UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

CHRISTINE McGEE Plaintiff, v. JOHNSON & JOHNSON; ETHICON, INC.; and MENTOR WORLDWIDE LLC, Defendants.	**COMPLAINTAND** **JURY DEMAND** CIVIL ACTION NO. 2:21-cv-639

1. This Complaint is brought on behalf of Plaintiff, Christine McGee, who suffered damages as a direct and proximate result of the negligent and wrongful misconduct of Defendants Mentor Worldwide LLC, Ethicon, Inc. and Johnson & Johnson (hereinafter referred to as "Defendants") in connection with the research, testing, development, design, licensing, manufacture, packaging, labeling, distribution, sale, marketing, and/or introduction into interstate commerce of Mentor MemoryShape Siltex breast implants. As a result of having been surgically implanted with Mentor's (textured) MemoryShape Siltex breast implants, Plaintiff Christine McGee (hereinafter referred to as "Plaintiff") developed Breast-Implant Associated Large Cell Lymphoma ("BIA-ALCL") and severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for future medical treatment and follow-up.

2. Plaintiff Christine McGee files Complaint to bring parallel state-law claims that are not preempted by 21 U.S.C. § 360k(a). As shown herein, Mentor's MemoryShape® *textured*

breast implants ("the SILTEX implants") caused Plaintiff to develop Breast Implant-Associated Large Cell Lymphoma ("BIA-ALCL") that is a form of cancer as a direct and proximate result of violations of FDA laws, regulations and requirements applicable to manufacturing, warnings and post-marketing requirements.

3. Defendants Johnson & Johnson, Ethicon, Inc. and Mentor Worldwide LLC (hereinafter, collectively referred to as "Defendants") cannot avoid civil liability for these defective implants by asserting a preemption defense because Defendants failed to comply with: critical QSR & CGMP requirements required by the FDA; the FDA's Premarket Approval Application requirements; and FDA requirements to report adverse events to the FDA and thereby warn consumers and physicians of the known dangers and adverse events as required by conditions of approval and post-marketing regulations.

4. Mentor's SILTEX® implants have a textured shell created by pressing an uncured silicone mandrel into polyurethane foam. This texturing process produces defective and *adulterated* implants with excessive silicone and *debris* fragments and particles that remain on the implant surface in violation of FDA quality system requirements ("QSRs") and current good manufacturing practices ("CGMPs").[1]

[1] The failure to follow CGMPs, and particularly relevant here, 21 C.F.R. § 820.70(h) relating to removal of deleterious manufacturing material* precludes a preemption defense and provides a basis for liability as violations of federal law that are parallel state law claims. *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 496 (W.D. Pa. 2012); *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 897 (M.D. Pa. 2017) In addition, because Plaintiff alleges the implants were "adulterated" by foreign, decomposed and injurious unwanted silicone particles, federal law specifically incorporates CGMPs. 21 U.S.C. § 351.

*21 C.F.R. § 820.70(h) states:

5. Plaintiff brings this action against Defendants in relation to the manufacture, marketing, and distribution of the SILTEX® implants, the repeated failure to follow the requirements imposed by FDA, failure to warn Plaintiff's plastic surgeon of known dangers and known adverse events, and reckless violation of state law.

PARTIES, VENUE AND JURISDICTION

6. Plaintiff Christine McGee is, and at all material times was, a resident of Pennsylvania.

7. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

8. J&J's corporate family structure includes a multitude of wholly-owned subsidiaries and affiliated companies all over the world, including Defendants Ethicon and Mentor.

9. Defendant Ethicon, Inc. ("Ethicon") is a corporation incorporated under the laws of the State of New Jersey, with its principal place of business located at U.S. Route 22, Somerville, New Jersey, 08876.

10. Defendant Ethicon is a subsidiary of J&J. Its descriptions include the following:

ETHICON
a Johnson & Johnson company

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.

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
Shaping the future of surgery

11. Defendant Mentor Worldwide LLC ("Mentor") is a limited liability company incorporated under the laws of the State of Delaware, with its principal place of business at 201 Mentor Drive, Santa Barbara, California, 93111, and its headquarters at 33 Technology Drive, Irvine, California, 92618.

12. Founded in 1969, Mentor originally sold electronic laboratory instruments to measure activity within the nervous system. After introducing urethral catheters in the l970s, the company began delving into the plastic surgery field in the mid-l980s.

13. Mentor now touts itself as the global leader in aesthetic medicine, and the U.S. market leader in breast aesthetics.

14. Mentor is the only manufacturer whose breast implants are made in the United States.

15. For more than 30 years, Mentor's products have been implanted into millions of women's breasts and Mentor remains a leading supplier of medical products for the global aesthetic medicine market.

16. Mentor is a wholly owned subsidiary of Defendant J&J, and describes itself as follows:

MENTOR®
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

17. J&J acquired Mentor Corporation in January 2009. Under the terms of the acquisition of Mentor Corporation, Defendant Mentor was expected to operate as a stand-alone business unit reporting through Defendant Ethicon, another J&J company. *See* http://www.investor.jnj.com/releasedetail.cfm?releaseid=361253 (Jan. 23, 2009 J&J press release).

18. Further, a U.S. Securities and Exchange Commission ("SEC") filing made contemporaneously with the purchase of Mentor made the following statements about the purchase:

- "Mentor will become the cornerstone of a broader J&J leadership strategy in Aesthetic medicine – across consumers and professionals."
- "***Is breast augmentation a good "fit" for J&J and ETHICON?*** At J&J and ETHICON, we are committed to bringing forth innovative ideas, products and services to advance the health and well-being of patients. For some, choosing plastic/reconstructive surgery to enhance the way they look and feel can have a significant benefit on self-esteem and overall quality of life. While we are new to the breast implant business, we have served customers with surgical implants that ranged from permanent sutures to surgical meshes, stents, and Orthopedic implants. We believe that by combining forces with Mentor, we can meet the needs of this growing market."
- "***How much of an impact will this transaction have on J&J's sales in 2009?*** Bringing Mentor into the J&J family of companies will strengthen our growth prospects in 2009 and beyond. While we do not discuss specific sales numbers, we are confident about Mentor's growth prospects in the coming years."

https://www.sec.gov/Archives/edgar/data/64892/000095013408021428/v50669asc14d9c.htm (emphasis in original) (last viewed July 30, 2020).

19. Even today, Mentor is identified as one of J&J's "medical companies" And "part of the Johnson & Johnson Family of Companies." *See* https://www.e-ifu.com/ (last visited on April 19, 2021).

20. The all-important "Instructions for Use" for the SILTEX implants are provided by J&J for its "Johnson & Johnson Medical Devices Companies." *See id*.

21. 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 indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized and/or ratified the conduct of each and every other Defendant.

22. At all relevant times, Defendants acted in concert with one another in the State of Pennsylvania to fraudulently convey false and misleading information concerning the SILTEX implants and concealed the risks of serious adverse events associated with the SILTEX implants from Plaintiff, her physician, and the public. But for Defendants' actions, Plaintiff would not have suffered the severe injuries and harms that have resulted from implantation of the SILTEX implants into her body.

23. This Court has personal jurisdiction over Defendants. Defendants are, and at all material times were, residents of and/or authorized to conduct business in the State of Pennsylvania. Defendants conducted such business within the State including acts which caused or contributed to Plaintiff's injuries.

24. At all material times, Defendants maintained systematic and continuous contacts within this jurisdiction, employed numerous individuals in this district and regularly availed themselves to the benefits of this judicial district. Defendants received substantial financial gain as a result of the production and sale of its products within this jurisdiction.

25. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because there is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of $75,000, exclusive of interest and costs.

26. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

27. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to Plaintiff's causes of action occurred in this federal judicial district.

FACTS REGARDING MENTOR BREAST IMPLANTS

A. Mentor's Breast Implant Products

28. In the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress instituted a process for product review and clearance, using different pathways and processes to permit drugs and medical devices to be sold to U.S. consumers. Three classes of medical devices are regulated by the FDCA, Class I, Class II and Class III, with greater degrees of scrutiny and regulation imposed on the manufacturer as the levels go from I to III.

29. Class III devices are those that support or sustain huma life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

30. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

31. In 1988, the FDA reclassified breast implants from Class II medical devices to Class III, requiring Mentor to file a PMA application for its breast implants.

32. Under a Class III PMA, manufacturers have substantial and ongoing duties because of the degree of risk associated with products carrying the classification. Failing to fulfill the duties and comply with the associated requirements can result in the PMA being withdrawn.

33. On December 12, 2003, Mentor submitted a PMA application to the FDA for its MemoryGel™ silicone gel-filled breast implants.

34. On November 17, 2006, the FDA approved Mentor's PMA for its MemoryGel™ Silicone Gel-Filled Breast Implants, subject to certain conditions. One of the conditions was that Mentor was required to conduct six post-approval studies to further characterize the safety and effectiveness of its silicone gel-filled breast implants and to answer long term questions that the clinical trials were not designed to answer.

35. On June 14, 2013, Mentor's PMA application for its MemoryShape® breast implants was approved by the FDA.[2]

36. The 2013 PMA included FDA-approved labeling for the physician[3] (applicable to Plaintiff's January 2017 surgery when she was implanted with Siltex implants) but did not list BIA-ALCL as one of the risks/information to be discussed with the patient. Nor did this labeling list BIA-ALCL as one of the adverse events/risks associated with breast implants. Instead, Mentor's labeling for physicians merely mentioned BIA-ALCL as one of several "other reported conditions" and disclaimed any cause-effect relationship.[4]

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[2] A website for J&J's "Medical Devices Companies" touts Mentor's Breast Implants as follows,

> MENTOR® MemoryShape® Breast Implants shape the breast and have a unique, tapered appearance. Unlike round breast implants, MENTOR® MemoryShape® Breast Implants are teardrop shaped, meaning they are thinner at the top and gently slope to a fuller projection point near the implant's bottom to mimic the silhouette of a natural breast. The SILTEX® Microtexture Breast Implant gentle imprinting process is designed to help keep implants in place.

https://www.jnjmedicaldevices.com/en-US/product/mentor-memoryshape-breast-implants (last visited on July 23, 2020).

[3] https://www.accessdata.fda.gov/cdrh_docs/pdf6/P060028C.pdf (last visited May 10, 2021).

[4] *Id.* at 17. ("No cause-and-effect relationship has been established between breast implants and the conditions listed below…").

37. Likewise, the 2013 FDA-approved labeling for the patient (patient education brochure)[5](applicable to Plaintiff's January 2017 surgery when she was implanted with Siltex implants) did not list BIA-ALCL as one of the potential risks of Mentor's breast implants. Nor did the patient labeling list BIA-ALCL as a potential complication of Mentor's breast implants. Instead, the patient brochure merely mentioned BIA-ALCL as one of the "other reported conditions" and again disclaimed any cause-effect relationship.[6]

38. Plaintiff avers that Defendants were aware of serious cases of BIA-ALCL but failed to comply with their duties under federal and state law to report BIA-ALCL adverse events to the FDA.

39. A causal nexus exists between Defendants' failure to report adverse events to the FDA and Plaintiff's development of BIA-ALCL.

40. Cause-in-fact is present because:

> (1) Had Defendants properly and timely reported the true and known risk of BIA-ALCL as of January 2017 (the time of Plaintiff's surgery) the FDA would have required a more particularized warning concerning BIA-ALCL. As should have happened, if the FDA had been made aware of the true scope of risk, and if such a warning had been given, the Mentor breast implants would not have been implanted in Ms. McGee and she would not have developed BIA-ALCL[7].

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[5] https://www.accessdata.fda.gov/cdrh_docs/pdf6/P060028D.pdf (last visited May 10, 2021).

[6] *Id.* at 41. ("Studies have not shown that breast implants can cause these conditions. Most studies suggest that there is no connection between breast implants and these medical conditions.").

[7] *Cf. Plourde v. Sorin Grp. USA, Inc.*, No. 17-CV-10507-ADB, 2018 WL 1542361, at *8 (D. Mass. Mar. 29, 2018):

> In contrast, here, Plaintiffs have provided detailed factual allegations showing that, between 2007 and 2012, Defendants were aware or should have been aware of studies and incidents indicating that the Valve was more likely to calcify and rapidly deteriorate in patients under 30, such as occurred with Ms. Plourde's implanted Valve, but Defendants did not report this information to the FDA, in violation of federal regulations and state law. Plaintiffs further assert that the FDA

(2) If proper adverse event reports had been provided to the FDA more likely than not the FDA would have made these MAUDE (Manufacturer and User Facility Device Experience database reports publicly available.[8] Medical researchers/physicians would have written

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could have required a more particularized warning concerning patients under 30 if it had been aware of this issue, and that if such a warning had been given, the Valve would not have been implanted in Ms. Plourde and its failure leading to her death would not have occurred. Defendants emphasize that the device already carried a warning covering patients under 55, but the complaint alleges that the Valve posed a unique risk to patients under 30 which was not reflected in the warning. Defendants also assert that Plaintiffs will not be able to prove that the FDA would or should have issued a particular warning, but the Court need not make such a determination on a motion to dismiss. *See Rosen*, 41 F. Supp. 3d at 188 (finding allegation that plaintiff's "injuries may have been avoided or mitigated had [d]efendants timely complied with" the requirement to report adverse events to FDA "is not purely contingent or speculative" (internal quotation marks omitted)); *cf. Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI SK, 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014) (holding plaintiff had not demonstrated causation where the "only specific example provided in the complaint of [d]efendants' failure to report an adverse event notes that the event was ultimately reported three months after the fact," and complaint provided no dates "that might allow the inference that timely reporting could have affected" the use of the device during plaintiff's surgeries). Thus, even if Defendants did not waive this argument, and the Ninth Circuit causal nexus test applies here, Plaintiffs have stated sufficient factual allegations to survive the test at the motion to dismiss stage.

[8] *See Bull v. St. Jude Med., Inc., No. CV 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018):*

The Amended Complaint adequately states a claim that the Riata ST Lead was defective on a failure to warn theory, in that it alleges that St. Jude was aware of adverse events associated with the Riata ST Lead—instances in which it malfunctioned and posed a danger to patients—that it did not warn the FDA and the general public about, thereby putting potential users at risk from the danger it posed. Plaintiff also plausibly alleges the requisite causal nexus between St. Jude's alleged violation of this duty to report adverse events via MDRs, and Plaintiff's injury. Plaintiff alleges that the information included in MDRs is made publicly available and utilized by physicians in making treatment decisions regarding Class III medical devices. Plaintiff alleges that if St. Jude had made timely and complete MDR reports of all adverse events that it was aware of prior to the implantation of her ICD on November 1, 2010, her physicians would not have chosen to implant an ICD using Riata ST Leads, and instead would have chosen another such device using different leads. This sufficiently alleges a claim that if she had been warned about the deficiencies with the Riata ST Lead, then she would have avoided being injured by it.

articles or conducted studies that would have been published in the medical literature that would have seen by physicians in the plastic surgery community, including Plaintiff's surgeon and Mentor's textured implants would not have been implanted into Plaintiff.[9]

See also: In re: Allergan Biocell Textured Breast Implant Prod. Liab. Litig., No. 2:19-MD-2921-BRM-ESK, 2021 WL 1050910, at *10-11 (D.N.J. Mar. 19, 2021):

> Plaintiffs allege Allergan's improper submission to the FDA of Alternative Summary Reports ("ASRs"), which contain a series of alphanumeric codes (not a narrative description) and are not made publicly available for years, rather than Medical Device Reports ("MDRs"), which contain a full narrative description of the event and are published in the FDA's MAUDE database every month, violates both the state law duty to warn patients or their physicians and the parallel federal requirements. (Id. at 51–52.) The Court agrees. . . .
>
> The underlying rationale of a report-based failure to warn claim is that the FDA reporting regulations "are related to the manufacturer's duty to provide the [FDA] with information regarding a device's safety and effectiveness, which is then disseminated to the public." *Freed,* 364 F. Supp. 3d at 358 n.13 (citing *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 770–71 (5th Cir. 2011)). "A manufacturer's failure to provide such information to the FDA is a parallel violation of a state duty ... to provide reasonable and adequate information regarding a product's risks." Id. (citing *Hughes*, 631 F.3d at 770–71). "[T]he FDA may be reasonably relied upon to disclose information regarding medical device failures through the publicly accessible database when provided with that information." Silver, 236 F. Supp. 3d at 900. Accordingly, Plaintiffs' report-based failure to warn claims are not expressly preempted.

[9] *See e.g.,* Doren EL., Miranda RN., Selber JC., et al. (May 2017). *U.S. Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma.* Plast Reconstr Surg. 139(5):1042-1050.(reporting 5 cases of BIA-ALCL [Mentor only] and 3 cases of BIA-ALCL [Mentor and another manufacturer]); Johnson *et al., Breast implant associated anaplastic large cell lymphoma: The UK experience. Recommendations on its management and implications for informed consent,* Eur J Surg Oncol., 2017 Aug;43(8):1393-1401. 10.1016/j.ejso.2017.05.004. Epub 2017 May 18 (2 cases of BIA-ALCL with Mentor and another manufacturer); de Boer M, *et al., Breast implants and the risk of Anaplastic Large-Cell Lymphoma in the breast*. JAMA Oncol. 2018;4(3):335-341 (1 case of BIA-ALCL with mentor and another manufacturer); Magnusson M, *et al., The epidemiology of Breast Implant Associated Large Cell Lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants*. Plast Reconstr Surg. 2019 Feb 13 (1 case of BIA-ALCL with Mentor only; 6 BIA-ALCL cases with mentor textured implants and another manufacturer).

(3) Plaintiff's implanting surgeon (and a reasonably prudent plastic surgeon) more likely than not, would have seen MAUDE reports or medical literature describing MDRs and adverse events (B)A-ALCL) associated with Mentor's Siltex textured breast implants or would have seen a revised/updated FDA warning identifying the risk of BIA-ALCL with Mentor's implants and would not have used the Mentor implants implanted into Ms. McGee in January 2017.[10]

41. As further evidence of a causal nexus, Plaintiff avers that in the same year as her 2017 implant surgery on December 6, 2017 the FDA approved stronger labeling and warning language in both the physician and patient labeling that identified BIA-ALCL as a risk of breast implants and as information that should be discussed with the patient.[11]

42. The PMA for Mentor's MemoryShape breast implants required Mentor to comply with federal regulations which are set forth in detail below.

B. Facts Specific To Christine McGee

43. On February 21, 2000 Plaintiff underwent bilateral transaxillary augmentation mammoplasty with normal saline filled smooth implants (Mentor Model No. Number 350-1655).

44. On or about July 3, 2013 genetic testing revealed that Plaintiff was positive for the BRAC1 deleterious gene mutation and a significant family history of breast cancer and ovarian cancer.

45. On January 9, 2017at St. Clair Memorial Hospital in Pittsburgh, Pennsylvania Plaintiff underwent bilateral total mastectomy as a precaution against developing breast cancer. The mastectomy surgery was performed by Dr. Raye Budway This surgery was followed on that date with bilateral immediate reconstruction with the implantation of Mentor textured

[10] *See* footnotes 7-9 *supra*.

[11] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060028S027

implants—Model No. 334-1202 MemoryShape Breast Implants Medium Height, High Profile. The breast implant surgery performed by plastic surgeon Dr. Robert Bragdon.

46. On May 30, 2019 Plaintiff underwent a right breast ultrasound due to acute swelling of the right breast. The radiologist's impression was a ruptured implant.

47. On June 4, 2019 Plaintiff underwent surgery (bilateral open capsulotomies with debridement) and replacement of implants with Mentor Model No. 334-1202 Memory Shape Breast Implants Medium Height, High Profile. This surgery was performed by Dr. Robert Bragdon.

48. On June 6, 2019 the results of the surgical pathology were reported that showed Breast Implant-Associated Anaplastic Large Cell Lymphoma with tumor cells in the fibrinous exudate of the capsule.

49. On June 11, 2019 Plaintiff had a post-operative appointment where she was told of her positive BIA-ALCL diagnosis.

50. On July 17, 2019 Plaintiff underwent removal surgery with bilateral open en bloc total capsulectomy. This surgery performed by Dr. Bragdon.

51. Defendants were aware of the defects in the Mentor® Breast Implants before Plaintiff's implantation procedure in January 2017 and were well-aware of the risk for development of BIA-ALCL but did not respond in accordance with their obligations under federal law, Mentor's PMA and state-law.

52. Had Mentor reported adverse events of BIA-ALCL to the FDA as required by federal law Dr. Bragdon would have been made aware of the actual risk of BIA-ALCL associated with Mentor's textured Breast Implants and Dr. Bragdon would not have advised Plaintiff to select Mentor Breast Implants and proceed with their implantation.

53. Christine McGee suffered tremendously from the pain of her explant surgery, symptoms of her BIA-ALCL disease, and recovery.

54. Prior to her development, diagnosis and treatment of ALCL, Plaintiff enjoyed an active, full life, and did not experience the symptoms which arose after the Mentor® Breast Implants were placed in her body. Subsequently, she endured pain, swelling, and embarrassment of her deformed chest.

55. Defendant Mentor, through its misrepresentations and omissions including its refusals or reckless failures to disclose or report defects and significant events as required by federal law (21 C.F.R. §§ 803.10(c), 803.50, §803.52 and other C.F.R. sections identified herein), and by state law that does not impose duties or requirements materially different from those imposed by federal law, concealed from Plaintiff and her healthcare providers the risk of BIA-ALCL associated with its Breast Implants.

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

57. Defendants, through their misrepresentations and omissions including their refusals or reckless failures to disclose or report defects and significant events as required by federal law, and by state law which does not impose duties or requirements materially different from those imposed by federal law, concealed from Plaintiff and her healthcare providers the risk of BIA-ALCL associated with its Breast Implants.

MENTOR'S DUTIES PURSUANT TO ITS PMA AND FEDERAL REGULATIONS

58. As conditions of Mentor's PMA approval for its MemoryShape breast implants, the FDA required Mentor to conduct the following post-approval studies to characterize the long-term performance and safety of the devices:

a. **"Post-Approval PMA Cohort Study (PACS)"** - To assess long-term clinical performance of breast implants in the 955 women that enrolled in studies to support premarket approval applications. Prior to approval, this study yielded six years of data, and it was designed to follow these women for a total of ten years after initial implantation.

b. **"Post-approval Continued Access Study (PACAS)"** – To collect additional safety and effectiveness data from approximately 350 women who received Mentor's MemoryShape Medium Height Moderate Profile (CPG Style 321) Breast Implants prior to approval but outside of the Core Cohort Study.

c. **"MemoryShape Post-Approval Study (MemoryShape PAS)"** - To assess long-term outcomes by enrolling and following more than 2,500 women receiving MemoryShape Breast Implants and following them for ten years

d. **"Breast Implant Case-Control Studies To Address Rare Disease Outcomes"** - To identify rare adverse events by enrolling 10,750 women in five case-control studies on rare connective tissue diseases, neurological diseases, brain cancer, cervical/vulvar cancer and lymphoma.

e. **"Focus Group Study"** - To improve the format and content of the patient labeling.

f. "**Device Explant Analyses"** – "Mentor must conduct non-PAS Device Explant Analyses for all MemoryShape Breast Implants that are retrieved in the commercial setting outside of the post-approval studies . . .." Mentor was required to report on these results on an annual basis.

59. In the PMA approval letter, the FDA further stated, "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA."

60. The FDA continued, "The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law."

61. In addition to the duties in Mentor's PMA, Mentor was required to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications set forth in applicable federal regulations, including, but not limited to, 21 C.F.R. Parts 803, 814 and 820.

62. Mentor was also required to notify the FDA of any unexpected serious problems with its breast implants.

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

64. Mentor is prohibited from selling and distributing misbranded products. A medical device is deemed misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling. This duty is ongoing. *See* 21 U.S.C. § 352(a). Moreover, restricted devices are deemed misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. § 352(q).

65. Mentor was also required to do the following:

a. Report 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 C.F.R. § 803.50];

b. Monitor the product and report to the FDA any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 C.F.R. § 814];

c. Follow quality system requirements, found in 21 C.F.R. § 820, the CGMPs, that require manufacturers do the following:

- Document all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues [21 C.F.R. § 820.100];
- **Maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality [21 C.F.R. § 820.70(e)];**
- **Ensure the removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that the amount of manufacturing material does not adversely affect the device's quality [21 C.F.R. § 820.70(h)].**

66. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as the SILTEX implants, rests with the manufacturer.

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

68. Similarly, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

69. These duties establish that time is of the essence for Mentor when reporting adverse events, especially, but not limited to, those adverse events indicating an association between its product and breast cancer, Anaplastic Large-Cell Lymphoma ("ALCL") and/or BIA-ALCL.

70. Delayed reporting prevents the healthcare community and the public from timely learning of risks which informs physician and patient decision-making regarding treatments and procedures, and thereby exposes countless of additional women to potential harm.

MENTOR'S INADEQUATE POST APPROVAL STUDIES AND DESIGN VALIDATION

71. A fundamental concern with breast implants has been their long-term side effects, in particular unique reactions.[12] In an attempt to validate the design of the implants under general

[12] *See generally The FDA's Regulation of Silicone Breast Implants* (Dec. 1993) House of Representatives Committee on Government Operations, at https://play.google.com/books/reader?id=Yf9QPmwYU64C&hl=en (as of Apr. 19, 2021).

conditions of use in the post-market environment, as required under federal manufacturing standards (21 C.F.R. § 820.30(g)), the FDA devise and mandated a number of post-approval studies. Because validating long-term biocompatibility under simulated conditions is impossible, these human trials served as the primary avenue for breast implant design validation.

72. In 2016, the FDA approved Mentor's revised study protocol to modify the MemoryShape® Post-Approval Study (Requirement 3 in the PMA) to include both MemoryShape® and MemoryGel® devices in one study called the "MemoryGel® and Shape Glow Study."

73. Based on the approved revised study protocol, Mentor was required to conduct a ten-year post-approval observational study to include a total of 2,518 women undergoing breast augmentation, breast reconstruction, or revision surgery with MemoryShape® or MemoryGel® Breast Implants.

74. By February and August 2017, Mentor had failed to enroll the required number of participants in the study but nonetheless received a "progress adequate" letter from the FDA as it had met enrollment milestones. However, the FDA noted that if enrollment rates did not improve, it would not reach the required enrolment rate per the approved study protocol.

75. In February 2018, Mentor issued the following in a press release – "Mentor Worldwide LLC, a global leader in breast aesthetics *and part of the Johnson & Johnson Medical Devices companies*, announced today the Plastic and Reconstructive Surgery® publication of a U.S.-based 10-year clinical study involving 955 patients which highlights the safety of MENTOR® MemoryShape Gel Breast Implants."[13]

[13]*See* Plastic and Reconstructive Surgery Journal Publishes Ten-Year Clinical Study Data Highlighting Safety of MENTOR® MemoryShape® Gel Breast Implants, Feb. 14, 2018, available at https://www.jnjmedicaldevices.com/en-US/news-events/plastic-and-reconstructive-

76. The report provided information on Mentor's MemoryShape "Breast Implant Core Study."[14]

77. By December 2018, Mentor had enrolled only 102 participants in the Core Study.

78. On March 18, 2019, Mentor received a warning letter from the FDA setting forth numerous violations of its PMA requirements.[15]

79. The FDA spelled out multiple specific compliance failures by Mentor, including:

a. Failure to evaluate "the long-term clinical performance of MemoryShape Breast Implants **under general conditions of use in the post-market environment**."

b. Failure to "enroll 2,518 women receiving MemoryShape Breast Implants and 300 women undergoing other aesthetic surgery as the comparison group."

c. Failure to "follow the study subjects annually for 10 years." (emphasis added).[16]

80. This letter from FDA was addressed to Alex Gorsky as the Chairman and CEO of Mentor. Gorsky is also, and has been since 2012, the Chairman and CEO of J&J.

81. Mentor was given 15 working days from the date of the letter to provide a plan to address the issues and has yet to comply with this request.

82. After sending the March 2019 warning letter, the FDA allowed Mentor more time to meet its target follow-up and enrollment rates and the opportunity to address the data inconsistencies received in its reports.

83. In the FDA's March 2019 warning letter, *supra*, the FDA concluded that, based on Mentor's failure to enroll the required number of study participants, the FDA is unable to

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surgery-journal-publishes-ten-year-clinical-study-data (last viewed April 19, 2021) (emphasis added).

[14] *See id.*

[15] *See* Ann M. Ferriter, *Warning Letter to Mentor Worldwide LLC*, March 18, 2019, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mentor-worldwide-llc-acclarent-573520-03182019 (last viewed April 19, 2021).

[16] *See id.*

adequately evaluate the safety, effectiveness and reliability of these implants. The FDA stated, "**[y]ou are thereby in violation of the requirements established as condition to your device's approval under 21 C.F.R. § 814.82(a). Failure to promptly correct this failure may result in withdrawal of your PMA under 21 C.F.R. § 814.82(c).**" (emphasis added).

84. At all relevant times, under federal law and regulation, Mentor was required to comply with the Post-Approval Study requirements under 21 C.F.R. Part 814 and FDA's Quality System Regulations under 21 C.F.R. Part 820, which, among other things, required that Mentor test the implants under actual use conditions and validate its design accordingly.

85. By failing to appropriately conduct the federally mandated human trials, Mentor failed to establish by objective criteria that its design processes conformed to user needs and intended use(s). As a result, Mentor failed to review the procedures in place to expose deficiencies in the original assumptions concerning user needs and intended uses. Rather, despite knowing by objective evidence that its processes for the implants were leading to the development of BIA-ALCL, Mentor maintained the same operations.

86. It was the duty of the Defendants to comply with the FDCA, and the regulations promulgated pursuant to it. Yet, notwithstanding this duty, Defendants violated the FDCA and regulations in one or more of the following ways, resulting in a defective and unreasonably dangerous design:

a. failing to properly conduct the post approval study requirements established pursuant 21 C.F.R. § 814.82(a)(2) and (9) to ensure the safety and effectiveness of the device design under the conditions of use prescribed, recommended or suggested in the labeling of the device; and

b. failing to validate the device design of the SILTEX implants to ensure that the implants conformed to patients' needs and intended uses, including failing to test production units under actual or simulated use conditions (21 C.F.R. §820.30).

87. Defendants' insufficient follow-up rates and inadequate data, as detailed above, establish and confirm Defendants' reckless and intentional disregard for the safety of thousands of women.

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

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

90. Had Defendants substantially complied with its post-approval study requirements rather than flagrantly under-performing the post-approval requirements as alleged above:

a. Mentor's disclosures would have led to much wider knowledge of the risk of BIA-ALCL associated with the SILTEX implants;

b. Dr. Bragdon would have learned of the actual level of risk of BIA-ALCL associated with the SILTEX implants and would have advised Plaintiff to purchase a safer product.

91. These deviations contributed to the manufacture and sale of adulterated breast implants.

92. Because of Mentor's failure to properly meet its post-approval study requirements, the unvalidated and cancerous nature of Mentor's SILTEX implants was not determined and not made known to Plaintiff and her plastic surgeon, Dr. Bragdon.

CHRISTINE McGEE's MEMORYSHAPE BREAST IMPLANTS HAD MANUFACTURING DEFECTS

93. The fundamental purpose of breast implants is for aesthetics, as opposed to having meaningful medical benefits, in that they were intended to give Plaintiff some sense of normality following the removal of her breast tissue due to cancer. To continuously ensure that the breast implants could adequately fulfill this purpose, they were subjected to numerous conditions, including the requirement that every implant and tissue expander manufactured by Mentor would strictly adhere to the approved design standards and current good manufacturing practices.

94. By evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, and utilization of standard operating procedures, Mentor could have assured the production of the SILTEX implants that complied with its specifications and met the appropriate quality standards. Mentor was under a continuing duty to follow the manufacturing and design specifications mandated by the FDA as part of the PMAs, and the general requirements set forth current good manufacturing practices ("CGMPs") provisions of the MDA governing the safety and effectiveness of a PMA medical device. *See* 21 U.S.C. 351; 21 C.F.R. Part 820.

95. Pursuant to the CGMPs regulations, Mentor was obligated to implement and maintain quality control systems to validate processes and conduct inspections and testing to ensure the purity and stability of the implants and not produce adulterated implants, specifically those with excessive particles on the implant surface at the time of manufacture in violation of 21 U.S.C. 351; 21 C.F.R. § 820.

96. Notwithstanding this obligation, Mentor distributed, at times, adulterated implants that had unwanted particles and solid fragments of silicone on the implant surface in violation of manufacturing/ design specifications and CGMP regulations designed to ensure device quality and patient safety.

97. As a result, Mentor failed to perform its duties properly, and failed to implement and maintain quality control systems with respect to the texturization process for its SILTEX implants, even though it was aware that its textured implants regularly contained contaminants, fragments, particles, and impurities in violation of 21 C.F.R. § 820 and 21 U.S.C. 351.[17]

98. Plaintiff's implants were adulterated within the meaning of 21 U.S.C. 351(h) when they were placed in the stream of commerce by Mentor, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the manufacturing/design specifications and CGMP design controls enumerated in 21 C.F.R. Part 820 designed to prevent exposing patients to risks of serious injury or death when the device is used as intended by the surgeon.

99. Mentor violated these regulations, in part, by failing to establish norms and guidelines for biocompatibility, mechanical properties of the shell, modes of sterilization, packaging, and, most importantly, surface texturing. It was Mentor's duty to comply with the PMAs and the FDA's Quality System Regulations and Current Good Manufacturing Practices.

100. Notwithstanding this duty, Mentor violated 21 U.S.C. §§ 331, 351(h), and 21 C.F.R. Part 820 by delivering for introduction into interstate commerce adulterated devices.

A. Mentor Failed To Remove Manufacturing Material As Required By FDA Specifications And 21 C.F.R. § 820.70(h)

101. As one condition of approval, the FDA required each textured implant marketed and sold by Defendants to be manufactured in exact compliance with the standards and specifications approved by the FDA.

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[17] A recent research study found that "Siltex [breast implants] had overwhelmingly additional amounts of retrieved silicone debris." Hallab et al, *Particulate Debris Released from Breast Implant Surfaces Is Highly Dependent on Implant Type,* Aesthetic Surgery Journal (February 2021). Available at: https://academic.oup.com/asj/advance-article-abstract/doi/10.1093/asj/sjab051/6132026?redirectedFrom=fulltext (Last visited May 8, 2021).

102. Mentor's SILTEX texturing process uses negative-contact polyurethane foam to stamp its MemoryShape breast implants. This technique involves pressing an uncured silicone mandrel into polyurethane foam to imprint the texture that is supposed to be free from pores and interstices.[18] In other words, Mentor uses foreign polyurethane texture to form the surface texture of its silicone shells.

103. **However, the polyurethane foam stamp does not always easily peel away from the silicone shell without fragmenting. Sometimes, in contravention with its federal requirements, the peeling away of the polyurethane foam stamp leaves residual silicone and polyurethane debris on the surface of the implant and causes pores and larger than intended cavities.**

104. **The larger, unintended pores and cavities, and the residual unintended polyurethane debris left on the implants are *not* part of the PMA-approved design for the MemoryShape implants.**

105. This texturing process is inconsistent with the PMAs, the approved design and manufacturing specifications and processes for the MemoryShape product line, including the applicable CGMPs, QSRs, and other federal regulations, as well as parallel state law.

106. Mentor SILTEX imprinting technique creates a microtextured surface, "substantially free of pores and interstices that continues to demonstrate advantages over other macrotextures."[19] An important feature of the textured surface is the lack of pores which can accumulate or sequester body fluids and provide a volume in which infection can proliferate. This

[18] Webb, et al., *Textured Breast Implants: A Closer Look at the Surface Debris Under the Microscope,* Plastic Surgery 2017, Vol. 25(3) 179-183.

[19] *See* https://web.archive.org/web/20170316001939/https://www.mentorwwllc.eu/cpx4 (last visited April 18, 2021).

particularly essential since a foam material is used as the texturized medium leading to irregularly shaped indentations.

107. **Despite specifications requiring the removal of manufacturing material that could adversely affect the device's quality, pursuant to 21 C.F.R. § 820.70(h), Mentor failed to establish procedures to remove such debris.**

108. **Mentor's uncontrolled and un-validated texture imprinting technique often left *unintended* particles on the implant surface which exposed patients, including Plaintiff, to particles that caused chronic inflammation and ultimately, the development of ALCL.**

109. **Mentor's uncontrolled and un-validated texture imprinting technique often left *unintended* particles on the surface of its textured implants and tissue expanders resulting in the manufacture of products different than the product approved by the FDA, causing severe harm to patients, including Christine McGee.**

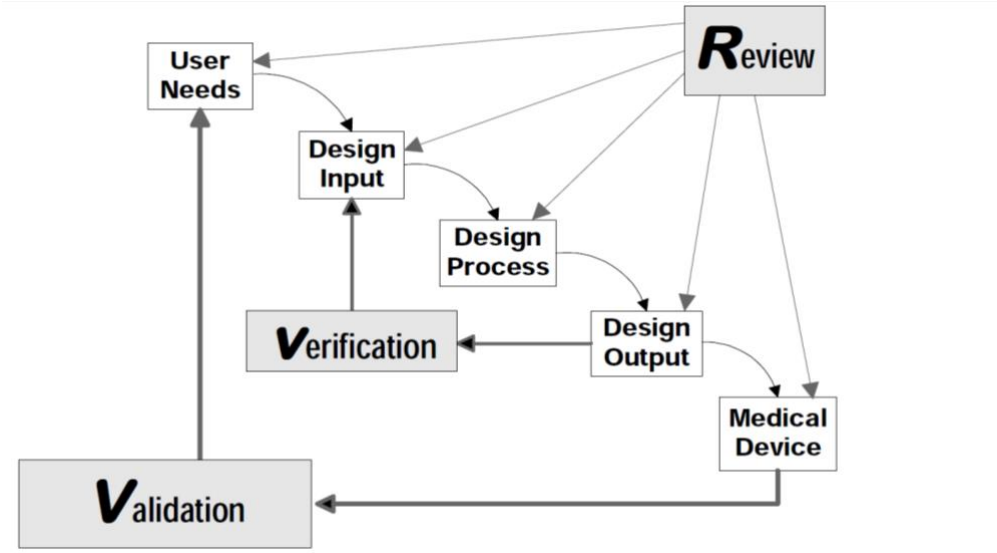
B. Mentor Violated 21 C.F.R. §§ 820.30(a)-(g), 820.70(a), 820.75 By Failing To Maintain Procedures To Control The Implant's Design and Manufacturing

110. The FDA mandates that medical device manufacturers must implement design control processes to assure: 1) user needs and intended uses are met, and 2) design is adequately transferred into manufacturing. Design controls are an interrelated set of practices and procedures incorporated into the design and development process, *i.e.*, a system of checks and balances. A manufacturer must develop a design control consistent with the design's risk, which will, in turn, determine the depth/level of actions required. Design controls make a systematic assessment of the design an integral part of post-approval requirements.

111. Design control does not end with the transfer of a design to production. Design control applies to all changes to the device or manufacturing process design, including those occurring long after a device has been introduced to the market. This includes evolutionary

changes such as performance enhancements, and revolutionary changes such as corrective actions resulting from failed product analysis. The changes are part of a continuous, ongoing effort to design and develop a device that meets the user and/or patient's needs. Thus, a manufacturer must revisit the design control process frequently during the life of a product.

112. The example shown below illustrates the influence and import of design controls on the manufacturing process:



113. The quality system requirements dictate that, no matter what a manufacturer's processes may be, design controls must be applied appropriately to ensure device quality. That is to say, manufacturers must establish and maintain procedures *at all stages* of the production process to ensure quality by requiring the ultimate output to conform to specified design requirements. 21 C.F.R. § 820.30(a). Pursuant to 21 C.F.R. § 820.3(s), quality refers to the totality of features and characteristics that bear on the device's ability to satisfy fitness-for-use, including safety and performance.

114. On October 29, 2015, 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 Mentor's operations. ANSM conducted an inspection to assess whether Mentor had adequate systems and measures in place to prevent, investigate, and correct serious adverse events associated with its breast implants.[20]

115. While inspecting Mentor's manufacturing procedures, the ANSM found "major" deviation" in Mentor's manufacturing and reporting processes concerning governing international consensus standards virtually identical to those applicable to medical devices domestically. Notably, the French inspection documented a major deviation from standards and requirements in connection with ALCL. As events of ALCL continued to rise in frequency, Mentor limited their evaluation to an analysis of medical and scientific literature, "**without further investigations**."[21]

116. As a consequence of this unlawful and unapproved limitation, Mentor never engaged in process validation to establish by objective evidence that its texturizing process consistently met its predetermined specifications; nor design validation to establish by objective evidence that device specifications conform with user needs and intended use(s). 21 C.F.R. §§ 820.3(z), 820.30(g), 820.75(a). This includes failing to:

a. Establish the performance characteristics that are to be assessed with corresponding validation methods and acceptance criteria;

b. Review the procedures in place to expose deficiencies in the original assumptions concerning user needs and intended uses;

c. Account for unexpected variations in components, materials, manufacturing processes, and the use environment;

d. Adopt validation methods that included analysis and inspection methods, compilation of relevant scientific literature, provision of historical evidence that similar designs and/or materials are clinically safe, and full clinical investigations and trials.

117. Of particular importance, the ANSM investigation showed production batch records (21 C.F.R. § 820.184) were not systematically reviewed and challenged in the processing

[20] Attached as Exhibit A.
[21] *Id*. at 19.

of the ALCL complaints, and as a consequence excluded "any assessment of the production impacts."[22] In essence, despite occurrences of ALCL arising in patients implanted with their textured implants, Mentor did not even make the bare effort to review the device history records for the implants involved to confirm they were manufactured in accordance with the device master record (21 C.F.R. § 820.3(j)).

118. In turn, Mentor violated 21 C.F.R. §§ 820.30(a)-(g), 820.70(a), 820.75 by failing to establish and maintain procedures for validating the design of textured implants and expanders. In particular, after the receipt of complaints of a deadly and disfiguring lymphoma demonstrating the device's failure to satisfy fitness-for-use, Mentor failed to maintain proper procedures to ensure those finished devices were in conformance with the PMA quality requirements. Mentor likewise failed to update its design quality procedures following corrective actions resulting from the analysis of products involved in ALCL events. [23]

C. Mentor Violated 21 C.F.R. § 820.50(a) By Failing To Ensure All Product Components Conform To Quality Requirements.

119. Pursuant to 21 C.F.R. § 820.50(a), manufacturers are required to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to quality requirements. Product refers to the components, manufacturing materials, in-process devices, finished devices, and returned devices. 21 C.F.R. § 820.3(r). Component includes

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[22] *See* Exhibit A at 14.

[23] *See In re Allergan*, 2021 WL 1050910, at *28 (finding that the plaintiffs identified federal parallels for their manufacturing defect claims based on violations of specific CGMP regulations in addition to the FDCA's adulteration provisions which prohibits the manufacture of implants that are not in conformity with CGMP requirements). *See also* 21 U.S.C. §§ 351(h), 360j(f) ("That is to say, adulteration is found if specific CGMP violations are identified. Since Plaintiffs have specified the CGMP regulations that Allergan allegedly violates, Plaintiffs can assert manufacturing defect claims based on Allergan's alleged violation of the FDCA's adulteration provisions.").

any raw material, substance, piece, part, software, firmware, labeling, or assembly, which is intended to be included as part of the finished, packaged, and labeled device. 21 C.F.R. § 820.3(c).

120. The intent of Section 820.50(a) is to ensure that device manufacturers select only those suppliers, contractors, and consultants who can provide quality product and services. This is because the finished medical device's quality depends on the quality of the components and raw materials. Poor quality can cause injuries from the medical device, as well as recalls. Moreover, manufacturer diligence in complying with these requirements is critical because the FDA does not inspect component suppliers. Product or service suppliers are to be reviewed at intervals consistent with the significance of the product or service provided and demonstrate conformance to specified requirements.

121. Mentor violated 21 C.F.R. § 820.50(a) with respect to polyurethane foam employed in their imprinting technique in that it failed to resist peeling and fragmenting in conformance with quality requirements. In contravention to federal requirements, the foam employed in the imprinting technique used in the manufacture of Plaintiff's implants could not satisfy basic fitness for use. As detailed above, it is the application of this component that ultimately leads to ALCL.

D. Mentor Violated 21 C.F.R. § 820.90(a) by Failing to Identify and Address Nonconforming Product and Processes

122. Anytime a device, or component thereof (21 C.F.R. § 820.3(r)), fails to meet any of its specifications (21 C.F.R. § 820.3(y)) that constitutes a nonconformity (21 C.F.R. 820.3(q)). Pursuant to 21 C.F.R. § 820.90(a), manufacturers shall establish and maintain procedures to control such nonconforming product that does not meet specifications. Nonconformances can occur in both product and process, and importantly, nonconforming processes, like Mentor's imprinting technique, are those can lead to nonconforming product.

123. When a nonconforming product or process is identified, a manufacturer must evaluate the nonconforming product. The evaluation of nonconformance must include a determination of the need for an investigation into the nonconformance. Investigations are required unless one has already been performed on a similar issue.

124. Upon identifying a nonconforming product or process, a manufacturer must segregate those devices to ensure they are not released and are ultimately disposed. Disposition of nonconforming product must be documented, including the justification for use of nonconforming product. Any such justification is to be based on objective scientific evidence.

125. Mentor violated 21 C.F.R. § 820.90(a) by failing to establish and maintain procedures to control texturized implants and expanders that do not conform to specification. This includes failing to identify texturized implants and expanders with compromised surface topography and evaluating the cause of the nonconformity. Rather than disposing of nonconforming texturized products as required by the prevailing scientific evidence, Mentor allowed them to be sold on the open market to consumers, including Plaintiff.

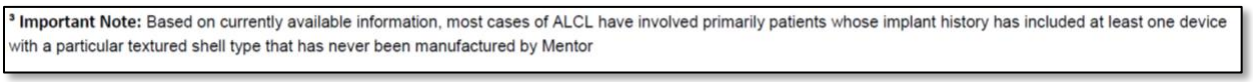
E. Mentor Violated 21 C.F.R. § 820.100(a) by Failing to Take Necessary and Required Corrective and Preventive Action

126. A manufacturer's Corrective and Preventive Action ("CAPA") subsystem is intended to be the ultimate fail-safe against product and quality problems. CAPA requirements include collecting and analyzing information to identify actual and potential product and quality problems, investigating any problems discovered, taking appropriate and effective, and validate the effectiveness of the action taken. Whereas corrective action deals with eliminate the cause of a detected non-conformity or other undesirable situation, preventative action is designed to eliminate the cause of a potential non-conformity or other undesirable situation. Preventative action is required even when there is more than one cause for a potential nonconformity.

127. The procedures for implementing corrective and preventive action required under 21 C.F.R. § 820.100(a) must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities. CAPA requirements likewise apply to process and quality system nonconformities. The need for such action can be triggered by information coming from internal sources, such as test/inspection data and process control data, and external sources such as medical device reporting, customer complaints, and issues in similar devices from competitors.

128. Once a nonconformity is identified, a manufacturer must investigate the root cause of the nonconformities relating to product, processes, and the quality system. Nonconforming product discovered before or after distribution must be investigated to the degree commensurate with the significance and risk of the nonconformity. Similarly, the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered.

129. Tellingly, in an apparent effort to shift blame for ALCL on a competitor brand of implant, Mentor included as an "Important Note" in its submissions ANSM the following:[24]


[3] **Important Note:** Based on currently available information, most cases of ALCL have involved primarily patients whose implant history has included at least one device with a particular textured shell type that has never been manufactured by Mentor

130. Despite possessing knowledge of the role of texture shell type and manufacture processes played a role in the occurrence of ALCL, Mentor failed to take corrective action with respect to its own manufacturing practices to mitigate the risk to patients like Plaintiff.

131. Mentor, in violation of 21 C.F.R. § 820.100(a), failed to establish and maintain procedures for implementing corrective and preventive action in order to properly detect recurring

[24] https://ansm.sante.fr/uploads/2020/12/14/implants-mammaires-lagc-mentor-reponse-au-courrier-ansm-du-20052016-annexe-4-26042019.pdf (last viewed May 8, 2021).

quality problems related to the imprinting technique of the SILTEX implants, investigate causes of nonconformities in these processes and products, identify necessary action to correct and prevent recurrence of nonconforming implants, and implement changes in methods to correct such quality problems. Despite repeatedly receiving reports and information about BIA-ALCL from internal and external sources, Mentor conducted no investigations into the nonconformities and failed to take appropriate and required corrective action. Worse yet, out of pecuniary interests, Mentor failed to thereafter take preventive action to prevent reoccurrence of the nonconformity.

F. Mentor's Violations of Current Good Manufacturing Practices Rendered the Textured Siltex Implants Adulterated Which Led to Plaintiff's Harm

132. Mentor's post approval misconduct violated the PMAs, the manufacturing and design specifications, CGMPs, QSRs, other federal regulations and parallel state law, caused an uncontrolled and unintended increase in the surface area of the implants and expanders and left residual manufacturing material on the SILTEX surfaces. The unintended increase in surface area due to pores and interstices and the unintended residual debris left on the surface caused or contributed to the proliferation of T-cells. In addition, Mentor's uncontrolled and un-validated texturing process caused or contributed to a chronic inflammatory response in patients' bodies which caused or contributed to the development of ALCL. This inflammatory response which can lead to ALCL is exacerbated by shear forces from the excessive number of unintended particles on the implant surface, micro-movement shear forces caused by mechanical attachment and detachment of the over-aggressively textured surface to the tissue capsule, which also result from Mentor's defective manufacturing processes. The chronic inflammation caused by Mentor's defective manufacturing processes stimulates T-cells and can cause malignant mutations in T-cells, ultimately leading to anaplastic large cell lymphoma.

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

134. The MemoryShape breast implants implanted into Plaintiff were *adulterated* in that they were not manufactured in conformity with the CGMP requirements identified above. *See* 21 U.S.C. §§ 351(h), 360j(f); s*ee also In re Allergan*, 2021 WL 1050910, at *28.

135. 21 C.F.R. § 808.1(d)(2)(ii) provides that, generally, § 521(a) of the FDCA does not preempt a state or local requirement prohibiting the manufacture of adulterated or misbranded devices.

136. Adulterated medical devices are not subject to preemption.

137. In a recent conference held in Rome relating to BIA-ALCL, Dennis Hammond, M.D., a Board-certified plastic surgeon, made the following comment - "Silicone particle induced inflammation is the primary cause of BIA-ALCL."[25]

[25] Presentation at 1st World Consensus Conference on BIA-ALCL (Rome Italy, Oct. 5, 2019), 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").

138. These specific allegations of violations of the federal PMAs, laws, regulations, and requirements due to manufacturing in violation of federal law are not subject to federal preemption.[26]

139. Mentor's violations of the PMAs and violations of FDA requirements set forth in the QSRs and CGMPs, specifically, failure of 21 C.F.R. § 820.70(h) requiring the removal of manufacturing material that could reasonably be expected to have an adverse effect on product quality, caused Christine McGee's ALCL.

140. Plaintiff's claims are governed by multiple theories of the CPLA, none of which are preempted as they pertain to manufacturing defects. *See Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017) ("We easily conclude that the FDA may be reasonably relied upon

[26] See *Gravitt v. Mentor Worldwide*, LLC, 289 F. Supp. 3d 877, (N.D. Ill. 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))."). *See also 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, 1207 (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); *Cf. Delfino v. Medtronic, Inc*., No. A18-1462, 2019 Minn. App. Unpub. LEXIS 530 (June 10, 2019) (failing to follow FDA manufacturing and performance standards that paralleled state law claims would not be preempted; however, facts failed to show a violation or departure of federal requirements).Plaintiff avers 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 CGMPs and QSRs, the failure to follow the CGMPs and QSRs also provide a basis for liability as violations of federal law that are parallel state law claims. *See Warren v. Howmedica Osteonics Corp*., No. 4:10 CV 1346 DDN, 2011 U.S. Dist. LEXIS 32643, 2011 WL 1226975, at *9 n.2 (E.D. Mo. Mar. 29, 2011). In addition — because Plaintiff alleges the implants were "adulterated" by foreign, decomposed and injurious unwanted silicone particles — federal law specifically incorporates CGMPs. 21 U.S.C. § 351.

to disclose information regarding medical device failures through the publicly accessible

database when provided with that information. As such, we will follow our sister court and reject Medtronic's preemption argument); *McLaughlin v. Bayer Corp*., 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016)("Plaintiffs have, however, identified Pennsylvania law that imposes such a duty.").

141. Pennsylvania law permits allegations of generalized CGMPs as sufficient to support a parallel CPLA claim based on strict liability for a manufacturing defect. *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 898-899 (M.D. Pa. 2017).

142. But for the Defendants' failure to comply with the above requirements, including established post-market validation and correction obligations, Plaintiff would have decided against implantation and her injuries would not have occurred.

143. Mentor violated its parallel common law duty to exercise reasonable care in the manufacture of its implants in failing to ensure conformity to its own PMA specifications and compliance with CGMPs, resulting in adulterated devices.

144. Had Dr. Bragdon been adequately warned of the risk of BIA-ALCL with the SILTEX implants, he would have recommended a safe alternative and Plaintiff would not have been injured.

MENTOR'S UNLAWFUL COMPLAINT HANDLING PRACTICES

145. In 1984, FDA issued a final rule requiring medical device manufacturers and importers to process complaints and file medical device reports ("MDR") for device-related events. The final rule explained both the purpose of the complaint handling and reporting requirements and the broad scope:

> To carry out its responsibilities, the agency needs to be informed whenever a manufacturer . . . becomes aware of information about device problems. Only if

> FDA is provided with such information will it be able to evaluate the risk, if any, associated with a device and take whatever action is necessary to reduce or eliminate the public's exposure to the risk.

49 Fed. Reg. 36326 (Sep. 14, 1984).

146. Approximately 97 days later, Mentor submitted its first breast implant medical device report. By the end of 1991, Mentor, along with the other mandatory reporters, had reported several thousand adverse event reports involving breast implants, including events of ruptures, infections, and reactions.

147. Then in early 1992, following the FDA's call for a moratorium on the sale and implantation of silicone gel-filled breast implants, the number of adverse event reports associated with breast implants saw exponential growth with 20,160 mandatory reports in the year 1992 and up to 32,884 in 1994. Because a large number of reports the FDA was receiving were well-known problems, the FDA began devising a method to allow breast implant manufacturers to submit MDRs associated with these specific events in a more efficient fashion.

148. Accordingly, in 1995, the FDA announced its decision to grant a written exemption to some or all of the requirements when it determines compliance with all MDR requirements is not necessary to protect the public health. 60 Fed. Reg. 63,592 (December 11, 1995); 21 C.F.R. § 803.19. The examples of applicable qualifying situations included when the adverse events are known and well-documented and occurring at a normal rate. This program later became known as Alternative Summary Reporting ("ASR").

149. That same year the FDA began offering a summary reporting pilot program to Mentor. This program allowed breast implant manufacturers to report eligible events in a concise and condensed report:[27]

> manufacturer, a user facility, or a distributor. Alternatively, summary reporting was offered to breast implant manufacturers in 1995. Manufacturers can summarize reports of rupture, leaks, deflation/inflation, wrinkling, capsular contracture, and non-specific complaints. Some manufacturers accepted this proposal and send us aggregated data on a quarterly basis.

150. Under ASR, manufacturers submit a report of injuries to the FDA once every three months in summarized form, instead of submitting individual reports for each adverse event. As a consequence of this implementation, the number of traditional medical device reports for silicone gel breast implants fell to 7,926, down by approximately 25,000 reports from the year prior.

151. On July 31, 1997, the FDA expanded the summary reporting program to other medical device types with a high frequency of specific adverse events. The announcement was clear that while many of the adverse events associated with these devices could be summarily reported, it was not without exception. Specifically, events may have contributed to a death, and events that are *unusual, unique or uncommon* were ineligible. In order to enroll in the ASR program, the manufacturers were required to provide a list of the exempted events that will be summarily reported to the FDA.[28]

152. The FDA's August 1997 progress report, explaining the periodic summary program, stressed that traditional medical device reports are still essential when the adverse event is new or unforeseen, since they serve as a vital early-warning signal to the FDA that an unexpected problem is surfacing. However, when the adverse event is one that has been experienced many times, then the function of the report is simply to give the FDA information about the frequency

[27] https://www.accessdata.fda.gov/cdrh_docs/pdf/P990075B.pdf.
[28] https://web.archive.org/web/20000914063243/http:/www.fda.gov/cdrh/offerlet.htm.

with which an expected event is occurring. This is because, for these kinds of events, individual reports may not be necessary or even helpful. The stated goal was to increase the number of ASR reports to redirect resources to problems that may pose a higher risk.

153. In 1999, the FDA rolled out the third generation of the ASR program to increase uniformity by requiring only selected data elements for individual adverse events in a line-item format. The guidelines reemphasized that *unusual, unique or uncommon* events remained ineligible for summary reporting.[29] For each eligible ASR entry received during the applicable reporting period, Mentor was only required to provide crude and rudimentary event information:

a. the internal identification number;
b. basic device identifier (model number, catalog number, etc.);
c. event type (death, serious injury or malfunction);
d. manufacturer awareness date (21 C.F.R. § 803.3(c)); and
e. evaluation codes (21 C.F.R. § 803.52(f)(6)).

154. The product evaluation codes are the only form of information describing the underlying device problem(s) and patient outcome(s) for any particular event provided in the ASR reports. The FDA assigned Mentor eligible codes corresponding to occurrences of ruptures, leaks, deflation/inflation, wrinkling, capsular contracture, migration, and non-specific complaints (*i.e.*, they contained no information other than that a woman had an implant and was ill or injured as a result). These reportable events were deemed eligible because they were expected to occur based on data provided from the premarket clinical trials. Besides these well-known and well-established risks, no other events were eligible for ASR reporting. This is because, due to the rudimentary nature, an evaluation code must exist for the underlying event to be identifiable and classifiable.

[29] https://wayback.archiveit.org/7993/20180724222258/https://www.fda.gov/downloads/MedicalDevices/Device Regulation andGuidance/GuidanceDocuments/ucm072102.pdf.

155. For example, a portion of the 2017 ASR report for Mentor's implant events is as follows: [30]

exemptn_no	mfr_no	mfr_name	report_id	date_of_event	mfr_aware_date	event_type	dev_prob_cd	report_year	report_qtr	initial_report_flag	dev_id
2007003	1645337	MENTOR	1-10IX7QSRight	3/29/2017	3/31/2017	IN	1546	2017	1	I	350-2251BC
2007003	1645337	MENTOR	1-10IXCHGA	3/31/2017	3/31/2017	IN	2993	2017	1	I	Unknown Gel Implant
2007003	1645337	MENTOR	1-10IXF6RRight	3/31/2017	3/31/2017	IN	2993	2017	1	I	Unknown Gel Implant
2007003	1645337	MENTOR	1-10IXLKPB	2/27/2017	3/30/2017	IN	2993	2017	1	I	3501501BC
2007003	1645337	MENTOR	1-10IYIJ2Right	3/6/2017	3/31/2017	IN	2993	2017	1	I	350-3751BC
2007003	1645337	MENTOR	1-10IYITILeft	3/6/2017	3/31/2017	IN	2993	2017	1	I	350-3751BC
2007003	1645337	MENTOR	194935A	2/17/2010	1/6/2011	IN	2682	2017	1	I	334-1157
2007003	1645337	MENTOR	194935B	2/17/2010	1/6/2011	IN	2682	2017	1	I	334-1157
2007003	1645337	MENTOR	195015A	12/14/2010	1/7/2011	IN	2203	2017	1	I	3507504BC
2007003	1645337	MENTOR	195015B	12/14/2010	1/7/2011	IN	2203	2017	1	I	3507504BC
2007003	1645337	MENTOR	196615A	11/3/2010	2/15/2011	IN	1546	2017	1	I	350-2751BC
2007003	1645337	MENTOR	196620A	NI	2/15/2011	IN	2203	2017	1	I	350-3001BC
2007003	1645337	MENTOR	197260A	2/17/2011	3/4/2011	IN	2682	2017	1	I	334-1205
2007003	1645337	MENTOR	199567A	4/26/2011	5/3/2011	IN	1546	2017	1	I	3504251BC
2007003	1645337	MENTOR	199758A	5/2/2011	5/9/2011	IN	2203	2017	1	I	3504251BC
2007003	1645337	MENTOR	199843A	4/28/2011	5/10/2011	IN	1546	2017	1	I	3504751BC

156. Mentor, however, began reporting events of BIA-ALCL in the ASR reports and assigning evaluation codes designed to mask the underlying event. Because these codes could not remotely describe a unique event like BIA-ALCL, these entries in the ASR reports were wholly *indiscernible and unidentifiable* as BIA-ALCL events, even by the FDA. The intended consequence was the FDA was not aware of—and therefore not warned about—these events.

157. In 2006, the FDA designed the Post-Market Spreadsheet Reporting ("PSR") program specifically to monitor the post-market performance of silicone gel-filled breast implants.[31] At the time PSR was authorized, the FDA once again defined the types of events that could be submitted and provided the silicone gel-filled breast implants manufacturers with specific patient outcome and device problem codes based on the clinical data. Again, because an evaluation

[30] Device Problem Code "1546" refers to a material rupture; "2993" refers to an adverse event without identified device or use problem; "2682" refers to patient-device incompatibility; and "2203" refers to device difficult to maintain.

[31] The PSR program, like the ASR program, sometimes served as an alternative to the requirement for submitting individual MDR. The PSR system differs because it includes additional details include the patient's race/ethnicity, the reason for implanting the device, whether a reoperation was performed as a result of the adverse event, whether the removed implant was replaced, and the type of surgery performed. It still relies on proper coding for describing device outcomes and patient problems.

code must exist for a particular event to be identifiable, new or emerging diseases, like BIA-ALCL, remained ineligible.

158. In 2011, the FDA published its Update on the Safety of Silicone Gel-Filled Breast Implants. Reports from the FDA reporting systems are described therein and grouped according to assigned patient outcome and device problem codes. Importantly, the PSR tabulations did not identify a single instance of BIA-ALCL from November 17, 2006 to December 31, 2010.[32]

159. In 2017, the FDA announced its decision to wind down the ASR program. The FDA also began to require manufacturers to submit companion MDRs so that some information collected through the ASR program would be visible publicly. As a result, it became known that Mentor has been misusing the ASR program to report ineligible events.

160. In 2019, the FDA formally ended all summary reporting of breast implant medical device reports and notified breast implant manufacturers of this decision. The FDA's announcement again reemphasized that the program was established to more efficiently review adverse events for well-established risks. Further, the FDA was unambiguous and deliberate when it stated that the ASR program "was not allowed for patient deaths and *unusual, unique or uncommon* adverse events, which, in the case of breast implants, *included BIA-ALCL*."[33]

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

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[32] https://www.fda.gov/media/80685/download, at Table 17.

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

162. Pursuant to these regulations, Mentor was obligated to file within a mandatory timeframe individual medical device reports for *all* BIA-ALCL events related to its products that it had knowledge of, *foreign or domestic*, and this includes any event that could reasonably be interpreted as BIA-ALCL given the nature of the complaint.

163. Notwithstanding this obligation, Mentor failed to investigate complaints of adverse events and submit such adverse events concerning the implants as MDRs in violation of general medical device regulations designed to ensure patient safety.

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

A. Mentor Violated 21 C.F.R. § 803.19(b) And 21 C.F.R. §§ 803.50, *et seq*. By Employing A Flawed Database Algorithm That Ignored Cases Of ALCL

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

166. This reporting duty is triggered not just for events occurring within the United States and its territories, but also adverse events occurring in a foreign country concerning the device. *See* 21 C.F.R. § 803.52(e)(3) (incorporating by reference FDA Form 3500A, Block G).[34] Under the FDA's Medical Device Reporting for Manufacturers Guidance for Industry, the FDA considers an event that occurs in a foreign country reportable under the MDR regulations if it

[34] https://www.fda.gov/safety/medical-product-safety-information.

involves a device that has been cleared or approved in the United States—or a device similar to a device marketed by the manufacturer that has been cleared or approved in the United States—and is also lawfully marketed in a foreign country.

167. Thus, even when a device is manufactured to modify specifications to meet standards in different countries, if these changes do not substantially alter device's performance, then any device events that are MDR reportable events relating to such modified devices should be reported under the MDR regulations.

168. Notwithstanding this reporting obligation for events worldwide, since at least 2010, Mentor documents submitted by the company to ANSM in 2015 shows Mentor received a number of worldwide complaints of BIA-ALCL associated with its implants:

PERTHESE® Gel Breast Implants

Années *Years*		Monde / *Worldwide*			Dont France / *For France*		
		Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total	Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total
2004	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2005	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2006	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2007	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2008	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2009	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2010	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2011	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2012	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2013	Nombre d'unités mises sur le marché *Number of units marketed*				0		
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2014	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2015	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	2[1]	2[1]

Mentor Gel® Breast Implants

Années *Years*		Monde / *Worldwide*			Dont France / *For France*		
		Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total	Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total
2004	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2005	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2006	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2007	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2008	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0

2009	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2010	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1	1	0	0	0
2011	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2012	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2013	Nombre d'unités mises sur le marche *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2014	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1[1]	1[1]	0	0	0
2015	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0

Mentor Gel® Breast Implants (Texas)

Années *Years*		Monde / *Worldwide*			Dont France / *For France*		
		Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total	Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total
2004	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2005	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2006	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2007	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2008	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2009	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2010	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	1[1]	0	1[1]	0	0	0
2011	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	1[2]	0	1[2]	0	0	0
2012	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	1[1]	0	1[1]	0	0	0
2013	Nombre d'unités mises sur le marche *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1[1]	1[1]	0	0	0
2014	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1	1	0	0	0
2015	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1 1[1]	2	0	0	0

Mentor Saline® Breast Implants

Années *Years*		Monde / *Worldwide*			Dont France / For France		
		Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total	Implants lisses *Smooth implants*	Implants texturés *Textured implants*	Total
2004	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2005	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2006	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2007	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2008	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2009	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2010	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	1[1]	0	1[1]	0	0	0
2011	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0
2012	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1[2]	1[2]	0	0	0
2013	Nombre d'unités mises sur le marche *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1 1[3]	2	0	0	0
2014	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	1	1	0	0	0
2015	Nombre d'unités mises sur le marché *Number of units marketed*						
	Nombre de cas de LAGC signalés *Number of ALCL cases reported*	0	0	0	0	0	0

169. Despite the public health crisis implicated by such data, Mentor unlawfully failed to timely and appropriately file MDRs for these events of BIA-ALCL to the FDA and other regulatory authorities.

170. A corresponding investigation of Mentor's complaint handling and reporting practices with respect to BIA-ALCL revealed numerous "Deviations" from international consensus standards virtually identical to Mentor's domestic reporting obligations. That is to say, Mentor was found to be in non-compliance with particular legal references applicable to medical devices.

171. The predominate focus of the investigation was critical safety flaws in Mentor's TRACKWISE™ database. The TRACKWISE™ utilizes a database decision tree and other algorithms for evaluating the gravity and reportability of serious incidents related to the implants. These algorithms, however, were found to make decisions which were not consistent with governing legislation and guidelines in force, and which jeopardized the reporting of the serious incidents with the required due diligence. **As a consequence, algorithms employed by Mentor made the determination "that ALCL cases will not be reported as complaints."**[35] Corrective action was only taken after the inspection began.

172. The ANSM authorities dictated that appropriate action needed to be taken with respect to the database so as to include fields that collect event information that is also required as part of Mentor's domestic complaint investigation responsibilities. *See* 21 C.F.R. § 820.198(d)-(e). Specifically, Mentor had not been collecting information, documents, or references concerning:

a. The date and mode of reception of the source document related to the case notification to Mentor (letter, fax, e-mail, report of phone call...), with the identification of the notifier and Mentor staff addressee;

b. The gravity of the case (serious and non-serious);

c. The causality of the medical device(s) involved (established, possible, excluded or unknown);

d. The risk(s) related to the patient;

e. Potentialities of use error;

f. Potentialities of misuse;

g. The reportability of the incident to the concerned competent authorities;

h. The reference of the notification of the incident (is serious) to the concerned competent authorities;

i. The final evaluation, conclusion and decision related to the case;

j. The criteria triggering the closure of the case.[36]

[35] *See* Exhibit A, at 24 (emphasis added).
[36] *See id.* at 15.

173. Mentor's reporting requirements under federal law are stringent and any deviations therefrom requires express authorization by the FDA. 21 C.F.R. § 803.19(b). Absent an affirmative exemption, Mentor was required to collect all of the information required by 21 C.F.R. § 803.52 that is known or reasonably known. By deliberating excluding pertinent event information, Mentor failed to comply with 21 C.F.R. § 803.19(b) through its use of its algorithm in this manner and as a result excluded reportable BIA-ALCL events from reporting despite never being granted an exemption to do so by the FDA. Mentor—who has been reporting to the FDA since 1984—was well-versed in the information to be collected and disclosed and had been fulfilling that obligation for decades for a variety of adverse events. And yet, when presented with a deadly and emerging cancer, it deliberately implemented a system that turned a blind eye to it.

174. Worse yet, the report further identified that not only did Mentor's database fail to trace the source notification documents, but it fails to reference them in their reports.[37] This deprived the authorities from referencing the source documents attesting to the actual dates of receipts of the complaints when they were communicated to Mentor staff with the notifier's details. Rather, Mentor's evaluation of ALCL cases was unlawfully limited to the analysis of the medical and scientific literature, *without further investigation*. *See id.* [38] In particular, production batch records where not reviewed and challenged in the processing of the complaint, particularly since these ALCL cases refer to know and anticipated incidents, and which in turn excluded assessment of production impacts. This Deviation was determined to be "Major," *i.e.*, a breach in the system, the processes and the practices of materiovigilance which may cause important effects going

[37] *See id*. at 14.
[38] *See id*.

against the right, the safety or the well-being of the patients or may induce a risk of public health or refers to a major deviation to the current legal provisions.

175. As a result, Mentor was found to have inadequate post-market surveillance concerning:

a. The analysis of the incident outcomes broken down by breast implants surfaces (smooth and textured), in order to allow the inter-comparison of the Benefit/Risk ratio of the textured breast implants versus smooth breast implants;

b. the exhaustive list of the typologies of reported incidents, from the most frequent to the rarest ones; and

c. the in-depth analysis of the key points, issues and stakes stemming from the data related to ALCL cases, including the demonstration of the preservation of the breast implants' Benefit/Risk ratio.

176. Under federal law, a medical device report must contain all the information required by 21 C.F.R. § 803.52 that is known or reasonably known to the manufacturer. Information considered reasonably known includes any information: 1) that can be obtained by contacting a user facility, importer, or other initial reporter; 2) that is in the manufacturer's possession; or 3) that can be obtained by analysis, testing, or other evaluation of the device. 21 C.F.R. § 803.50(b).

177. Likewise, the information to be disclosed is equally expansive. The reporting requirements are expansive, and a manufacturer "must include," amongst other items:

a. an identification of the adverse event or product problem;

b. a description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;

c. a summary of the evaluation of the device, or an explanation of why an evaluation was not performed;

d. evaluation codes;

e. whether remedial action was taken and the type of action; and

f. an explanation of why any required information was not provided in the MDR and the steps taken to obtain this information.

21 C.F.R. § 803.52.

178. Rather than complying with these obligations, Mentor deliberately limited its reports to medical and scientific literature, *without further investigation.* This conduct falls well-short of the requirements of 21 C.F.R. §§ 803.50, *et seq*. Despite the public health crisis implicated by the product complaints it was receiving, for years Mentor deliberately and unlawfully limited the information it was collecting about BIA-ALCL, concealed how and when it was collecting it, and performed virtually no assessment of production impact on these events.

B. Mentor Violated 21 C.F.R. §§ 803.1, 803.19(b), And 803.50 By Concealing Pertinent Adverse Event Reports

179. As ALCL complaints continued to rise in frequency, rather than complying with the federal statute and regulations on medical device reporting, Mentor devised a scheme to use ASRs to report ALCL events associated with its products.

180. Under the FDA's October 19, 2000, ASR Guidance for Industry, the FDA required that any medical device manufacturer seeking to use the ASR reporting system affirmatively apply for an exemption, in writing, for specific device events, as set forth under 21 C.F.R. § 803.19(b).

181. Mentor failed to comply with 21 C.F.R. § 803.19(b) and the corresponding ASR Guidance and used the ASR reporting system to report BIA-ALCL events associated with its implants and expanders despite never being granted an exemption to do so by the FDA.

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

183. Likewise, the FDA was unambiguous and deliberate in its May 2, 2019 statement regarding the agency's efforts to protect women's health and help to ensure the safety of breast

implants: "[The ASR] program was established in 1997 to more efficiently review adverse events for well-established risks but was not allowed for patient deaths and *unusual, unique or uncommon* adverse events, which, in the case of breast implants, included BIA-ALCL."

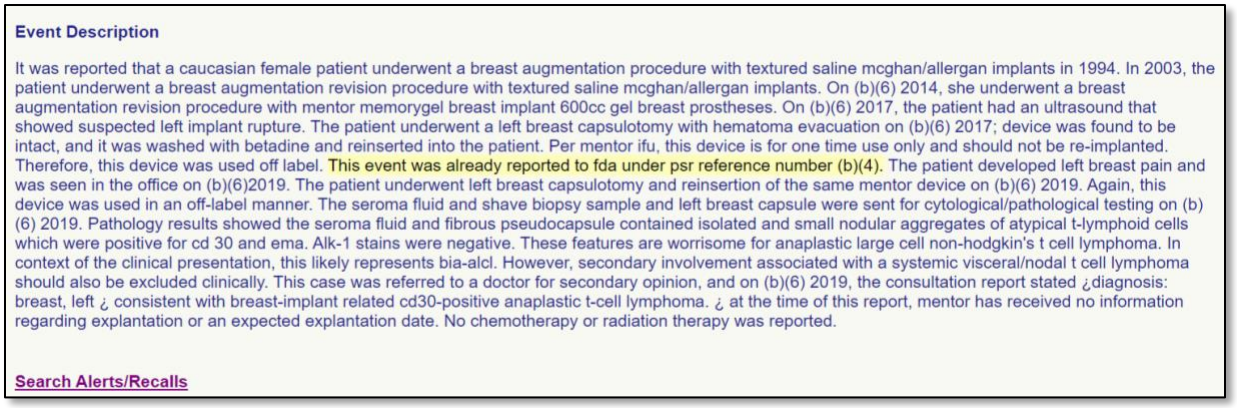
184. Despite numerous complaints related to BIA-ALCL, and symptoms associated therewith, surfacing in patients, and despite Mentor's awareness of these events and the fact they were unusual, unique, and uncommon events, Mentor—rather than reporting these events in compliance with the MDR reporting requirements—misused the ASR reporting system in violation of 21 C.F.R. § 803.1; 21 C.F.R. § 803.19(b); 21 C.F.R. § 803.50; 21 C.F.R. § 820.198(a)(3); 21 U.S.C. § 360i; and its duty to report to the FDA.

185. For example, shortly after the FDA discontinued the ASR program, in July 2019, Mentor submitted the following report to the FDA acknowledging their misuse of the privilege (and identifying as the underlying device problem as "Off-Label Use"):

MENTOR TEXAS MENTOR MEMORYGEL BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED Back to Search Results

Catalog Number 3506004BC
Device Problem Off-Label Use (1494)
Patient Problems Seroma (2069); No Code Available (3191); Anaplastic Large Cell Lymphoma (3264)
Event Date 05/24/2019
Event Type Injury
Manufacturer Narrative

At the time of this report, mentor has received no information regarding explantation or an expected explantation date. It is unknown at this time if the device will be made available for return. As a result, no product failure analysis can be conducted, and no determination of possible contributing factors can be made. As such, the investigation will be closed. If the complaint device is received in the future, the investigation will be reopened and conducted as appropriate. A manufacturing record evaluation (mre) was performed, and no anomalies were found related to this complaint. In addition, the mre verifies that the device was manufactured in accordance with documented specification and procedures. Reason for device explant and/or reoperation: left breast capsulectomy performed due to pain. Left breast biopsy performed for cytological/pathological testing. Concomitant medical products: mentor memorygel breast implant 600cc gel breast prosthesis, catalog #3506004bc, serial #(b)(4). Manufacturer¿s reference number: (b)(4).



Event Description

It was reported that a caucasian female patient underwent a breast augmentation procedure with textured saline mcghan/allergan implants in 1994. In 2003, the patient underwent a breast augmentation revision procedure with textured saline mcghan/allergan implants. On (b)(6) 2014, she underwent a breast augmentation revision procedure with mentor memorygel breast implant 600cc gel breast prostheses. On (b)(6) 2017, the patient had an ultrasound that showed suspected left implant rupture. The patient underwent a left breast capsulotomy with hematoma evacuation on (b)(6) 2017; device was found to be intact, and it was washed with betadine and reinserted into the patient. Per mentor ifu, this device is for one time use only and should not be re-implanted. Therefore, this device was used off label. This event was already reported to fda under psr reference number (b)(4). The patient developed left breast pain and was seen in the office on (b)(6)2019. The patient underwent left breast capsulotomy and reinsertion of the same mentor device on (b)(6) 2019. Again, this device was used in an off-label manner. The seroma fluid and shave biopsy sample and left breast capsule were sent for cytological/pathological testing on (b)(6) 2019. Pathology results showed the seroma fluid and fibrous pseudocapsule contained isolated and small nodular aggregates of atypical t-lymphoid cells which were positive for cd 30 and ema. Alk-1 stains were negative. These features are worrisome for anaplastic large cell non-hodgkin's t cell lymphoma. In context of the clinical presentation, this likely represents bia-alcl. However, secondary involvement associated with a systemic visceral/nodal t cell lymphoma should also be excluded clinically. This case was referred to a doctor for secondary opinion, and on (b)(6) 2019, the consultation report stated ¿diagnosis: breast, left ¿ consistent with breast-implant related cd30-positive anaplastic t-cell lymphoma. ¿ at the time of this report, mentor has received no information regarding explantation or an expected explantation date. No chemotherapy or radiation therapy was reported.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8834075.

186. The FDA was not aware, did not consent, and did not grant an exemption to Mentor to use ASR reporting for BIA-ALCL events. The FDA did not review or investigate ASR-reported events for new or emerging adverse events and reserved its resources for incidents requiring a medical device report.

187. Because this information about BIA-ALCL was for years routinely transmitted by Mentor to the FDA in the unscrutinized spreadsheets, the true extent of the nexus between the implants and BIA-ALCL took decades to be determined by the FDA.

188. The use of the ASR reporting system by Mentor buried BIA-ALCL events, in that they were not identifiable by the FDA and could not be discovered by physicians either. Had Mentor lawfully reported BIA-ALCL events until the time of Plaintiff's implantation or symptoms, she would not have suffered her injuries. Instead, the Plaintiff and her physician were both unaware of the extent of the risk of BIA-ALCL when the subject devices were implanted, causing her serious injuries.

C. Mentor Failed To Investigate Complaints Of BIA-ALCL Per 21 C.F.R. §§ 820.198 And 803.18(e) And Prepare Corresponding MDRs

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

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

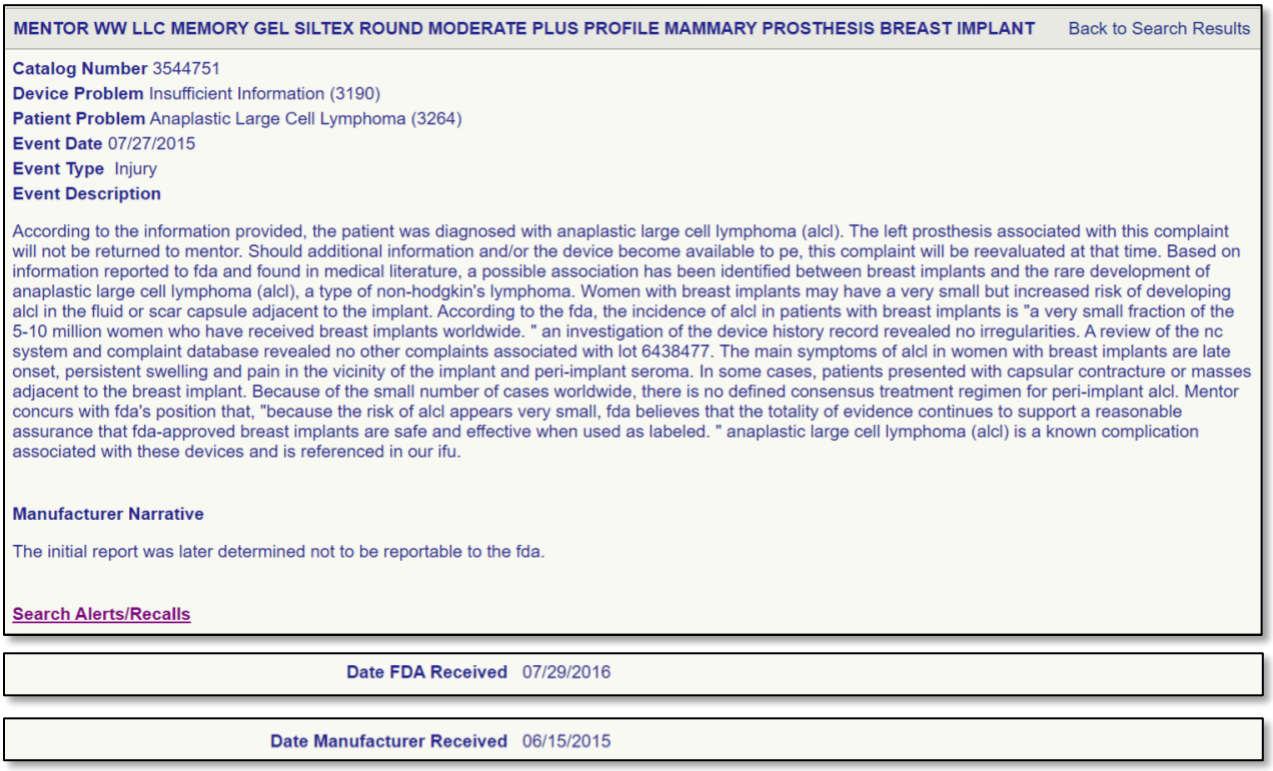
191. Upon receipt of a complaint by *any* employee, Mentor was required to evaluate all available information related to the complaint to determine whether it represents an MDR reportable event. 21 C.F.R. §§ 820.198(a) and 803.18. Said evaluation must include information in the manufacturer's possession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

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

193. Accordingly, under these general complaint handling requirements, Mentor was under the continuing duty to receive, evaluate, and investigate such events related to BIA-ALCL and make a determination as to the relationship between the implants and BIA-ALCL.

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

194. Two particularly egregious examples reveal that Mentor failed to submit the mandatory MDRs concerning BIA-ALCL until *over a year* after the underlying adverse event:



MENTOR WW LLC MEMORY GEL SILTEX ROUND MODERATE PLUS PROFILE MAMMARY PROSTHESIS BREAST IMPLANT Back to Search Results

Catalog Number 3544751
Device Problem Insufficient Information (3190)
Patient Problem Anaplastic Large Cell Lymphoma (3264)
Event Date 07/27/2015
Event Type Injury
Event Description

According to the information provided, the patient was diagnosed with anaplastic large cell lymphoma (alcl). The left prosthesis associated with this complaint will not be returned to mentor. Should additional information and/or the device become available to pe, this complaint will be reevaluated at that time. Based on information reported to fda and found in medical literature, a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl), a type of non-hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing alcl in the fluid or scar capsule adjacent to the implant. According to the fda, the incidence of alcl in patients with breast implants is "a very small fraction of the 5-10 million women who have received breast implants worldwide. " an investigation of the device history record revealed no irregularities. A review of the nc system and complaint database revealed no other complaints associated with lot 6438477. The main symptoms of alcl in women with breast implants are late onset, persistent swelling and pain in the vicinity of the implant and peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. Because of the small number of cases worldwide, there is no defined consensus treatment regimen for peri-implant alcl. Mentor concurs with fda's position that, "because the risk of alcl appears very small, fda believes that the totality of evidence continues to support a reasonable assurance that fda-approved breast implants are safe and effective when used as labeled. " anaplastic large cell lymphoma (alcl) is a known complication associated with these devices and is referenced in our ifu.

Manufacturer Narrative

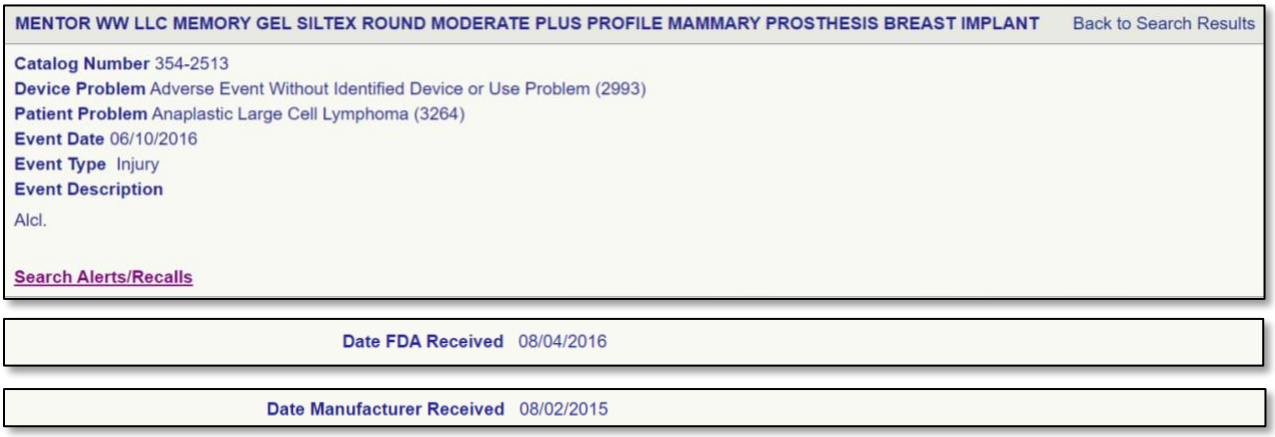
The initial report was later determined not to be reportable to the fda.

Search Alerts/Recalls

Date FDA Received 07/29/2016

Date Manufacturer Received 06/15/2015

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=5834667.



MENTOR WW LLC MEMORY GEL SILTEX ROUND MODERATE PLUS PROFILE MAMMARY PROSTHESIS BREAST IMPLANT Back to Search Results

Catalog Number 354-2513
Device Problem Adverse Event Without Identified Device or Use Problem (2993)
Patient Problem Anaplastic Large Cell Lymphoma (3264)
Event Date 06/10/2016
Event Type Injury
Event Description

Alcl.

Search Alerts/Recalls

Date FDA Received 08/04/2016

Date Manufacturer Received 08/02/2015

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=5846884.

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

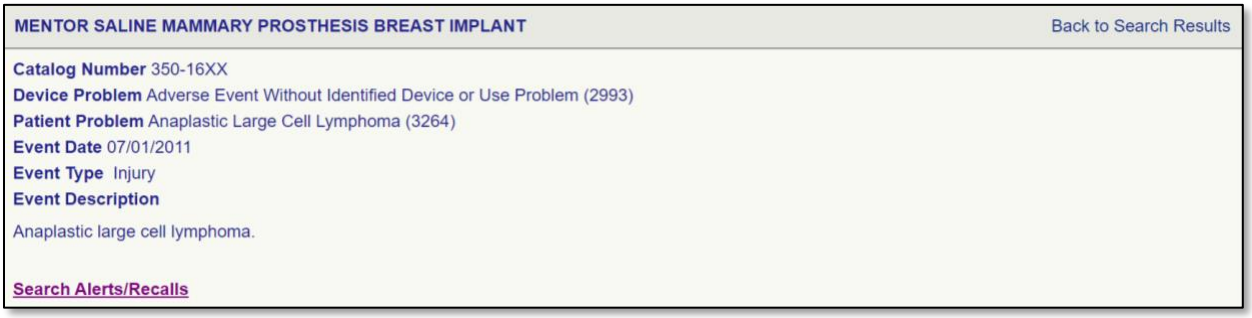
196. Notwithstanding these strict and mandatory reporting deadlines, as demonstrated above, Mentor has been submitting late adverse event reports to the FDA related to BIA-ALCL well-after first receiving knowledge of the event.

D. Mentor Failed to Provide All Information Reasonably Known Per 21 C.F.R. §§ 803.50(b) And 803.52

197. As discussed above, far from providing all information reasonably known it, Mentor failed to do any investigatory or remedial action. This is notwithstanding the fact that when a complaint qualifies for medical device reporting, Mentor was required to promptly investigate the relationship, if any, of the device to the reported incident or adverse event. 21 C.F.R. § 820.198(d)(3). Relatedly, a discussion of how the device was involved in the event must be included in the report to the FDA. 21 C.F.R. § 803.52(b)(5).

198. This utter failure to take seriously an ongoing safety trend is reflected in the reports themselves. The following reports, spanning years, demonstrates Mentor's caviler and reckless posture towards BIA-ALCL events

January 9, 2013:



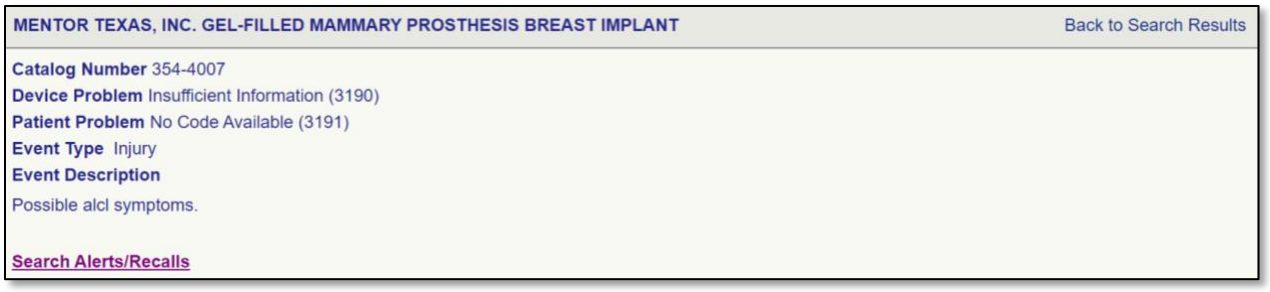
MENTOR SALINE MAMMARY PROSTHESIS BREAST IMPLANT — Back to Search Results

Catalog Number 350-16XX
Device Problem Adverse Event Without Identified Device or Use Problem (2993)
Patient Problem Anaplastic Large Cell Lymphoma (3264)
Event Date 07/01/2011
Event Type Injury
Event Description
Anaplastic large cell lymphoma.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=3340784.

January 15, 2013:



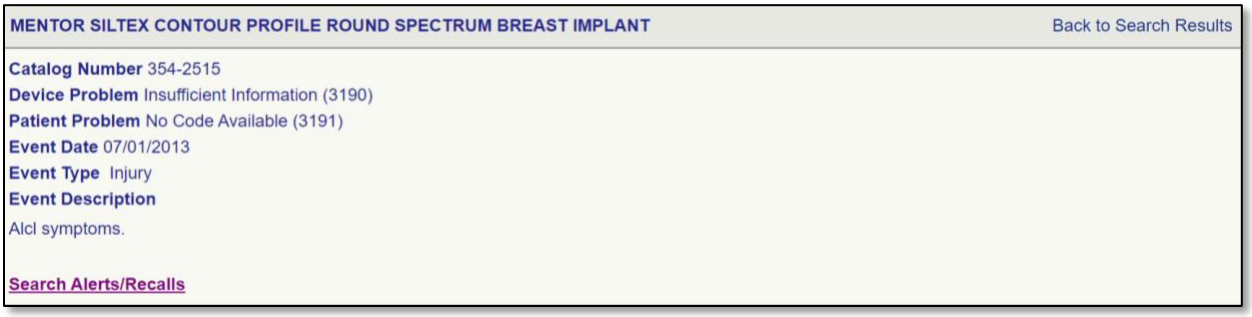
MENTOR TEXAS, INC. GEL-FILLED MAMMARY PROSTHESIS BREAST IMPLANT — Back to Search Results

Catalog Number 354-4007
Device Problem Insufficient Information (3190)
Patient Problem No Code Available (3191)
Event Type Injury
Event Description
Possible alcl symptoms.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2926371.

July 26, 2013:



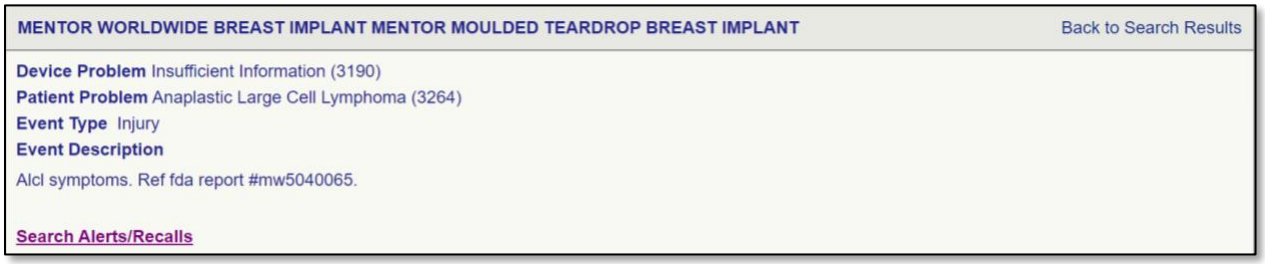
MENTOR SILTEX CONTOUR PROFILE ROUND SPECTRUM BREAST IMPLANT — Back to Search Results

Catalog Number 354-2515
Device Problem Insufficient Information (3190)
Patient Problem No Code Available (3191)
Event Date 07/01/2013
Event Type Injury
Event Description
Alcl symptoms.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=3264885.

March 17, 2015:



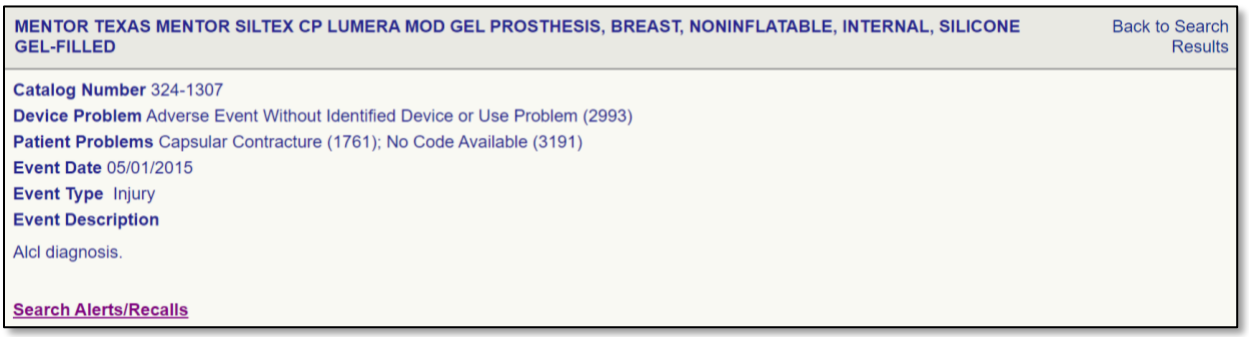
MENTOR WORLDWIDE BREAST IMPLANT MENTOR MOULDED TEARDROP BREAST IMPLANT Back to Search Results

Device Problem Insufficient Information (3190)
Patient Problem Anaplastic Large Cell Lymphoma (3264)
Event Type Injury
Event Description
Alcl symptoms. Ref fda report #mw5040065.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=4626734.

July 17, 2015 (miscoded [21 C.F.R. § 803.52(f)(6)] as "Capsular Contracture" and "No Code Available"):



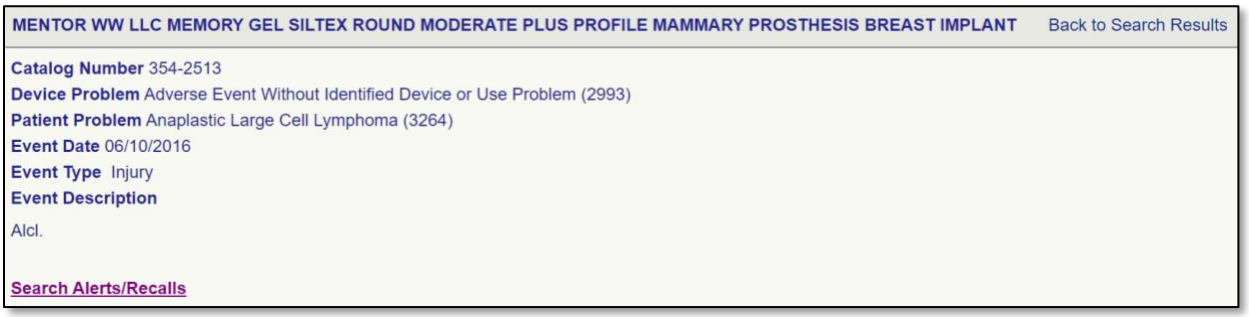
MENTOR TEXAS MENTOR SILTEX CP LUMERA MOD GEL PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED Back to Search Results

Catalog Number 324-1307
Device Problem Adverse Event Without Identified Device or Use Problem (2993)
Patient Problems Capsular Contracture (1761); No Code Available (3191)
Event Date 05/01/2015
Event Type Injury
Event Description
Alcl diagnosis.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=4943508.

August 4, 2016:



MENTOR WW LLC MEMORY GEL SILTEX ROUND MODERATE PLUS PROFILE MAMMARY PROSTHESIS BREAST IMPLANT Back to Search Results

Catalog Number 354-2513
Device Problem Adverse Event Without Identified Device or Use Problem (2993)
Patient Problem Anaplastic Large Cell Lymphoma (3264)
Event Date 06/10/2016
Event Type Injury
Event Description
Alcl.

Search Alerts/Recalls

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=5846884.

199. By failing to provide all information reasonably known to it, and instead making virtually no effort to detail the event information, Mentor violated 21 C.F.R. §§ 803.50(b) and

803.52. As a result of Mentor's barebones reporting practices, the FDA, Plaintiff, Plaintiff's plastic surgeon, and the public was deprived for years of pertinent safety information.

E. Mentor's Reporting Abuses And Plaintiff's Harm Are Causally Related

200. Since the 1992 moratorium, the FDA has regularly made safety and effectiveness data regarding breast implants available to the public. In addition to publishing the actual MDR reports in MAUDE, the FDA has published annotated tabulations and fact sheets concerning the performance of breast implants based on MDR data. Such publications include the "FDA Consumer Magazine" (1967-2007), the "Breast Implants–An Information Update" (2000), "FDA Breast Implant Consumer Handbook" (2004), and the "Update on the Safety of Silicone Gel-Filled Breast Implants" (2011).

201. Likewise, the medical and scientific community relies on the FDA's MDR information, in particular the MAUDE database, for studying and evaluating new and emerging diseases. BIA-ALCL is no exception. For example, on December 8, 2014, a major analysis of the breast implant and BIA-ALCL nexus was published, which identified 173 cases of BIA-ALCL, including 94 previously unreported cases.[39]

202. Following suite, in April 2017, researchers from the M.D. Anderson Cancer Center in Houston performed a literature review on the etiology of BIA-ALCL and confirmed that "textured implants are commonly implicated in the development" of BIA-ALCL. Additionally, the study pulled information from the adverse events reports from the FDA's MAUDE database to determine the distribution of BIA-ALCL by manufacturer.

203. In light of FDA's regular publication of breast implant MDR data and the medical and scientific community's reliance on the same, had Mentor appropriately given effective post-

[39] G.S. Brody, et al., Anaplastic large cell lymphoma occurring in women with breast implants: analysis of 173 cases. Plast Reconstr Surg. 2015 Mar;135(3):695-705.

market notice to the FDA regarding BIA-ALCL, such information would have reached physicians and patients, including Plaintiff and her plastic surgeon, to put them on adequate notice of the risk.

204. Also, under state law, which imposes duties genuinely equivalent to those imposed by federal law, the manufacturer must act reasonably in conveying warnings concerning the safety of its products. Mentor was, thus, under a continuing duty under state law to adequately report injuries and problems with its devices, including the products, to the FDA.

205. As a result of Mentor's post-market failure to report to the FDA and as a result of Mentor's post-market misconduct, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise would have never would have been implanted in the Plaintiff at all.

206. Had Mentor properly reported the adverse events associated with its breast implants, the FDA would have included those adverse event reports in the MAUDE database. Plaintiff's implanting physician would have seen the adverse event reports related to BIA-ALCL and would have recommended safer breast implant products to Plaintiff.

MENTOR AND ETHICON ARE CONTROLLED BY J&J, AND PARTICIPATED IN THE MARKETING, PROMOTION AND SALE OF MENTOR BREAST IMPLANTS

207. Mentor is controlled by J&J and has been since December 2008, well before many of the above-described action occurred.

208. For example, a December 2008 J&J press release, underscores the importance of the transaction to both entities:

> Johnson & Johnson (NYSE: JNJ) and Mentor Corporation (NYSE: MNT), a leading supplier of medical products for the global aesthetic market, today announced a definitive agreement whereby Mentor will be acquired for approximately $1.07 billion in a cash tender offer. **Mentor is expected to operate as a stand-alone business unit reporting through ETHICON, Inc., a Johnson & Johnson company** and leading provider of suture, mesh and other products for a wide range of surgical procedures.

> Under the terms of the agreement, Johnson & Johnson will commence a tender offer to purchase all outstanding shares of Mentor at $31.00 per share. ... The boards of directors of Johnson & Johnson and Mentor have approved the transaction.
>
> The acquisition of Mentor will provide ETHICON with an opportunity to strengthen its presence in aesthetic and reconstructive medicine and raise the standard for innovation and patient outcomes in this market worldwide. Alex Gorsky, Company Group Chairman for Johnson & Johnson with responsibility for the ETHICON business worldwide, said, "The addition of Mentor, a market-leader and one of the most respected companies in the aesthetic space, expands our capacity to provide physicians with products that can restore patients' appearance, self-esteem and quality of life. ..."
>
> Josh Levine, President and Chief Executive Officer of Mentor, said, "ETHICON and Mentor share a common set of values in terms of commercial market leadership, the commitment to developing innovative, science-based products, and unwavering service to physicians and patients. This transaction allows Mentor to expand our product portfolio and significantly grow our global reach. The opportunity to become part of ETHICON, one of the largest and most respected surgical companies in the world, will have a positive impact on our business and on all our key constituents."
>
> Upon closing, **the transaction is expected to have a dilutive impact to Johnson & Johnson's 2009 earnings** per share of approximately $.03 - $.05. The transaction is expected to close in the first quarter of 2009.
>
> * * * * *
>
> SOURCE: Johnson & Johnson

Formerly available at http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=351111

(bold and underline added).

209. The press release confirming the acquisition included the following quote from Gary Pruden, J&J Company Group Chairman, explaining the affiliation between Mentor and J&J, "**Mentor will become the cornerstone of a broader Johnson & Johnson strategy** for aesthetic medicine -- serving both consumers and medical professionals. We will use **our combined strengths and experience** to build a market-leading aesthetic business **that capitalizes on Johnson & Johnson's broad-based** commercial capabilities, worldwide surgical care footprint,

and clinical scientific capabilities." Available at http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=361253.

210. J&J's website formerly included the following description: "MENTOR is a leading supplier of medical products for the global esthetic market. . . . Used in both breast augmentation and reconstruction procedures, our implant devices are subject to the strictest design end testing standards." (formerly available at https://www.jjmc.ca/our-products/mentor).

211. Similarly, a January 31, 2017 announcement on J&J's website touted "the combined technologies and innovations of Ethicon, Inc. and Mentor Worldwide, LLC." *See A Breakthrough in Breast Reconstruction*, available at https://www.jnj.com/caring/patient-stories/breakthrough-in-breast-reconstruction (last visited on July 30, 2020).

212. The announcement publicized an allograft available from Ethicon to use in conjunction with Mentor's Mentor® Breast Implants. *See id.*

213. J&J's publication also stated: "Mentor was a natural fit for Ethicon, a leading provider of suture, mesh and other products for a wide range of surgical procedures. In combining forces, Ethicon and Mentor aspire to be the trusted global leader in aesthetic medicine." *Id.*

214. The announcement also contains a link from J&J's website to Mentor's website.

215. Further, the "About Us" page on Mentor's former website discussed its acquisition by J&J and Mentor's "Investor Information" tab linked directly to J&J's website, specifically a web page entitled "Corporate Reports" with the J&J banner. (formerly available at https://www.jnj.com/about-jnj/annual-reports).

216. The current Mentor website consistently identifies Mentor as a J&J "Medical Device Company". Indeed, Mentor's website address is https://www.jnjmedicaldevices.com/en-US/companies/mentor.

217. Mentor's Customer Support webpage identifies the following email address as the person to contact for "Mentor Media Relations" – ewolfval@its.jnj.com. Upon information and belief, that email address is for Erin Wolf Valich, a long-time J&J employee. Her online bio identifies her as "Senior Manager, Worldwide Communications & Public Affairs (Mentor and Biosense Webster at Johnson & Johnson Inc."

PUNITIVE DAMAGES

218. 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, and reckless disregard for the public's safety and welfare.

219. 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 the SILTEX implants.

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

221. At all times relevant hereto, Defendants knew of the defective nature of the SILTEX implants, and continued to design, manufacture, market, label, and sell the SILTEX 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 the SILTEX implants, including Plaintiff who did suffer such harm.

222. Defendants misled regulators, the medical community and the public at large, including Plaintiff, by making false and misleading representations about the safety of the SILTEX

implants. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiff.

223. As a direct and proximate result of Defendants' reckless, willful and wanton acts in disregard of the safety of the public generally and of Plaintiff in particular, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, 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 –Strict Liability for Manufacturing Defect

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

242. A recent article relating to complications associated with textured breast implants stated as follows:

> Mentor uses negative-contact polyurethane foam to stamp its Siltex breast implant surfaces. Specifically, a chuck is dipped into uncured silicone to form the shell after which the uncured silicone shell is pressed into polyurethane foam to imprint pores measuring 70 to 150 mm in diameter and 40 to 100 mm in height.

Webb, et al., *Textured Breast Implants: A Closer Look at the Surface Debris Under the Microscope*, Plastic Surgery 2017, Vol. 25(3) 179-183.

243. Sometimes, in contravention with its federal requirements, the peeling away of the polyurethane foam stamp leaves residual polyurethane debris on the surface of the Siltex implants and causes pores and larger than intended cavities.

244. The larger, unintended pores and cavities, and the residual unintended polyurethane and silicone debris left on the implants are *not* part of the PMA-approved design for the MemoryShape implants.

245. **Mentor was required, but failed, to remove any manufacturing material that could adversely affect the device's quality, pursuant to 21 C.F.R. § 820.70(h). This failure left *unintended* particles on Christine McGee's breast implants that caused chronic inflammation and caused or contributed to the development of ALCL.**

246. The Mentor Breast Implants that were implanted into Plaintiff were adulterated in that they contained residual manufactured debris. As a result of a defective manufacture of Mentor's breast implants, unintended manufacture debris was left on the surface of the implants which was recognized as a foreign body and triggered a T-cell lymphoma.

247. Adulterated medical devices, like those of Ms. McGee's are not subject to preemption. 21 C.F.R. § 808.1(d)(2)(ii).

248. The defect is depicted here:

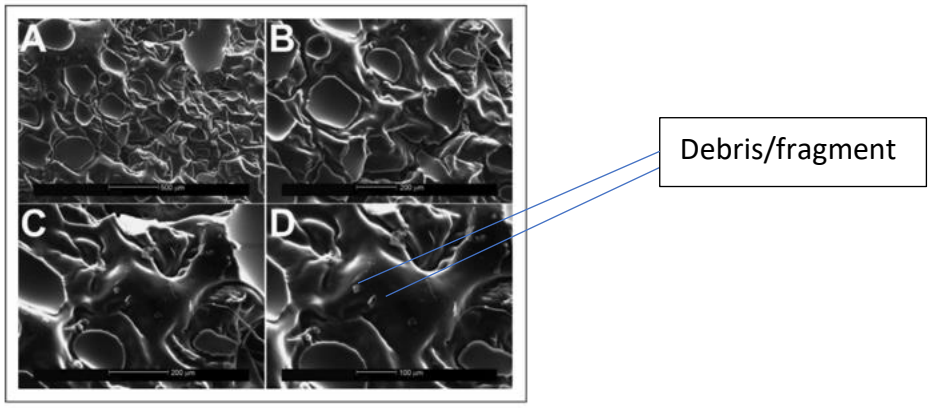


Figure 4. Ethylene vinyl acetate copolymer after spallation of the Mentor MemoryGel (Siltex) implant, shown on scanning electron microscopy (A, ×50; B, ×100; C, ×150; D, ×200).

248. Defendants are strictly liable for Plaintiff's injuries for:

a. Manufacturing their breast implant products in a manner that differed from the specifications agreed to by the FDA;

b. Failing to follow CGMPs and QSRs;

c. Failing to meet the applicable standard of care by not complying with applicable federal regulations and manufacturing protocols approved by the FDA;

d. Negligently failing to ensure a sterile manufacturing environment;

e. Failing to use reasonable care in inspecting and testing the product; and/or

f. Failing to use reasonable care in manufacturing, quality control, and quality assurance processes.

249. These requirements run parallel to traditional state tort duties in Connecticut to manufacture a product pursuant to its manufacturing standards and specifications.

250. Plaintiff's claims add no additional requirements than those required by the FDA.

251. Defendants' Siltex implants were in a defective condition at the time of sale, beyond which would be contemplated and expected by the ordinary consumer.

252. Defendants' SILTEX implants were expected to, and did reach, Plaintiff without substantial change to their condition which was defective and inherently unsafe and unable to be used without subjecting Plaintiff to an unreasonable risk of injury.

253. No ordinary consumer would have contemplated that the SILTEX x implants she had chosen for reconstruction of her breasts post-mastectomy would cause her an additional cancer.

254. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the manufacturing defect.

255. The defective manufacturing of SILTEX implants caused Plaintiff's injury.

256. At all material times, Defendants' SILTEX implants were defectively manufactured in a manner that violated the FDA approved manufacturing standards and specifications. Such violation runs parallel to Plaintiff's Connecticut based manufacturing defect claim.

257. The SILTEX implants Plaintiff received were not the breast implants approved by the FDA as they contained unintended manufacturing debris.

258. Defendants failed to adhere to federal specifications and thus manufactured defective products by:

a. manufacturing their textured breast implants in a non-conforming manner,
b. failing to sterilize the implants in conformance with the PMA,
c. failing to satisfy the study and follow-up requirements set forth in the PMA and other federal requirements,
d. failing to maintain procedures to prevent contamination of equipment or products, and
e. failing to timely and accurately submit adverse event reports on the occurrences of BIA-ALCL.

259. Plaintiff brings this claim pursuant to the CPLA for violations of federal requirements including violations of the following: 21 C.F.R. §§ 814.82(a)(2), (a)(9), and (c), among others.

260. At all material times, Defendants owed to Plaintiff a duty to use reasonable care, pursuant to the federal post-approval requirements, in the manufacture of its textured breast implant products and breached this duty by manufacturing and selling Plaintiff defective implants.

261. Defendants breached these duties by: failing to manufacture a safe breast implant so that implantation of such implants would be safe under the ordinary and foreseeable use of the SILTEX implants, by failing to report adverse events, failing to establish and maintain a quality system, failing to provide management responsibility, failure to perform quality audits, failure to maintain procedures to prevent contamination of equipment or product, failure to maintain procedures to ensure that design requirements are met, failure to identify nonconforming products, failure to identify the cause of nonconforming products, failure to identify the actions needs to prevent recurrence of nonconforming products, and failing to warn of nonconforming products.

262. Such manufacturing is in violation of state law, which does not impose duties or requirements materially different from those imposed by federal law including the PMA post-approval specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

263. This claim does *not* add to or change Mentor's manufacturing requirements. Nor does it require that Mentor's SILTEX implants be manufactured in a manner different from the FDA approved manner.

264. This claim exactly parallels the FDA requirements in that it requires Mentor to manufacture its SILTEX implants in accordance with the FDA regulations and PMA specifications.

265. Defendants had parallel duties under state and federal law pursuant to the federal post-approval requirements, to exercise reasonable care in manufacturing the products without deviations and defects.

266. For each of the statutes and regulations cited in this Second Amended Complaint, Plaintiff is within the class of persons the statutes and regulations are intended to protect, and Plaintiff's injuries are of the type of harm these statutes and regulations are designed to prevent. Defendants were negligent in their manufacture, sale and post-market surveillance of Mentor Breast Implants.

WHEREFORE, Plaintiff demands judgment against Defendants 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-- Breach of Implied Warranties

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

268. Plaintiff brings this claim for breach of the implied warranty of merchantability and the implied warranty of fitness for a particular purpose.

269. For goods to be merchantable, they must be fit for the ordinary purposes for which such goods are used" and "conform to the promises or affirmation of fact made on the container or label.

270. As set forth in the manufacturing defect section above, Mentor's Siltex implants were manufactured in a defective condition that violated the CGMPs, QSRs, and PMA requirements. These defects caused Plaintiff's breast implants to be defective and unfit for their ordinary and intended purpose. They did not conform to Mentor's implied warranty that they were fit for their ordinary purpose.

271. Plaintiff's claim for breach of warranty does not add to or differ from the federal requirements and is based on their manufacturing defect claim.

272. Selling Plaintiff adulterated products amounts to selling products unfit for their intended and ordinary purpose.

273. This breach of implied warranty, or the selling of defective Siltex implants as though they have met all federal requirements, induced Plaintiff and her physician to purchase the implants and have them implanted, ultimately causing Plaintiff's BIA-ALCL.

274. Plaintiff seeks to hold Mentor accountable *only* for what federal law mandated - nothing more. Nothing in this claim is different from, or in addition to, the federal requirements.

275. Defendants impliedly warranted that the product was fit for its particular purpose for which it was intended and of merchantable quality.

276. Defendants breached the implied warranty of merchantability by selling products that were not of merchantable qualify and were not safe and fit for their intended use.

277. Plaintiff and Plaintiff's physician relied upon Defendants' implied warranties that the Mentor Breast Implants were manufactured in accordance with federal specifications.

278. The availability of warranties under state law do not impose any different or additional requirements on defendants as required by federal law.

279. The SILTEX implants do not conform to these implied warranties because the SILTEX implants were not manufactured in the specifications required by the FDA.

280. Defendants' breach of implied warranty directly caused and was a substantial factor in causing Plaintiff and Plaintiff's physician to choose Mentor's SILTEX implants and develop BIA-ALCL and the profound injuries resulting therefrom.

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

WHEREFORE, Plaintiff demands judgment against Defendants 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 3 –Strict Liability for Failure to Warn

282. Plaintiff realleges and incorporates by reference all other paragraphs of this Complaint as if each were set forth fully and completely herein.

283. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, inspected, labeled, distributed, sold, marketed, promoted and/or introduced Mentor's textured breast implants the stream of commerce and in the course of same, directly advertised or marketed to consumers or persons responsible for consumers and, therefore, had a duty to warn of the risks associated with the use of the breast implants.

284. Mentor's implants were in a defective condition and unreasonably dangerous at the time that it left the control of the Defendants.

285. Due to the unreasonably dangerous condition of the implants, Defendants are strictly liable to Plaintiff.

286. The implants were under the exclusive control of Defendants and Defendants failed to comply with federal adverse event reporting requirements to the FDA such that Plaintiff's treating physician did not receive adequate information to make an informed decision to recommend the use of Mentor's implants.

287. Defendants thereby failed to timely and reasonably warn of material facts regarding the risks of BIA-ALCL.

288. Plaintiff did not have the same knowledge as Defendants and no adequate warning or contraindication was communicated to Plaintiff's physicians.

289. Had an adequate adverse events reports been made to the FDA as required by federal law (in effect a warning and/or contraindication) this information would have been

communicated to Plaintiff's physician and her physician would not have implanted Mentor's textured implants.

290. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from acute BIA-ALCL as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

291. WHEREFORE, Plaintiff demands judgment against the Defendants individually, jointly and/or severally and demand 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 just and proper.

Count 4--Negligence

292. Under Pennsylvania law, Mentor had a duty to use reasonable care in the manufacture of a medical device intended for human use.

293. The state common law duty to use reasonable care neither adds to nor changes any federal requirement. Instead, it is parallel as Mentor would have used reasonable care in its manufacture of its Breast Implants had it adhered to its PMA and post approval requirements.

294. As set forth above, Mentor was negligent in manufacturing its breast implants without controlling the texturing process leaving residual silicone and polyurethane particles, debris and fragments from the textured elastomer shell on the implant surface.

295. As such, Mentor's SILTEX implants were manufactured in a defective manner without complying with federal CGMPs, QSRs and PMA specifications.

296. The SILTEX implants purchased and implanted into Plaintiff were defective and adulterated as they contained silicone and/or polyurethane debris on the shell. The silicone debris became embedded in Plaintiff's tissue and was recognized as a foreign body which triggered a T-cell lymphoma.

297. Adulterated, nonconforming medical devices are not subject to preemption. 'The duty here, which supports the parallel claim, is the duty to use reasonable care by adhering to the federal requirements, including the general CGMP requirements and the device specific PMA requirements.

298. Nothing within this claim adds to or changes any federal requirements.

299. The breach of Mentor's duties, including the CGMP requirements and specific PMA requirements, caused Plaintiff's BIA-ALCL.

300. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of the SILTEX implants described herein, owed a duty manufacture its Breast Implants in accordance with federal requirements.

301. Defendants failed to exercise ordinary care in the manufacture, labeling, sale, marketing, quality assurance, quality control and distribution of Mentor's implants into the stream of commerce, in that the Defendants knew or should have known that the implants created an unacceptable risk of BIA_ALCL and unreasonable harm.

302. The negligence of the Defendants, their agents, servants and/or employees included, but was not limited to, the following acts and/or omissions:

(a) Failing to timely report adverse events to the FDA in violation of federal law;

(b) Failing to warn Plaintiff, the medical and healthcare community, including Plaintiff's physicians, the general public, and/or the FDA as soon as Defendants knew or should have known of the dangers of the use of BIA-ALCL;

(c) Concealing, suppressing, failing to warn about and/or failing to follow up on the adverse reports of BIA-ALCL;

303. Failing to conduct adequate post-marketing surveillance to determine the safety of Mentor's implants;

304. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of Mentor's implants including Plaintiff, by suppressing this knowledge from the general public.

305. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff developed BIA-ALCL, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish, diminished enjoyment of life and fear of cancer. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered these serious and dangerous side effects.

306. **WHEREFORE**, Plaintiff 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.

JURY DEMAND

Plaintiff demands a trial by jury on all of the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter judgment in her favor and against Defendants, awarding Plaintiff:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. exemplary and punitive damages sufficient to punish and deter Defendants and others from future fraudulent practices;

c. pre-judgment and post-judgment interest;

d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

e. any other relief the Court may deem just and proper.

Dated: May 13, 2021

Respectfully submitted,

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Pro hac vice motion pending