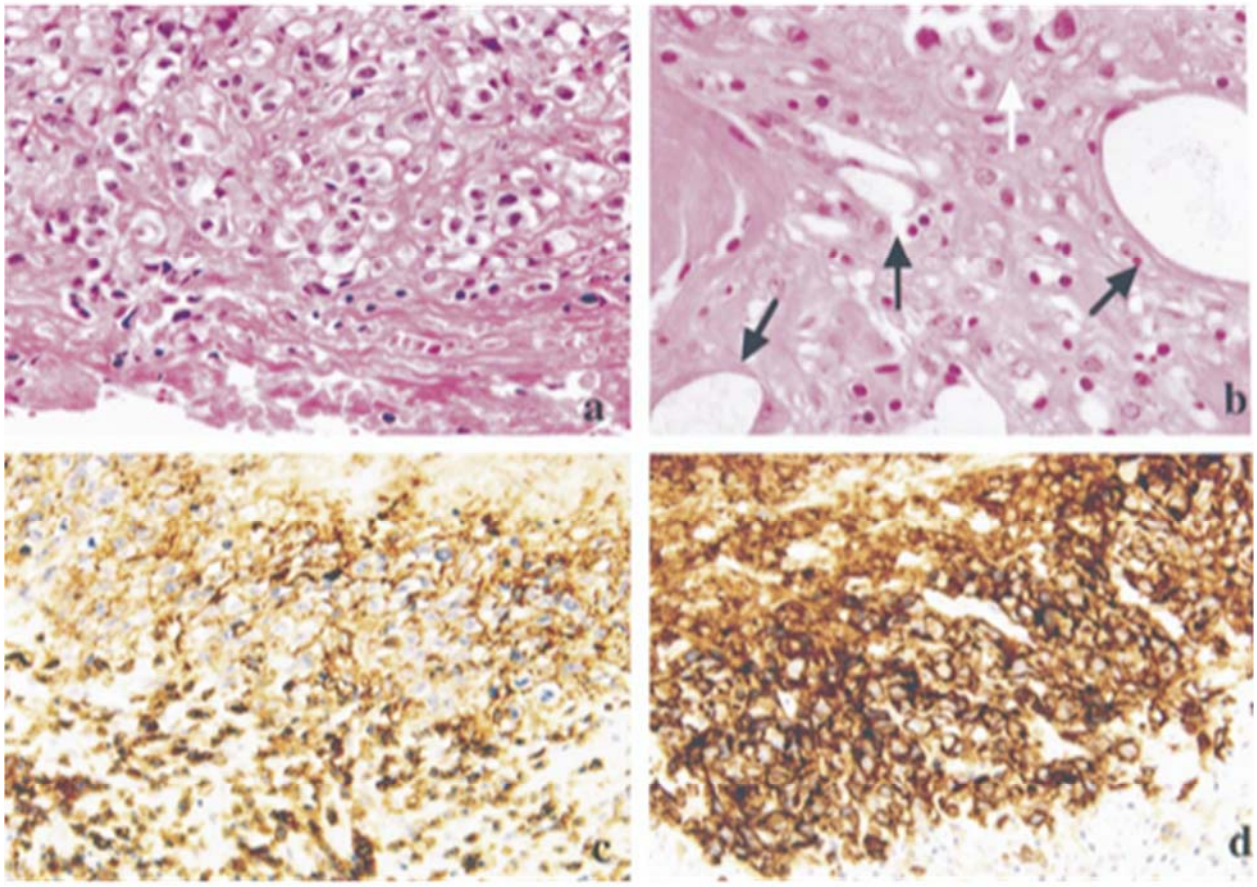
See also Silverman et al., *Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review,* Annals of Internal Medicine, April 15, 1996.[172] ("Evidence also indicates that the silicone shell of the implant may shed silicone fragments. **Textured silicone shells appear to be more likely than smooth shells to shed fragments**."); M Copeland, et al., *Silicone breakdown and capsular synovial metaplasia in textured-wall saline breast prostheses,* Plastic and Reconstructive Surgery (October 1994)[173] ("Our findings suggest that **smooth-walled prostheses are associated with less silicone fragmentation than textured devices in the peri-implant tissue capsules**."); C. Lesene, *Textured surface silicone breast implants: histology in the human,* Aesthetic Plast Surg. 1997 Mar-Apr.[174] (A prospective study was designed to examine the

[171] Available at: https://academic.oup.com/ajcp/article-abstract/102/5/655/1755654
[172] Available at: https://annals.org/aim/article-abstract/709588/reported-complications-silicone-gel-breast-implants-epidemiologic-review
[173] Available at: https://www.ncbi.nlm.nih.gov/pubmed/7938285
[174] Available at: https://link.springer.com/article/10.1007/s002669900091

interaction of **textured** silicone breast implants in a human over several years. **The results revealed 78% had silicone particles in the tissue immediately adjacent to the implant interface**.)

191. In 2003, S. Sahoo and P. Rosen reported in the medical literature **a BIA-ALCL case specifically associated with the presence of silicone particles in the breast capsule**: S. Sahoo, P. Rosen et al., *Anaplastic Large Cell Lymphoma Arising in a Silicone Breast Implant Capsule: A Case Report and Review of the Literature*, Arch Pathol Lab Med—Vol 127, March 2003.[175] The authors reported that BIA-ALCL was confirmed in a woman who received a silicone gel-filled prosthesis in 1991 and was diagnosed with BIA-ALCL in 2000. Notably, her pathology findings showed the presence of "refractile material consistent with silicone particles:"

[175] https://www.archivesofpathology.org/doi/pdf/10.1043/0003-9985%282003%29127%3Ce115%3AALCLAI%3E2.0.CO%3B2



a, Neoplastic breast cells are large and have clear cytoplasm, large nuclei, and prominent nucleoli. An overlying layer of fibrinous material is also present (hematoxylin-eosin, original magnification ×20). b, Empty spaces containing unstained refractile material consistent with silicone particles (black arrows) are often in close proximity to the tumor cells (white arrow) (hematoxylin-eosin, original magnification ×40). c, Neoplastic cells express the T-cell–associated antigen CD43 (immunoperoxidase, original magnification ×20). d, Tumor cells are strongly positive for CD30 (BerH2, immunoperoxidase, original magnification ×20).

192. In 2001, Danino et al. published a paper studying (with an electron microscope) the surfaces and breast tissue capsules in 10 patients—5 of whom had saline-filled Biocell textured

implants and 5 who had Mentor Siltex textured implants.[176] The comparison study looked at the "relation between the texturing surface and the periprosthetic capsular tissue morphology." The results showed that in the capsule from **all 5 of the Biocell textured implants** there were **"macrophage[s]" and "cylindrical particles"** and **no** macrophages or particles in the capsules from any of the Mentor Siltex implants:

TABLE III
Capsular Description

Case No.	Implant	Capsule Texturing	Diameter (μm)	Height (μm)	Density (μm)	Cells
1	Biocell	Mirror image	500	150	8	Red blood cell, macrophage, cylindrical particle
2	Biocell	Mirror image	550	150	8	Red blood cell, macrophage, cylindrical particle
3	Biocell	Mirror image	560	160	9	Red blood cell, macrophage, cylindrical particle
4	Biocell	Mirror image	650	170	7	Red blood cell, macrophage, cylindrical particle
5	Biocell	Mirror image	700	200	8	Red blood cell, macrophage, cylindrical particle
6	Siltex	Linear fibrosis	—	—	—	Red blood cell
7	Siltex	Linear fibrosis	—	—	—	Red blood cell
8	Siltex	Linear fibrosis	—	—	—	Red blood cell
9	Siltex	Linear fibrosis	—	—	—	Red blood cell
10	Siltex	Linear fibrosis	—	—	—	Red blood cell
TOTAL Five cases	Biocell	Mirror image	500–700	150–200	8	Red blood cell, macrophage, cylindrical particle
Five cases	Siltex	Linear fibrosis	—	—	—	Red blood cell

The results also showed silicone particles in the Biocell tissue capsule surface:

[176] Danino et al., *Comparison of the Capsular Response to the Biocell RTV and Mentor 1600 Siltex Breast Implant Surface Texturing: A Scanning Electron Microscopic Study*, Plastic and Reconstructive Surgery (December 2001). https://journals.lww.com/plasreconsurg/pages/articleviewer.aspx?year=2001&issue=12000&article=00032&type=abstract

FIG. 2. Suspicion of silicone globule in a scanning electron microscopic view of a Biocell's capsular surface (7500×).

193. A leading medical expert, Joshua Brody, M.D., director, Lymphoma Immunotherapy Program at The Tisch Cancer Institute at Mount Sinai, New York City, released a statement in connection with the July 2019 recall of Allergan's implants:

> **The recall of these textured implants [Allergan's] is a big deal in protecting women from the potential risks of developing, and dying from, this rare type of aggressive lymphoma.** While case reports have suggested a potential link between some types of breast implants and this disease – anaplastic lymphoma – for over 20 years, **it has taken time to gain sufficient evidence to suggest, and understand, the causality. Some types of implants induce inflammation, which can both increase the chance of developing cancer, and also help to 'hide 'developing cancers from the immune system.** By preventing further use of these implants, the FDA is helping women to protect themselves from the medically serious and emotionally exhausting effects of these risks.[177]

[177] HemOnc Today, *At FDA's request, Allergan recalls breast implants linked to rare lymphoma,* (July 24, 2019), https://www.healio.com/hematology-oncology/lymphoma/news/online/%7B9db178de-066d-412f-80e8-afc6acd363e5%7D/at-fdas-request-allergan-recalls-breast-implants-linked-to-rare-lymphoma. Last visited on November 1, 2019.

194. Dr. Garry S. Brody, a plastic surgeon in Los Angeles who has published numerous articles in the medical literature has written that the shed particles from the textured implant shell **likely** trigger an immune response causing BIA-ALCL.[178]

195. Plaintiffs aver that Allergan's Biocell textured breast implants caused Mrs. Pack's BIA-ALCL. Plaintiff further avers that, more likely than not, Biocell textured implants caused Mrs. Pack's BIA-ALCL by an immune system response to chronic inflammation induced by over texturing and silicone particles/unwanted contaminants and particulates from the negligent manufacturing process for Biocell.[179]

196. Dr. Fabio Santanelli di Pompeo's presentation at the Rome BIA-ALCL conference reported findings of "up to 400 microparticulates" from the surface of the Biocell implant, thereby creating 402 "foreign bodies" placed in the patient— the 2 implants plus the 400 microparticles from the Biocell implant[180]:

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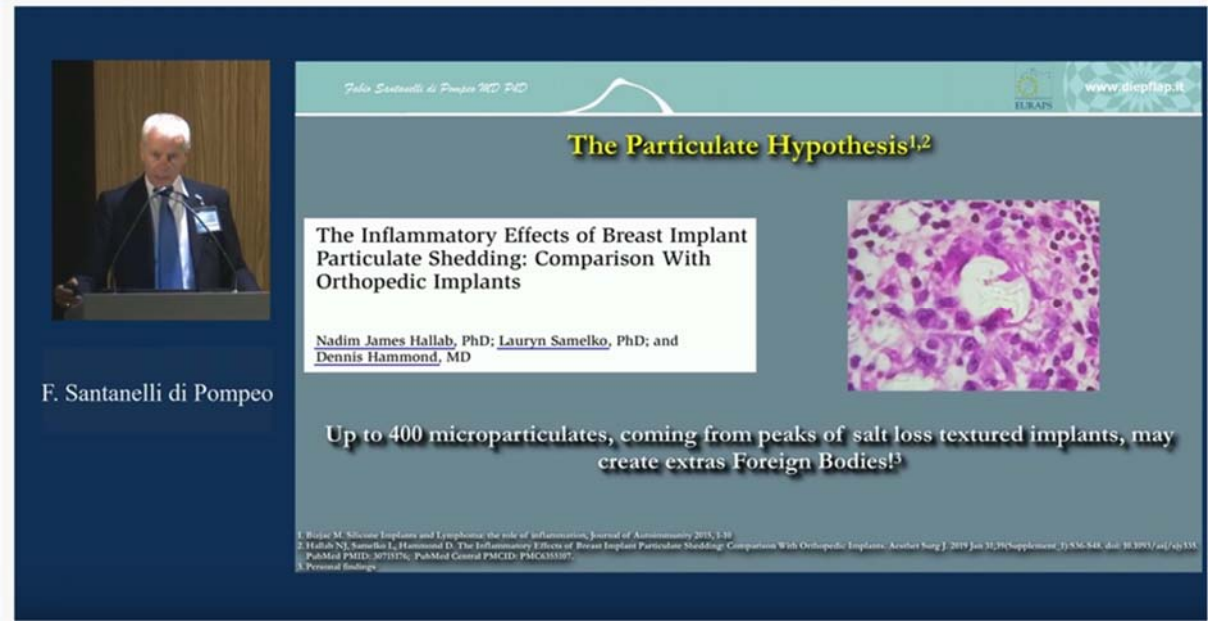
[178] Brody, *The Case Against Biofilm as the Primary Initiator of Breast Implant-Associated Anaplastic Large Cell Lymphoma,* Plastic Reconstr. Surg. 2016 ; 137:558e-559e. Available at: https://journals.lww.com/plasreconsurg/fulltext/2016/04000/The_Case_against_Biofilm_as_the_Primary_Initiator.67.aspx

[179] *See also* Bizjak M, Selmi C, Praprotnik S, et al. *Silicone implants and lymphoma: the role of inflammation*. J Autoimmun. 2015;65:64-73:

> A growing number of reports indicates an increased risk of lymphoma, particularly of the anaplastic large cell (ALCL) type. **The implants, specifically those used in the past, elicit chronic stimulation of the immune system against the prosthetic material.** This is particularly the case in genetically susceptible hosts. We suggest that polyclonal activation may result in monoclonality in those at risk hosts, ultimately leading to lymphoma.

Available at: https://www.sciencedirect.com/science/article/pii/S0896841115300275?via%3Dihub (emphasis added).

[180] https://youtu.be/YxPFayQsjUo?t=7433



ALLERGAN IS LIABLE FOR BARBARA PACK'S DISEASE

197. Mrs. Pack's Biocell Breast Implants were in a defective and unreasonably dangerous condition when put to a reasonably anticipated use. They were in fact used in such a manner; and Mrs. Pack's injuries are a direct result of such defects as they existed when the implants were sold. Allergan is liable under the parallel state law of Utah. Because of its negligent manufacturing sale of adulterated devices, and failure to comply with post-PMA reporting requirements, Allergan violated FDA PMAs, federal laws, and requirements. Plaintiffs further allege that the Biocell implants differed from Allergan's intended condition because, as negligently manufactured, the Biocell implants had harmful solid particles, fragments and residues that caused her BIA-ALCL. Plaintiffs therefore have a claim for a manufacturing defect claim to proceed despite Allergan's PMA, notwithstanding any "defense" of FDA preemption law because of "PMA approval." *See* *Sumpter v. Allergan Inc.*, No. 4:17-CV-2289 RLW, 2018 U.S. Dist. LEXIS 154467, 2018 WL 4335519, at *2 (E.D. Mo. Sept. 11, 2018) (holding that plaintiffs adequately

pleaded a manufacturing defect claim when the allegations demonstrated that the product at issue deviated from the manufacturer's intended result).

198. Allergan failed to use ordinary care to manufacture Barbara Pack's Biocell textured implants to be reasonably safe. These implants were unreasonably dangerous due to a specific manufacturing defect: adulterated solid silicone particles, fragments, residues and contaminants from the implant surface at the time of sale that ultimately caused her BIA-ALCL.

199. Allergan knew (or had information from which Defendants, in the exercise of ordinary care, should have known) that its Biocell implants were defective and unreasonably dangerous if the solid particles were not completely removed from the implant surface during manufacture or if abrading or brushing the implants left solid silicone particles or fragments on the textured surface of the implants.

200. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to make safe, not unreasonably dangerous breast implants that were safely and reasonably manufactured and designed and Allergan had a post-market duty to identify, monitor and report all adverse events and all risks associated with the product.

201. Despite having knowledge and possession of evidence showing that the use of Allergan's Biocell textured silicone-filled breast implants was dangerous and likely to place consumers' health at serious risk, Allergan refused or recklessly failed to identify, disclose and warn the FDA of the health hazards and risks associated with the product, and about all adverse events that were known to Allergan.

202. Instead, Defendants marketed, advertised and promoted the Biocell implants while at the same time consciously refusing and/or recklessly failing to monitor, warn, or otherwise ensure the safety and efficacy for users of Allergan's Biocell textured breast implants.

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

204. The 2002 PMA provided: "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." The 2006 PMA provided: "Failure 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."

205. Allergan's violations of the Food Drug and Cosmetics Act and FDA's regulations and requirements, as detailed herein, establish and confirm Allergan's reckless and intentional disregard for the safety of hundreds of thousands of women, including Barbara Pack.

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

207. Notwithstanding Allergan's failures to comply with post-approval requirements, including the failures described above, Allergan continued to commercially distribute its Biocell

Breast Implants. As expressly provided in the PMAs, such distribution was a violation of federal law.

208. Had Allergan substantially complied with the PMAs, rather than flagrantly under-performing the post-approval requirements as alleged above, Allergan's disclosures would have led to much wider knowledge of the risks associated with Allergan's products. In addition, Allergan's physician and patient labeling would have materially changed over time, and patients including Barbara Pack, and medical providers including Plaintiff's physicians, would not in ignorance have purchased or implanted Allergan's Biocell products, including, but not limited to, the causative association to BIA-ALCL.

209. Specifically, Defendants knew or should have known that Biocell textured breast implants, were the likely cause of BIA-ALCL.

210. To protect Allergan's silicone-filled breast implant brand, the Defendants intentionally failed in their post-market surveillance obligations, and thereby consciously and deliberately concealed its knowledge of known safety risks from the FDA, the medical community, and the public at large. Additionally, the Defendants ignored the available scientific studies and publications indicating an association between textured breast implants and ALCL

211. Defendants also had a duty to exercise reasonable care in the manufacture, marketing, labeling, distributing, and sale of the product in 2002 and after Biocell silicone gel implants were approved for sale by the FDA in 2006, which does not impose duties or requirements materially different from those imposed by federal law. Defendants failed or refused to do so.

212. At material times, Defendants routinely maintained manufacturing facilities that failed to comply with applicable law and regulations as set forth in detail above and in relation to:

i. The use of nonconforming products;

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

iii. The omission of any reference in Allergan's reporting to its manufacturing processes as a potential cause of health risk, product failures related to the inability to clean and sterilize the product free from particles;

iv. The omission of any reference in Allergan's reporting to its manufacturing processes as a potential cause of health risk and product failures relating to finished products that show particles of silicone salt encapsulated in silicone and sharp fragmented particles of silicone;

v. Deficiencies in Allergan's sampling methods and quality controls for finished product testing; and

vi. Deficiencies in Allergan's environmental monitoring control procedures.

213. These deviations contributed to the faulty manufacture of Allergan's Biocell breast implant products that were adulterated with silicone particles and residues and thus defective and unreasonably dangerous.

214. Allergan knew of the manufacturing failures, and multiple risks associated with negligent manufacturing and promoted self-serving research that it could control, thus misrepresenting the risks to the users, physicians, and regulatory agencies.

215. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information in the medical and scientific community to protect a patient's interest. Because Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with their Biocell textured breast implants and misrepresented the risk of BIA-ALCL, the public's knowledge of the risks associated with Allergan's textured breast implants was seriously hampered and delayed. This endangered patient safety, including Barbara Pack' health and safety.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

216. Plaintiffs hereby incorporate by reference all other paragraphs in this Complaint as if set forth fully herein.

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

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

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

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

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

222. Plaintiffs, consumers, and medical professionals could not have afforded to and

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

PUNITIVE DAMAGES

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

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

225. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Biocell Breast Implants. despite available information demonstrating that Biocell Breast Implants were likely to cause serious and potentially fatal side effects to users.

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

227. Defendants misled regulators, the medical community and the public at large, including Plaintiff, by making false and misleading representations about the safety of Biocell Breast Implants. Defendants knowingly withheld or misrepresented information required to be

submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiffs.

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

CAUSES OF ACTION

COUNT 1 - NEGLIGENCE AND NEGLIGENCE *PER SE*
(Against All Defendants)

232. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

233. At all material times, Defendants owed Barbara Pack and her implanting physician a duty to use reasonable care, pursuant to state tort law of Utah and pursuant to parallel federal FDA device law and regulations, including PMA and post-approval requirements, to manufacture, test, inspect and sell breast implants that were reasonably safe and not unreasonably dangerous.

234. At all material times, Defendants owed a duty to use reasonable care, pursuant to the federal post-approval requirements, to adequately warn of product dangers, including the development of BIA-ALCL, and any adverse events of BIA-ALCL related to Defendants' breast

implant products.[181]

235. Under Utah law Defendants had a duty to exercise reasonable care in updating the labeling of Biocell Breast Implants prior to sale to reflect newly- acquired safety information without advance approval by the FDA. Prior to Barbara Pack receiving her implants in 2009 and 2015, Defendants failed to add information concerning information Defendants knew concerning the increased risk of developing BIA-ALCL associated with their Biocell products and thus breached their duty to Barbara Pack. Utah law does not impose duties materially different from 21 C.F.R. § 814.39(d) and there is no §360k preemption.[182]

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[181] *Id.*

[182] This is especially applicable here since at the time the Allergan Biocell PMAs were approved by FDA in 2000 and 2006 BIA-ALCL MDRs were not reported to FDA. FDA has stated the first MDR case report of BIA-ALCL was received in 2010. *See* note 16 *supra*. In addition, Allergan only added a BIA-ALCL warning by a supplement request to FDA later—in 2011 (approved by FDA in 2013). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P990074S023.

This raises the issue in *Riegel* in Justice Ginsburg's dissent fn. 1 where Justice Ginsburg states that PMA preemption does not apply if the harm/risk does not come to light until *after* PMA approval. *Riegel*, 552 U.S. at 333 n.1 (Ginsburg, J. dissenting). There is scant law on this legal issue because heretofore plaintiffs in Class III/PMA medical device cases have not pleaded facts that placed that the "risk not considered by FDA" argument at issue. For example, two post-*Riegel* cases, *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917 (N.D. Ill. 2008) and *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174 (N.D. Ill. 2008), addressed Justice Ginsburg's footnote; however, these two district courts did not decide the issue by holding that the Plaintiffs had not pleaded facts that the risks were not considered by FDA.

By contrast, in the case of Allergan and BIA-ALCL, as set forth *passim* in this Complaint, Plaintiff squarely alleges (and the facts support) that FDA did not consider BIA-ALCL in connection with the 2000 and 2006 PMAs. This in turn raises the issue of whether preemption applies to a state-law duty to update warnings based on *later* information and 21 C.F.R § 814.39(d)(2) —the CBE regs—changes being effected. Allergan could have changed the label and warned of BIA-ALCL without prior FDA approval.

Plaintiffs aver there is no preemption where a later risk comes to light and state-law imposes a non-preempted duty to warn of the *new* danger. *See e.g.,* the well-reasoned position taken six years after *Riegel* by the *United States Solicitor General Brief in Medtronic v. Stengel*, No. 12-1351 (May 2014):

> Section 360k(a) does not preempt respondents' straightforward claim that petitioner should have brought new safety information to physicians' attention through a CBE revision to the device's

236. Under Utah law Defendants also had a duty to recall Biocell implants without advance approval by the FDA. Utah law does not impose duties different from or in addition to those imposed by the FDA because the July 2019 recall was initiated by a request from the FDA pursuant to 21 C.F.R. §§ 7.40, 7.45(a) for Allergan's "violation" of the FDCA .21 C.F.R. § 7.40. Defendants failed to recall Biocell implants until July 2019 despite Defendants knowledge of the increased risk of developing BIA-ALCL associated with their Biocell products and thus breached

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> labeling, because such a claim implicates no preemptive device-specific federal requirement. . . But here, respondents attack petitioner's conduct *after* its device received premarket approval (and after FDA approved any relevant supplemental application). That conduct, as alleged in the proposed complaint, would have been governed not by the terms of the device's premarket approval, but rather by FDA's general regulations governing adverse-event reporting and labeling revision in light of new safety information. Accordingly, respondents' failure-to-warn claim—whether styled as arising from petitioner's failure to make adverse event reports to FDA or from its failure to make a CBE revision to the device's labeling—is not expressly preempted.).

https://www.justice.gov/sites/default/files/osg/briefs/2013/01/01/2012-1351.pet.ami.inv.pdf at 7 and 12 (emphasis in original).

Here, the BIA-ALCL risk only came to light *after* PMA approvals in 2002 and 2006. Allergan's state-law duty to issue updated/post PMA warnings therefore does not conflict with federal law. *See also* *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019) (Supreme Court explained that just because the FDA approves a warning initially that is not the warning for all time and a manufacturer can and should change the warning based on new information not previously considered). While *Albrecht* was a drug case and not a medical device case (where §360k preemption must be considered), this Court should rule in accordance with the reasoning set forth in *U.S. Solicitor General's Brief opposing certiorari in Medtronic v. Lohr*, that there is no conflict or preemption in permitting a state-law failure to warn claim for failing to update a warning in a Class III medical device case notwithstanding the preemption provision for medical devices. *See also* the well-reasoned dissent by Circuit Judge Bye in *Brooks v. Howmedica, Inc.*, 273 F.3d 785,800 (8th Cir. 2001).

In short, Plaintiff pleads a *two*-pronged failure to warn case (and a negligent manufacturing case). Allergan not only breached its post-marketing duties (*Stengel*/*Freed. v. St. Jude*) in failing to warn FDA in accord with its post-approval duties to report adverse events and studies. Allergan also violated a non-preempted state-law duty to update warnings because the BIA-ALCL risk only came to light after the PMAs and Allergan's state-law duty does not conflict with federal law as articulated by the *U.S. Solicitor General in Medtronic v. Stengel* and by Circuit Judges Bye and Heaney in *Brooks v. Howmedica, Inc.*, 273 F.3d 785,800 (8th Cir. 2001)(arguing there should be no preemption where a later risk comes to light and citing 21 C.F.R. § 814.39(d)(2)).

their duty to Barbara Pack.

237. Barbara Pack and/or her physicians reasonably relied on the data regarding adverse events, or lack thereof, provided to the FDA by Defendants, and would not have made the same decision(s) regarding the use of the product if the FDA had been provided the scientific information regarding the risks of BIA-ALCL that was known or knowable when Barbara Pack was implanted with the Biocell implants.

238. If Defendants had properly reported the adverse events and adverse studies to the FDA, as required under federal law, that information would have reached Mrs. Pack's implanting physician in time to have prevented her injuries because Mrs. Pack (and a reasonable physician, including Mrs. Pack's surgeon) would not have chosen Biocell implants knowing that the risks of ALCL were greater than Allergan previously reported. This establishes a causal link between the failure to warn the FDA and Mrs. Pack's plastic surgeon and Mrs. Pack's injuries.

239. Thus, as a direct and proximate cause of Defendant's failure to comply with the above referenced federal statutes and regulations, Mrs. Pack endured great physical pain and from the development of BIA-ALCL.

240. Because Defendants failed to comply with their duties to discover and report adverse events to the FDA *after* pre-market approval, a requirement under federal law, they breached their duty to use reasonable care under Utah tort law regarding the duty of a manufacturer to provide adequate warnings.

241. Additionally, because the FDA requirement regarding the submission of information regarding adverse events is stated in general terms, and it applies to all devices that must undergo the [relevant] clearance process," this is "not the kind of federal requirement that

can have a preemptive effect." *See* *U.S. Supreme Court Brief of the Solicitor General in Buckman Company v. Plaintiff's Legal Committee,* No. 98-1768 at *11-13 (U.S. September 2000); *U.S. Supreme Court Brief of Solicitor General in Medtronic v. Stengel,* No. 12-1351 (May 2014) at * 7, 12 (U.S. May 2014).

242. Barbara Pack, having had Defendants' textured breast implant devices surgically placed into her chest, is within the class of persons that the above-referenced federal statutes and regulations are designed to protect, and her injuries are the type of harm these statutes and regulations are designed to prevent.

243. Defendants breached their duties of care and were negligent as described and above herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the Biocell Breast Implants in one or more of the following respects:

a. Failing to manufacture the implants so as to avoid an unreasonable risk of harm to women in whom the Products were implanted;

b. Failing to use reasonable care in the manufacturing process to adequately test all of the implants so as to avoid unreasonable risk of harm to women in whom the implants were implanted, including Mrs. Pack;

c. Failing to use reasonable care in inspecting the implants so as to avoid unreasonable risk of harm to women in whom the implants were implanted, including Mrs. Pack;

d. Failing to use reasonable care in training its employees regarding proper manufacturing processes, including washing, scrubbing, cleaning, testing, inspecting and applying safe quality control measures when making the Biocell implant surface via the "salt loss technique;"

e. Failing to use reasonable care in training and/or warning employees and health care providers related to the use of the implants, so as to avoid unreasonable risk of harm to women in whom the implants were implanted, including Mrs. Pack;

f. Failing to use reasonable care in warning the FDA as set forth in this Complaint, of the health risks associated with the implants so as to avoid unreasonable risk of harm to women in whom the implants were implanted including Mrs. Pack;

g. In negligently and carelessly marketing and promoting the Biocell implants, so as to avoid unreasonable risk of harm to women in whom the implants were implanted including Mrs. Pack;

h. In negligently and carelessly marketing and promoting the use of Biocell implants to physicians who had not received sufficient training to safely implant the Biocell implants and safely inspect the implants for particles, so as to avoid unreasonable risk of harm to women in whom the implants were implanted including Mrs. Pack;

i. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling studying, testing or selling the Biocell Products;

j. Negligently failing to conduct, or to adequately conduct, biocompatibility clinical studies in animals and humans to demonstrate safety with respect to the final Biocell product and surface;

k. Negligence under state law for violating FDA laws and regulations as set forth in this Complaint;

l. Failing to conduct post-market surveillance and vigilance by: i) Monitoring or acting on findings in the scientific and medical literature; ii) Monitoring or investigating and evaluating in the FDA adverse event databases for their potential significance for Defendants 'Breast Implant products; iii) Failing to identify the risk of BIA-ALCL in a timely manner; iv) Failing to warn the FDA of the risk of BIA-ALCL; v) Failing to conduct regular risk analyses of Allergan's Biocell Breast Implants; vi) misusing the FDA ASR and French IRF reporting system so as to fail to report or specifically identify the serious health risk, known to Allergan of BIA-ALCL

m. Failing to comply with manufacturer requirements of the Medical Device Reporting (MDR) regulations, specifically: i) Failed to report MDRs (Medical Device [adverse event] Reports; and ii) Failed to investigate reports of serious adverse events;

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

o. Failing to warn the FDA of the risk of BIA-ALCL;

p. Manufacturing, distributing and selling Allergan's Biocell Breast Implants that are dangerous to the consuming public;

q. Manufacturing, distributing and selling Allergan's Biocell Breast Implants that differ from the specifications set forth in the PMA, its Supplements, and the Conditions of Approval;

r. Failing to conduct regular risk analyses of Allergan's Biocell Breast Implants;

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

t. Failing to report the products' failure to meet performance specifications and expectations under the PMA and FDA requirements;

u. Failing to revise and update product labeling to reflect Allergan's current knowledge of BIA-ALCL;

v. Receiving but failing to warn or report to the FDA and the medical community Allergan's knowledge and information regarding complaints and specific events about Allergan's Biocell Breast Implants causing BIA- ALCL, and additional injuries including: i) Adverse events requiring removal; ii) Persistent and/or chronic inflammation or autoimmune impacts; iii) suspected lymphoma linked to breast implants; iv) and ALCL diagnoses linked to breast implants;

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

x. Negligently acting so that the medical community and/or patients would rely upon Defendants 'disseminated information in deciding whether to purchase and/or implant Allergan's Silicone-Filled breast implants. Mrs. Pack and/or Mrs. Pack's physicians reasonably relied on Defendants' negligent misrepresentations and omissions, as Defendants intended, and would not have made the same decision(s) if provided the required information;

y. Violating federal laws, requirements, PMA P020056 and PMA 990074, the C.F.R. provisions cited in this Complaint and the FDA's Current Good Manufacturing Practices (Quality System Regulations ("QSRs")).

z. For each of the statutes and regulations cited in this Complaint, Mrs. Pack was within the class of persons the statutes and regulations are intended to protect, and her injuries are of the type of harm these statutes and regulations are designed to prevent.

244. Because under Utah law the duty of reasonable care includes the duty to warn third persons (e.g. the FDA), this parallel state-law claim is not preempted. *See e.g., Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343 (D. Del. 2019)(state law failure to warn claims premised on Section 388 of Restatement(Second) of Torts, which focus on a manufacturer's failure to report

adverse events to the FDA, are not preempted); *In re Smith & Nephew Birmingham Hip Resurfacing (BUR) Hip Implant Prods. Liab. Litig.*, No. MDL No. 2775, 2019 U.S. Dist. LEXIS 131067 (D. Md. Aug. 5, 2019); *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, No. MDL No. 2775, 2019 U.S. Dist. LEXIS 206574 (D. Md. Nov. 26, 2019).[183]

245. As a direct, proximate and legal result of Defendants' failure to exercise reasonable care in the warning, design, manufacture, distribution and sale of the Allergan's Biocell Breast Implants implanted into Barbara Pack, Mrs. Pack suffered from BIA-ALCL and its accompanying symptoms. Plaintiff sues for all damages, compensatory and punitive, under Utah law. The proximately caused damages include, without limitation, physical injuries, pain and suffering, severe emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, loss of consortium and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

[183] In an MDL proceeding for PMA/Class III hip implants the Court held (twice):

> Even if the Fourth Circuit were to hold that claims targeting the hybrid system are subject to § 360k(a) analysis, a number of the plaintiffs' claims targeting [*33] the hybrid systems, including the claims for negligent failure to warn (as to the FDA), negligent misrepresentation, fraud, fraudulent concealment, unfair & deceptive trade practice, and off-label promotion, would still go forward under the court's analysis. The court found that these claims were not preempted as to the PMA-approved components because the state law claims were parallel and predated the MDA. Certain claims targeting hybrid systems, even if those systems are subject to § 360k(a), would therefore also survive preemption.

In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig., No. MDL No. 2775, 2019 U.S. Dist. LEXIS 206574, at *32-33 (D. Md. Nov. 26, 2019)

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

COUNT 2 –STRICT PRODUCTS LIABILITY: FAILURE TO WARN
(Against All Defendants)

246. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

247. At all material times, Defendants were engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Allergan's Biocell Breast Implants.

248. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Allergan's Biocell Breast Implants. including those that were implanted into Barbara Pack.

249. Barbara Pack was implanted with Allergan's Biocell Breast Implants which were defective, dangerous and adulterated upon manufacture, and that were manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements, resulting in product failure, serious injury to Mrs. Pack.

250. At all material times, Defendants intended for the Allergan's Biocell Breast Implants to be surgically implanted into the bodies of members of the general public, including

Mrs. Pack, and knew the products would be surgically implanted into members of the general public, including Mrs. Pack.

251. Defendants, in violation of federal law, failed to warn the FDA of BIA-ALCL cases and failed to comply with post- PMA approval requirements to report adverse clinical and laboratory studies that addressed the risk of serious defects, adulterations of the Biocell implants and life-altering complications faced by patients, including patients who had reported adverse, hazardous ailments and conditions, rendering the product defective and unreasonably dangerous.

252. Defendants also failed to revise its labeling to give warnings consistent with the adverse event information that was known or available to Allergan at the time of distribution.

253. Mrs. Pack's Biocell Breast Implants were defective and adulterated at the time of sale and distribution, and at the time they left Defendant Allergan's possession, and Defendants failed to adequately warn the FDA of: BIA-ALCL; adverse clinical and laboratory studies; and the risks that the product was vulnerable to degradation, deterioration, excessive particles harmful implant materials, and that the product was susceptible to causing ALCL and/or BIA-ALCL as suffered by Barbara Pack.

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

255. Defendants knew or should have known that Allergan's Biocell textured surface breast implants were unreasonably dangerous and would be likely to seriously jeopardize the health of consuming patients, Defendants failed to identify, monitor and warn FDA of the defects, adulterations, health hazards and increased risks associated with the product.

256. The failure to warn not only including failing to warn of the risk of the known risk of BIA-ALCL but also a failure to warn of the known risk of inflammatory reaction based upon studies evaluating capsules around Biocell Breast Implants that showed silicone particles within giant cells indicative of a foreign body reaction and silicone granuloma formation.[184]

257. The defects, adulterations and increased risks inherent in Allergan's Biocell Breast Implants were not readily recognizable to the ordinary consumer, including Mrs. Pack and Mrs. Pack's physicians. Neither Mrs. Pack nor her medical providers could, in the exercise of reasonable care, have discovered the defects but would have if Defendants had properly warned the FDA as required by post-approval legal requirements.

258. At all relevant times, the Allergan Biocell Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

259. Allergan's Biocell Breast Implants were manufactured, promoted, marketed, distributed, and sold by Defendants and were expected to, and did, reach Mrs. Pack's physician without substantial change in the condition in which they were sold.

260. Defendants knew that Allergan's Biocell Breast Implants would be used by the ordinary purchaser or user without inspection for defects and adulterations and without knowledge of the hazards involved in such use.

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[184] Allergan included a "possible adverse events" warning for its 510k Biocell tissue expander regarding the risk of inflammatory reaction based upon that studies evaluating capsules around Biocell textured tissue *expanders* that showed silicone particles within giant cells indicative of a foreign body reaction and silicone granuloma formation. https://www.allergan.com/products/natrelle-133.
Allergan did not, however, include any such warning (of inflammatory reaction, silicone particles and giant cell foreign body reaction) for Biocell breast implants despite studies that showed these results occurred in Biocell implants as well as expanders. Biocell tissue expanders and Biocell implants are identical products (both have the same Biocell textured surface) with the only difference being that the expander is a Biocell breast implant that can be inflated to increase its size.

261. Allergan's Biocell Breast Implants, were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, and caused Mrs. Pack's injury from of BIA-ALCL. Her injuries would not have occurred but for the use of Allergan's breast implants.

262. The defective warnings directly caused and directly contributed to Mrs. Pack's injuries, which would not have occurred but for the use of Allergan's Biocell implants.

263. As a proximate cause of Allergan's Biocell Breast Implants 'defective and adulterated condition at the time they were sold, Mrs. Pack suffered physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

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

COUNT 3 — STRICT PRODUCTS LIABILITY FOR DEFECTIVE MANUFACTURING
(Against All Defendants)

264. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

265. At all material times, Defendants were engaged in the business of manufacturing, selling, distributing, marketing, and promoting Allergan's Biocell Breast Implants.

266. Defendants formulated, manufactured, sold, distributed, marketed, and promoted Allergan's Biocell Breast Implants, including those that were implanted into Barbara Pack.

267. Plaintiff was implanted with Allergan's Biocell Breast Implants in 2009 and 2015 that were defective, unreasonably dangerous and adulterated upon manufacture, and were manufactured with nonconforming materials and uncertified components, or with inappropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Barbara Pack.

268. At all material times, Defendants intended the Allergan's Biocell Breast Implants to be surgically implanted into the bodies of members of the general public, including Barbara Pack, and knew the products would be surgically implanted into members of the general public, including Barbara Pack.

269. Plaintiff's Allergan Biocell Breast Implants were defective and adulterated at the time of sale and distribution and at the time they left Defendants 'possession and thereby caused BIA-ALCL as suffered by Barbara Pack.

270. Defendants knew or should have known that there was a significant risk that Allergan's Biocell implants caused, and did in fact increase the risk of contracting, BIA-ALCL.

271. Defendants knew or should have known that implantation of Allergan's Biocell Breast Implants were unreasonably dangerous and were associated with an increased risk of serious injury to consuming patients. Defendants failed to manufacture Mrs. Pack's implants free from manufacturing defects, adulterations and health hazards and increased risks associated with the product.

272. The defects, adulterations in Allergan's Biocell Breast Implants were not readily recognizable to the ordinary consumer, including Mrs. Pack and/or Mrs. Pack's physicians. Neither Mrs. Pack nor her medical providers could, in the exercise of reasonable care, have discovered the defects.

273. At all relevant times, Mrs. Pack's Allergan Biocell Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

274. Allergan's Biocell Breast Implants that were manufactured, promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Mrs. Pack and/or her physician without substantial change in the condition in which they were sold.

275. Defendants knew that the Allergan Biocell Breast Implants would be used by the ordinary purchaser or user without inspection for defects and adulterations, and without knowledge of the hazards involved in such use.

276. Allergan's Biocell Breast Implants were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants and were a direct and directly contributing factor in bringing about Mrs. Pack's injuries, which would not have occurred but for the use of Allergan's Biocell Breast Implants.

277. The defective and adulterated products were a direct cause and directly contributing cause in bringing about the injuries to Barbara Pack and would not have occurred but for the use of Allergan's Biocell Filled Breast Implants.

278. As a proximate result and/or direct cause and directly contributing cause of Allergan's Biocell Breast Implants' defective and adulterated condition at the time they were sold, Mrs. Pack suffered severe physical injuries, pain and suffering, emotional distress, mental anguish,

economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys 'fees.

COUNT 4 — BREACH OF EXPRESS WARRANTY (Against All Defendants)

279. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

280. Defendants in their manufacturing, design, distribution, marketing and promotion of Allergan's Biocell Implants expressly warranted same to be safe and effective for Mrs. Pack and members of the public generally.

281. Defendants in their manufacturing, design, distribution, marketing and promotion of Allergan's Biocell Breast Implants expressly warranted same to be safe and effective for Plaintiff and members of the public generally.

282. At the time of making of these express warranties, Defendants had knowledge of the purpose for which the product was to be used and warranted same to be in all respects safe, effective, fit and proper for such purpose and use.

283. Defendants further expressly warranted that Allergan's Biocell Breast Implants were of "premium" and "proven" quality with "mild tissue adherence."

284. Allergan's Biocell Breast Implants do not conform to these express warranties and representations because Allergan's Biocell implants are not premium, are not proven and do not

promote Mild tissue adherence" as may produce serious side effects, including among other things BIA-ALCL.

285. Allergan's Biocell implants do not conform to these express warranties and representations because Allergan's Biocell implants are not safe or effective, nor are they safer or more effective than other breast implants available, and they may produce serious side effects, including among other things BIA-ALCL.

286. As a direct and proximate result of the breach of express warranties by Defendants, or some or any one of them, Mrs. Pack suffered injuries which are permanent, required extensive medical treatment and hospitalization and resulted in medical and hospital expenses, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

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

COUNT 5 — BREACH OF IMPLIED WARRANTY (Against All Defendants)

287. Plaintiffs re-allege and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

288. Defendants marketed, manufactured, promoted, distributed and/or sold Allergan's Biocell Breast Implants for use by the public at large and including the Mrs. Pack. Defendants knew the use for which their product was intended and impliedly warranted said product to be of merchantable quality, safe and fit for use.

289. Mrs. Pack reasonably relied on the skill and judgment of Defendants, and as such their implied warranty, in using Allergan's Biocell Breast Implants. Allergan's Biocell Breast Implants were not of merchantable quality or safe or fit for its intended use, because implants were unreasonably dangerous and unfit for the ordinary purpose for which it was intended and used.

290. As a direct and proximate result of the breach of implied warranties by Defendants, Mrs. Pack suffered injuries that are permanent, required extensive medical treatment and hospitalization and resulted in medical and hospital expenses, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

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

COUNT 6 — NEGLIGENT MISREPRESENTATION (Against All Defendants)

291. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

292. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and/or promotion of Allergan's Biocell Breast Implants described herein, owed a duty to provide accurate and complete information regarding their product.

293. Defendants falsely represented that it manufactured Biocell implants in a "*controlled* environment utilizing specialized equipment for *precision* measurement, quality control, packaging, and sterilization." (emphasis added). These statements were false because

controls were not adequate or precise with respect to particles, residues and contaminants, as proven by inspections by medical device regulators. Defendants further misrepresented that the Biocell implants were: of "premium quality" when in fact they were "adulterated" under federal and parallel state law; caused "mild tissue adherence" when in fact they caused a major inflammatory macrophage reaction; was a "PROVEN Biocell surface" when in fact the final product was not tested for biocompatibility as this was the reason the Biocell implant lost its CE mark in Europe. These representations by Defendants were in fact false and the negligently manufactured implants were not safe and were in fact dangerous to the health of Mrs. Pack. Defendants concealed, omitted, or minimized the potential harms (particulate contamination) and serious side effects (BIA-ALCL) of Allergan's Biocell Breast Implants or provided misinformation about adverse reactions, risks and breast implants and succeeded in persuading consumers, physicians (including Mrs. Pack's plastic surgeons) to use, purchase and implant Allergan's Biocell Breast Implants despite the product's lack of safety and the risk of adverse effects, including BIA-ALCL.

294. At the time the aforesaid representations were made, Defendants concealed from Mrs. Pack and healthcare providers information about the propensity of their Biocell textured breast implant products to cause particulation in human tissue and harm (BIA-ALCL). Defendants negligently misrepresented claims regarding the safety and efficacy of said product despite the lack of information regarding same.

295. Defendants' misrepresentations in promoting and marketing Allergan's Biocell Breast Implants created and reinforced a false impression as to the safety of Allergan's Biocell Breast Implants, thereby placing consumers at risk of serious and potentially lethal effects.

296. The aforesaid misrepresentations were made by Defendants with the intent to induce patients such as Mrs. Pack to use the Biocell products, to the detriment of Mrs. Pack.

297. At the time of Defendants 'misrepresentations and omissions, Mrs. Pack was ignorant of the falsity of these statements and reasonably believed them to be true.

298. Defendants breached their duties to Mrs. Pack by providing false, incomplete and/or misleading information regarding their product. Mrs. Pack reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Allergan's Biocell Breast Implants.

299. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Mrs. Pack suffered injuries that are permanent, required extensive medical treatment and hospitalization and resulted in medical and hospital expenses, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

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

COUNT 7 — FRAUDULENT MISREPRESENTATION (Against All Defendants)

300. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

301. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Allergan's Biocell Breast Implants described herein, owed a duty to provide accurate and complete information regarding their product.

302. Defendants' fraudulently misrepresented information regarding their products including, but not limited to, its propensity to cause serious physical harm and for the reasons pleaded in Count 6.

303. At the time of Defendants' fraudulent misrepresentations and omissions, Mrs. Pack was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

304. Defendants breached their duties to Mrs. Pack by providing false, incomplete and misleading information regarding their products.

305. Defendants acted with deliberate intent to deceive and mislead Mrs. Pack.

306. Mrs. Pack and her doctors reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

307. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Mrs. Pack suffered injuries that are permanent, required extensive medical treatment and hospitalization and resulted in medical and hospital expenses, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

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

COUNT 8 — LOSS OF CONSORTIUM (Against All Defendants)

308. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

309. As a result of the injuries and wrongful death and damages suffered by Mrs. Pack in violation of federal law and the post-approval requirements, Mr. Pack suffered a loss of his wife's love, companionship, services, society, guidance and companionship and may therefore sue for the loss of his wife's consortium.

310. As a result of Defendants' defective and adulterated Allergan Biocell Breast Implants and the development of his wife's BIA-ALCL, Plaintiff Mr. Pack lost the companionship and accompaniment of his wife.

311. As a direct and proximate result of the injuries caused to Mr. Pack by Defendants' tortious conduct, spouse Plaintiff Mr. Pack suffered and will continue to suffer the loss of his wife's consortium, companionship, society, intimacy, affection, services and support, and suffered and will continue to suffer economic damages, including lost wages and income.

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

COUNT 9 — PUNITIVE DAMAGES (Against All Defendants)

312. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

313. Defendants 'manufacture, marketing, promotion, distribution and sale of defective Biocell implant products, suppression of adverse data from particulation studies, and their failure to provide adequate warnings and instructions concerning its hazards was willful, wanton, reckless and without regard for the public's safety and welfare.

314. Defendants misled both the medical community and the public at large, including Barbara Pack, by making false representations about the safety of Allergan's Biocell Breast Implants.

315. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Allergan's Biocell Breast Implants despite available information demonstrating that Allergan's Biocell Breast Implants were likely to cause serious and potentially fatal side effects to users.

316. At all times relevant hereto, Defendants knew the defective nature of Allergan's Biocell Breast Implants, and continued to design, manufacture, market, label, and sell Allergan's Biocell Breast Implants so as to maximize sales and profits at the expense of public health and safety, with wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by Allergan's Biocell Breast Implants, including Barbara Pack.

317. Defendants misled regulators, the medical community and the public at large, including Barbara Pack, by making false and misleading representations about the safety of Allergan's Biocell Breast Implants. Defendants knowingly withheld and misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harms and suffered by Barbara Pack.

318. As a direct and proximate result of Defendants' reckless, willful and wanton acts in disregard of the safety of the public generally and of Barbara Pack in particular, Mrs. Pack suffered profound injuries, required extensive medical treatment and hospitalization and resulted in medical and hospital expenses, lost future earning capacity, and other damages for which Plaintiff is entitled to compensatory and other damages in an amount to be proven at trial.

PRAYER FOR RELIEF

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

JURY DEMAND

Plaintiffs demand trial by a jury on all of the triable issues of this complaint.

Dated: June 15, 2020

Respectfully submitted,

ROSS FELLER CASEY, LLP

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