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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
TRENTON VICINAGE

LORY D'ADDARIO, and
PETER D'ADDARIO, h/w
4 AP Gates Road
East Haddam, CT 06423

Plaintiffs,

v.

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933;

ETHICON, INC.
U.S. Route 22
Somerville, New Jersey 08876;

MENTOR WORLDWIDE LLC
33 Technology Drive
Irvine, California 92618.

Defendants.

Civil Action No.

COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiffs LORY AND PETER D'ADDARIO, h/w, bring this action against Defendants Johnson & Johnson ("J&J"), Ethicon, Inc. ("Ethicon") and Mentor Worldwide LLC ("Mentor") (hereinafter, collectively referred to as "Defendants"), and each of them, in relation to the design, manufacture, marketing, labeling and distribution of Mentor® Breast Implants, the pervasive, reckless and continuous failure to comport with the Premarket Approval Application requirements imposed by the U.S. Food & Drug Administration ("FDA"), and failure to warn consumers of the known dangers and known adverse events.

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

3. Defendant Mentor is the only manufacturer whose breast implants are made in the United States. Over 20 years, more than five million women have used Mentor® Breast Implants, making Mentor one of the global leaders in breast aesthetics.

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

PARTIES, VENUE AND JURISDICTION

5. Plaintiff Lory D'Addario is, and at all material times was, a resident of Connecticut.

6. Plaintiff Peter D'Addario is, and at all material times was, the husband of Plaintiff Lory D'Addario and a resident of Connecticut.

7. Defendant 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 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.

11. Defendant Mentor is a 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. For more than 30 years, Mentor's products have been implanted into millions of women's breast regions and Mentor remains a leading supplier of medical products for the global aesthetic medicine market. The company develops, manufactures, and markets products for aesthetic medical procedures.

14. Defendant Mentor is a wholly owned subsidiary of Defendant J&J.

15. 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 Ethicon, a J&J company. *See* http://www.investor.jnj.com/releasedetail.cfm?releaseid=361253 (Jan. 23, 2009 J&J press release).

16. 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).

17. Even today, Mentor is identified as one of J&J's "medical companies." *See* https://www.jjmc.ca/our-products/mentor (last reviewed on Nov. 26, 2018).

18. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

19. 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 Plaintiffs for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized and/or ratified the conduct of each and every other Defendant.

20. At all relevant times, Defendants acted in concert with one another in the State of New Jersey to fraudulently convey false and misleading information concerning Mentor® Breast Implants, and concealed the risks of serious adverse events associated with its breast implants from Plaintiffs, the public, physicians, and other healthcare providers. But for Defendants' actions, Plaintiff Lory D'Addario would not have suffered the severe injuries and harms that have resulted from implantation of Mentor® Breast Implants into Plaintiff Lory D'Addario's body.

21. 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 New Jersey. Defendants conducted such business within the State including acts which caused or contributed to Plaintiffs' injuries.

22. At all material times, Defendants maintained systematic and continuous contacts within this jurisdiction, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district. Defendants received substantial financial gain as a result of designing, formulating, testing, packaging, labeling, producing, assembling, advertising, marketing, promoting, distributing, manufacturing, and selling the product within this jurisdiction.

23. 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, Plaintiffs seek damages in excess of $75,000, exclusive of interest and costs.

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

25. 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 Plaintiffs' causes of action occurred in this federal judicial district.

FACTS REGARDING MENTOR® BREAST IMPLANTS

General Information Relating To Breast Implants

26. Silicones, which are also called polysiloxanes, are polymers that include a synthetic compound made up of repeating chains of alternating silicon and oxygen atoms, frequently combined with carbon and/or hydrogen. Silicones are typically heat-resistant and rubber-like, and are used in sealants, adhesives, lubricants, medicine, cooking utensils, and thermal and electrical insulation. Being purely synthetic, silicones do not exist in nature.

27. A breast implant is a prosthetic product used to change the size, shape, and contour of a woman's breast. There are three general types of breast implant products, defined by their filler material: saline solution, silicone gel, and composite filler.

28. Silicone gel-filled breast implants have a silicone outer shell that is filled with silicone gel. They are available in various sizes and can have either a smooth or textured shell. Silicone gel-filled breast implants are approved for breast augmentation in women age 22 or older and for breast reconstruction in women of any age.

29. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Upon enactment of the MDA, the FDA deemed saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process. The devices could be publicly sold so long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2).

30. In 1988, in response to growing safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices requiring premarket approval ("PMA").

31. In April 1991, upon final publication of new regulations, FDA began requiring

breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants.

32. Through its PMA process, the FDA engages in scientific evaluations of the safety and effectiveness of Class III medical devices. The FDA considers Class III devices to create the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public.

33. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk);

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should be reasonably be known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

34. Where Conditional Premarket Approval ("CPMA") is granted, a device marketed by a manufacturer which fails to perform any requirements of the CPMA is considered to be adulterated under § 501 of the FDCA and may not be further marketed.

35. In November 1991, the FDA held an Advisory Panel meeting to discuss several

PMAs for silicone gel-filled breast implants. While the Advisory Panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, they unanimously recommended that the FDA permit the implants to remain on the market.

36. In January 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that the manufacturers stop supplying them and that surgeons stop implanting them while the FDA engaged in a further review of the products' safety and effectiveness.

37. In April 1992, the FDA determined that none of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support premarket approval for silicone breast implants. From that time, implantation of the products in the United States was limited to reconstruction and revision patients.

38. On December 12, 2003, Mentor submitted a request to the FDA for PMA for its silicone gel-filled breast implants.

39. On November 17, 2006, the FDA approved Mentor's PMA for its 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.

40. Specifically, the FDA required Mentor to: (a) Continue and complete the "Core" post-approval study; (b) Conduct a large post-approval study to assess long-term outcomes and identify rare adverse events and follow patients for ten years; (c) Conduct a device-failure study in concert with their large post-approval study to further identify the modes and causes of failure of explanted devices over the ten-year period; (d) Complete a focus-group study to evaluate how

easily patients understand the information in the informed decision brochure about the risks associated with the use of silicone breast implants; (e) Complete an informed decision study to monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants; and (f) Complete the "adjunct" study and continue to follow existing participants through their five-year post-implant evaluations.

41. Mentor failed to ensure that these mandated studies were performed properly, in part by not ensuring that the participants were followed after implantation. Accordingly, the information which the FDA was seeking regarding adverse events and device failures was never gathered.

42. For example, the "Core" study involved 1008 patients and Mentor was required to continue to follow these patients for the ten years following implantation to assess the long-term clinical performance of the silicone gel-filled implants. This was required to include 11 follow-up visits, at six months post-operation, and annually one year to ten years after surgery.

43. The FDA also stated that all non-MRI patients should have an MRI at years six, eight, and ten, and that all patients who were explanted without replacement were to be evaluated through ten years.

44. Mentor was further required to update the patient and physician labeling or its product to reflect the results of the five- and ten-year Core Study findings and to report to the FDA significant new information regardless of when the information became available.

45. Although the actual follow-up rates for the "Core" study at nine years post-implant were only 59 percent, Mentor reported that the follow-up rate at ten years post-implant was 62 percent.

46. Furthermore, the FDA requirements specifically mandated evaluation through ten

years, but the core post-approval study report schedule illustrates that reporting was only done for six years.

47. There were also other significant flaws and shortcomings in the information which Mentor provided to the FDA related to this study.

48. The lack of a sufficient statistical sample, due to the low follow-up rate, as well as the inconsistent data and the failure of Mentor to ensure that the study was completed violated the FDA requirements and significantly limited the information available regarding the long-term effects of use of the product.

49. The manner in which Mentor conducted the large Post-Approval Study (the "Large" study) and reported the information which it did gather was equally flawed.

50. The purpose for the "Large" study was to address specific issues such as long term local complications experienced by patients, such as connective tissue disease ("CTD"), CTD signs and symptoms, neurological disease, neurological signs and symptoms; offspring, reproductive, and lactation issues; cancer rates, suicide, mammography issues, rupture results, and MRI compliance.

51. The study data was to be collected through annual patient questionnaires completed over the internet, by mail, or by telephone.

52. The study also required physician evaluations at years one, four to six, nine and ten to collect data on complications.

53. Mentor was required to update their patient and physician labeling to reflect the five- and ten-year study findings, as well as at any other time if necessary to report significantly new information from the study.

54. As with the other mandated studies, the follow up rate for the "Large" study was

so low that the information obtained was not sufficient to allow for the identification of problems and adverse effects from long term use of the product.

55. By the seventh year of this study, the overall follow-up rate was 20.1 percent (approximately 8,331 participants out of 41,452), leaving 79.9 percent of the desired statistics unavailable for evaluation.

56. This was a study of significant importance required by the FDA for post-market approval. The study was designed to address a critical spectrum of health issues for women with breast implants. Mentor did not comply with the required data collection. With nearly an 80 percent dropout rate, the study failed to collect data to demonstrate that use of the Mentor silicone gel implants was safe.

57. The inadequate results are even more disconcerting because the data collection was designed to examine reasons for reoperation, previously unevaluated, including MRI results, and rheumatologic or neurological symptoms.

58. The lack of participation and reliable results from this study show that Mentor has failed to comply with FDA requirements.

59. Mentor did not follow through with required data collection. The Year 1 follow-up rate of surgeon visit for study participants was 22.8 percent, leaving nearly 80 percent unaccounted for. Similarly, the Year 1, 2, and 3 follow-up rates were 21.4 percent, 24.3 percent, and 23.0 percent, respectively, leaving nearly 80 percent unaccounted for. At Year 7, the overall follow-up rate was 20.1 percent; leaving 79.9 percent of participants unaccounted for and did not have follow-ups for data collection. No follow-up rates were provided for the ten-year data collection.

60. These follow-up rates were too low for Mentor to provide meaningful safety

information to the FDA and insufficient to allow for the identification of adverse effects or other problems resulting from long-term use of the product.

61. Mentor was also required to conduct a Device Failure Study to ascertain the reasons for, and frequency of, device failure. Specifically, the FDA required that "Mentor must continue preclinical studies to characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large post-approval study."

62. The study design involved two components: 1) the collection of implant/surgery information and clinical data at the time of explantation, and 2) visual inspection and physical testing of the explanted devices. No study population was stated, and there was no patient follow-up.

63. Mentor's Device Failure post-approval study failed to contain an adequate sample size to provide meaningful data.

64. Further, Mentor's Device Failure post-approval study report of summary findings failed to meet the requirements established by the FDA as it did not list results of the data findings (no clinical data and no visual inspection data), did not list safety findings, did not list any recommendations or summary of safety and data or follow-up on the data, and did not list any changes to labeling, all in violation of the FDA’s requirements.

65. Mentor was also required to conduct a Focus Group Study to gather information regarding the adequacy of the format and content of the approved product labeling.

66. Mentor used an inadequate number of individuals to properly evaluate how patients understood the safety and labeling brochures.

67. The FDA also required that Mentor conduct as Informed Decision Study to determine the success of the informed decision process provided to women who seek breast

implant surgery. Both the physician and the patient were intended to sign designated sections in order to best assure that the patient had obtained the labeling in sufficient time prior to surgery to read it and understand the risks and other information associated with the Mentor device.

68. Mentor failed to provide sufficient information regarding the methodology used or the results obtained from this study.

69. The FDA further mandated that Mentor continue the Adjunct Study, which had been approved in 1992, including the requirement that Mentor continue to follow-up on all patients currently enrolled in that study for five years. The data from this follow-up was to be reported as part of the annual reports required by the FDA.

70. The Adjunct Study was designed to follow-up with patients post-operatively at Years 1, 3, and 5 to assess satisfaction and occurrence of local complications. The study was to gather data regarding short-term and local (tissue) implant complications.

71. The overall patient follow-up rates declined as follows: Year 1 – 44 percent; Year 3 - 24.7 percent; and Year 5 - 13.8 percent. Mentor sought to attribute the poor follow up rates to a lack of patient compliance. Mentor also admitted that the lack of sufficient data significantly limited interpretation of the available safety results.

72. In addition to Mentor's failure to follow up on the Post-Approval Studies, from the time of the investigational device exemption ("IDE") until today, Mentor is solely responsible for designating and reporting all injuries as they relate to breast implants, and reporting any related injuries to the FDA and health care providers as required under both Connecticut state and federal law. The details regarding this information remain solely in the hands of the Defendants.

73. On information and belief, Plaintiffs allege that if injuries, including the occurrences of diagnosed cases of Breast Implant-Associated Anaplastic Large Cell Lymphoma

("BIA-ALCL"), had been properly reported, Plaintiffs would have been notified of the risk of developing BIA-ALCL with Mentor Breast Implants.

A. Information Specific to Mentor® MemoryShape® Breast Implants

74. On June 14, 2013, Mentor's Premarket application for its MemoryShape® breast implants was approved by the FDA.

75. As conditions of approval, the FDA required Mentor to conduct five post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Mentor's MemoryShape® silicone-filled breast implants included:

a. **Core Cohort Study** - 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. **U.S. Post-Approval Study** - To assess long-term outcomes by enrolling more than 2,500 silicone gel-filled breast implant patients and following them for ten years

c. **Case-Control Studies** - 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.

d. **Continued Access Study** - To collect additional safety and effectiveness data from about 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.

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

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

77. 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."

78. Mentor's obligations after the PMA included, but are not limited to:

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

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

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

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

e. Establishing and maintaining procedures for validating the device design, including testing of production units under actual or stimulated use conditions, and creation of a risk plan and conduction of risk analyses [21 C.F.R. § 820.30];

f. Documenting 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];

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

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

i. Reporting on Post-Approval Studies in a timely fashion [21 C.F.R. § 814.80]; and

j. Advertising the device accurately and truthfully [21 C.F.R. § 801].

79. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as Mentor® Breast Implants, rests with the manufacturer.

80. This primary reporting obligation instills in a manufacturer, such as 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.

81. 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.

82. 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.

83. Delayed reporting prevents the healthcare community and the public from timely learning of risks which must inevitably play a part in their decision-making, by both physicians and consumers, regarding treatments and procedures, and thereby expose countless additional women to potential harm.

84. On March 18, 2019, Mentor received a warning letter from the FDA setting forth Mentor's PMA violations. *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 July 19, 2019).

85. Specifically, the FDA spelled out Mentor's compliance failures as follows:

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.

86. 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."

87. 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.

88. 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.

89. By December 2018, Mentor had only enrolled 102 MemoryShape® participants.

90. The FDA repeatedly 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.

91. In the FDA's March 2019 warning letter, the FDA concludes that based on Mentor's failure to enroll the required number of study participants, the FDA is unable to 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)."**

92. 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.

93. In addition to the failures set forth in the FDA's March 2019 waning letter, Mentor also failed to report adverse events from the post-market approval studies commissioned as part of the implant's PMA approval, which would have led to reports suggesting the device's contribution to serious injury, such as those suffered by Plaintiff Lory D'Addario.

94. Mentor reported serious injuries, including death, caused by its breast implants in a summary format that caused the incredibly delayed correct reporting of these adverse events as medical device reports.

95. On information and belief, Plaintiffs allege that if injuries, including the occurrences of diagnosed cases of BIA-ALCL, had been properly reported, Plaintiffs would have been notified of the risk of developing BIA-ALCL with Mentor® Breast Implants and would have opted for either no implants or safer implants.

96. Defendants violated other federal requirements including the requirements to:

a. establish and maintain a quality system. [21 C.F.R. § 820.5];

b. provide for management responsibility [21 C.F.R. § 820.20];

c. provide for quality audits [21 C.F.R. § 820.22];

d. establish and maintain procedures to control the design of the device in ordered to ensure that specified design requirements are met [21 C.F.R. § 820.30];

e. establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonable be anticipated to have an adverse effect on product quality [21 C.F.R. § 820.70(e)];

f. establish and maintain procedures for acceptance activities, including inspections, tests, or other verification activities [21 C.F.R. § 820.80];

g. identify the "conformance or nonconformance of product with acceptance criteria ... throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed" [21 C.F.R. § 820.86];

h. establish and maintain procedures to control product that fails to conform with specified requirements, including the evaluation of non-conforming products [21 C.F.R. § 820.90(a)];

i. establish and maintain procedures for implementing corrective and preventive action including:

i. identifying the cause of product nonconformities,

ii. identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems,

iii. ensuring that information related to quality problems or nonconforming product is disseminated to hose directly responsible for assuring. [21 C.F.R. § 820.100(a)(1)-(7)].

97. Defendants failed to fulfill these obligations, and, but for the Defendants' intentional failure to comply with the above requirements as well as their clearly-established post-market surveillance obligations, Mrs. D'Addario would have decided against implantation and her injuries would not have occurred.

98. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Mentor had a duty to exercise reasonable

care in adequately warning Plaintiff and/or Plaintiff's treating and implanting medical professionals about the dangers of Mentor's Mentor® Breast Implants, and about all adverse events of which Mentor became aware, and had a post-market duty to identify, monitor and report all adverse events and all risks associated with the product.

99. Despite having knowledge and possession of evidence showing that the use of Mentor® Breast Implants was dangerous and likely to place consumers' health at serious risk, as will be detailed further below, Mentor refused or recklessly failed to identify, disclose and warn of the health hazards and risks associated with the product, and about all adverse events which were known to Mentor.

100. Instead, Defendants marketed, advertised and promoted the product while at the same time consciously refusing and/or recklessly failing to monitor, warn, or otherwise ensure the safety and efficacy for users of Mentor® Breast Implants.

101. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Mentor had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in Mentor® Breast Implants. Mentor refused or recklessly failed to do so.

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

103. The FDA publishes the adverse events in a public, searchable Internet database called the Manufacturer and User Device Experience, or "MAUDE," and updates the report

monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

104. In 2011, the FDA granted an exemption to Mentor for submitting the required adverse event reports related to silicone gel-filled implants by instead submitting post-market spreadsheet reports (PSR) or alternative summary reports (ASR) for "well-known" or expected injuries or malfunctions. *See* FDA Update on the Safety of Silicone Gel-Filled Breast Implants (June 2011) (available at https://www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/breastimplants/ucm260090.pdf). *See also* 21 C.F.R. §§ 803, 803.19.

105. The summary reporting would *not* apply to reportable death or serious injury events which must still be reported to the FDA within 30 days. *See* 21 C.F.R. § 803.50. If the FDA finds that a manufacturer has failed to comply with the reporting requirements, they may revoke the manufacturer's summary reporting exemption. *Id*. at §§ 803.19(d), 803.52. Plaintiffs have to reason to believe that the FDA has revoked Mentor's summary reporting exemption for violating its summary reporting requirements. Over the last two years, the number of adverse event reports pertaining to breast implants has increased exponentially. *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.

106. As of July 18, 2018, the FDA had received 39,406 adverse event reports for breast implants. *See id*. 36 percent of those reports were submitted in the last two years alone. *See id*. Thus, Plaintiffs believe that in July 2017, the FDA rescinded Mentor's privilege to file its adverse events through PSR reports for violation of its reporting requirements hence the enormous uptick in MDR reports filed. In the first seven months of 2018, the number of searchable MDRs grew from 5,158 to 9,019. *See id*.

107. Mentor's state and federal obligations for honest, accurate and timely adverse event reports are at the crux of this case. Indeed, some courts have held that adverse event reports are appropriate to show that a defendant manufacturer was *on notice* of potential serious injuries. *See In Re Tylenol Marketing, Sales Practices and Products Liab. Lit.*, 181 F. Supp. 3d 278, 285–86 (E.D. Pa.2016) ("The extent to which the defendants were on notice of the potentially adverse effects of Tylenol would be relevant to showing how intentional their behavior was in not addressing a potential problem or safety signal").

108. Here, the adverse event reports would be evidence of Mentor's pre-2011 knowledge of BIA-ALCL. *See In re Gadolinium–Based Contrast Agents Products Liability*, 956 F. Supp. 2d 809, 814-15 (N.D. Ohio Jul. 25, 2013) (finding that adverse event reports represent "a safety signal . . . once a safety signal has been identified, the drug manufacturer must take affirmative steps to investigate").

109. As summary reports are not publicly accessible through the MAUDE database, they can only be accessed through a Freedom of Information Act ("FOIA") request to the FDA. Mentor's failures in truthful reporting has led to the concealment of adverse event rates of BIA-ALCL and other serious injuries from Mrs. D'Addario and the general public.

110. 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.

111. 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 the law.

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

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

114. To protect the Mentor® brand, the Defendants intentionally failed in their post-approval study and conditions of approval, and thereby consciously and deliberately concealed its knowledge of known safety risks from the FDA, the medical community, and the public at large. Additionally, the Defendants ignored the available scientific studies and publications indicating an association between textured breast implants and ALCL.

115. At material times, Defendants routinely maintained manufacturing facilities that failed to comply with applicable law and regulations in relation to:

a. The lack of approved software and systems;

b. The use of nonconforming products;

c. Documents which failed to include data or statistical rationale to support sampling plans used to test saline and gel-filled products;

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

e. The omission of any reference in Defendants' reporting to its manufacturing processes as a potential cause of product failures relating to the inability to sterilize the product;

f. The omission of any reference in Defendants' reporting to its manufacturing processes as a potential cause of product failures relating to finished products which showed an "absence of material" or a "fail[ure] to contain gel";

g. The failure to adhere to an appropriate Environmental Monitoring Program;

h. Deficiencies in Defendants' sampling methods for finished product testing;

i. Deficiencies in Defendants' risk analyses and its investigation of non-conformances;

j. Deficiencies in Defendants' environmental monitoring control procedures; and

k. Citations to incomplete data and missing statistical or technical rationales to justify the performance of finished product testing.

116. These deviations contributed to faulty manufacture of Mentor® Breast Implants which were textured, prone to rupture and which were thus defective and adulterated.

117. Mentor failed to warn consumers, healthcare providers, the general public, and the FDA that ALCL or BIA-ALCL, and symptomatology attenuated thereto, was a potential risk of Mentor® Breast Implants, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk.

118. The risk of ALCL or BIA-ALCL was not disclosed or discussed in the product's consumer labeling, despite the availability of substantial evidence that an association existed and was established by at least 2008, but probably much earlier, as further detailed below.

119. Mentor knew of the manufacturing failures and multiple risks associated with implants design, and consciously responded by terminating the studies required within post-market surveillance, in favor of self-serving research that it could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

120. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with Mentor® Breast Implants, the public's knowledge of the risks associated with Mentor® Breast Implants were seriously hampered and delayed. This endangered patient safety, including Plaintiff Lory D'Addario's safety.

B. Breast Implant-Associated Anaplastic Large-Cell Lymphoma

121. Approximately 300,000 total breast implants are placed per year in the U.S. From 2000 to 2016, the number of breast augmentations in the United States rose 37 percent, and reconstructions after mastectomy rose 39 percent.

122. BIA-ALCL is a rare T-cell lymphoma that can develop following breast implants. It is a type of non-Hodgkin's lymphoma, a cancer of the cells of the immune system.

123. The most common presenting symptom for BIA-ALCL is a swollen breast caused by the formation of a delayed unilateral idiopathic seroma occurring between the implant surface and the breast capsule.

124. Upon information and belief, the first case of ALCL in association with silicone breast implants was diagnosed in the early 1990's.

125. In November 2008, the Journal of the American Medical Association ("JAMA") published a retroactive analysis of 11 cases of ALCL between 1994 and 2006, and based upon preliminary findings, concluded that the evidence indicated an association between silicone breast prosthesis and ALCL.

126. In 2011, a summary of published studies, evidence and reports was published that

identified 27 cases of ALCL, and concluded that there was an association between breast implants and ALCL.

127. In March 2015, an analysis identified 173 cases of ALCL. That same month, the French National Cancer Institute announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

128. On May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and classified it as a distinct clinical entity, *separate from other categories of ALCL*.

129. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to discuss the association between breast implants and ALCL and provide ongoing advice.

130. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL.

131. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after receiving breast implants and stated that "[a]t this, time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

132. In May 2017, a global analysis of 40 governmental databases identified 363 cases of BIA-ALCL with 258 being reported to the FDA.

133. A July 2017 article stated that "[e]xperts have called for a common type of breast implant to be banned after it was revealed two people died and 23 developed the same type of cancer in the UK following breast enlargement surgery." Katie Forster, *Calls to ban textured breast implants after two die and 23 develop same type of cancer*, The Independent Online, July

10, 2017, available at https://www.independent.co.uk/news/health/breast-implants-cancer-ban-two-die-23-develop-same-type-textured-common-women-enlargement-cosmetic-a7832996.html. In July 2014, the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") issued a Medical Device Alert "to further encourage healthcare professionals to report cases of ALCL in women who have breast implants or who have had them removed."

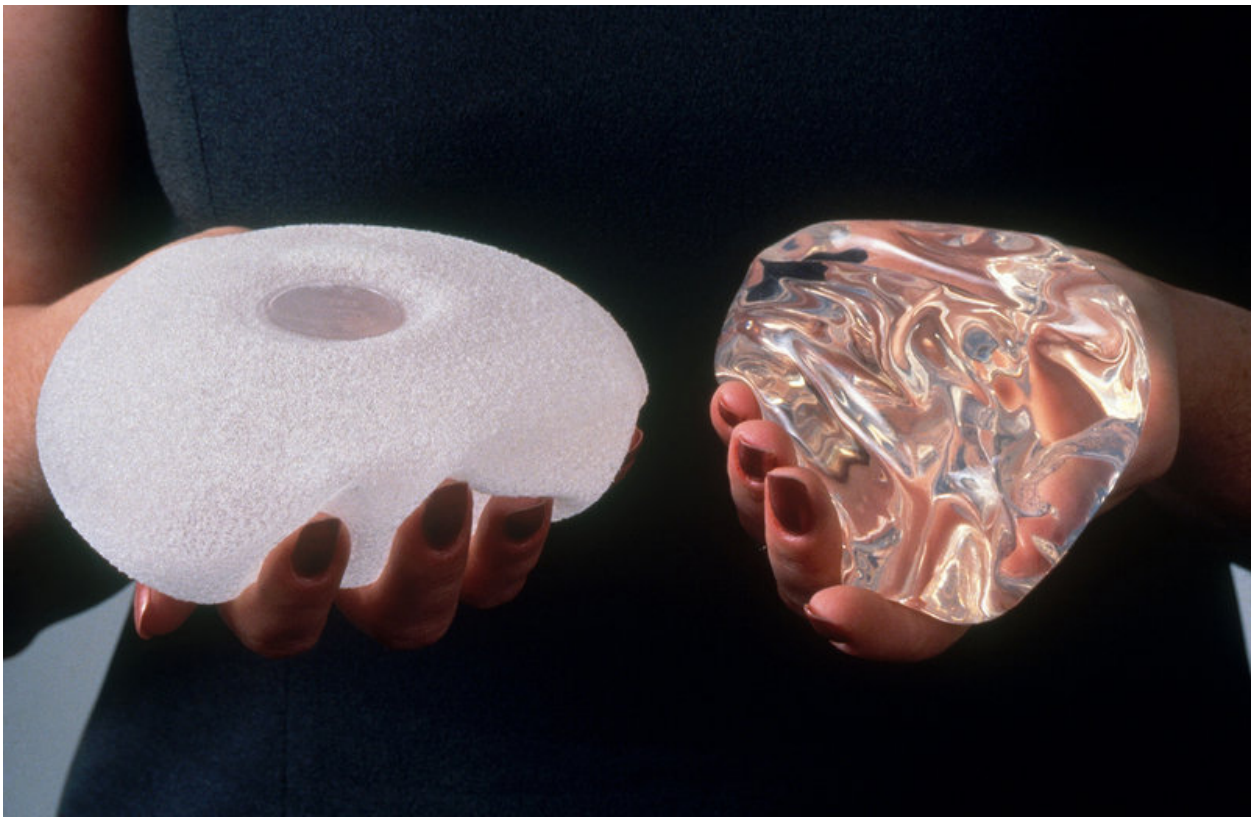
134. A September 2017 update from the FDA reported that the agency had received a total of 414 MDRs related to breast implants and ALCL, including 9 deaths.

135. A recent JAMA Oncology article concluded that "[b]reast implants are associated with increased risk of breast-ALCL", but the absolute risk has not been determined. Mintsje de Boer, et al., *Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast*. JAMA ONCOL. (published January 4, 2018).

136. On May 9, 2018, Australia's Therapeutic Goods Administration ("TGA") reported 72 cases of ALCL in Australian patients.

137. The natural occurrence of this cancer is 1 in 300,000. However, FDA recently cited to studies that place the estimated current risk of BIA-ALCL in women with textured implants to be between 1 in 3,817 and 1 in 30,000. This is consistent with risks reported in Europe. A December 2016 update from the TGA reported a risk of 1 in 1,000 to 1 in 10,000 for textured implants

138. Upon information and belief, BIA-ALCL is mainly associated with textured breast implants.



139. Despite Defendants' knowledge of an association between breast implants and ALCL dating back to the 1990's, Defendants purposefully failed to comply with their clearly-established post-market surveillance obligations and in doing so have exposed many hundreds of thousands of women to the risk of an avoidable cancer.

140. To date, dozens of countries around the world have banned textured breast implants due to their risk of BIA-ALCL and new bans are being imposed frequently.

141. Some of those countries that have not banned textured implants have recommended the use of smooth surface over textured.

142. Additionally, plastic surgeons throughout the United States have publicly denounced the use of textured implants for this reason.

Mentor And Ethicon Are Controlled By J&J, And Participated In Mentor's Marketing, Promotion And Sale Of Mentor® Breast Implants

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

144. For example, a December 2008 J&J press release, still available on J&J's website 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

Available at http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=351111 (bold and underline added).

145. 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.

146. Moreover, a review of J&J's website shows that the "Johnson & Johnson Medical Companies" website prominently lists Mentor and includes 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." Available at https://www.jjmc.ca/our-products/mentor.

147. 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.

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

149. 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.*

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

151. Further, the "About Us" page on Mentor's website discusses its acquisition by J&J and Mentor's "Investor Information" tab links directly to J&J website, specifically a web page entitled "Corporate Reports" with the J&J banner. *See* https://www.jnj.com/about-jnj/annual-reports.

FACTS SPECIFIC TO LORY D'ADDARIO

152. In July 2015, after a diagnosis of breast cancer and mastectomy, Lory D'Addario underwent breast reconstruction during which Mentor® MemoryShape® Breast Implants were implanted.

153. At the time the Mentor implants were placed into Mrs. D'Addario's body, she was not advised, nor did she have any independent knowledge, that the Implants were anything other than safe, life-long products. Nor was she advised that the Implants were associated with and/or known to cause ALCL.

154. Mrs. D'Addario was not advised, and had no independent knowledge that:

a. A significant risk of ALCL existed; or

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

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

d. She might need future surgery in the event of rupture, leakage or seepage, or

e. She might need future imaging and/or diagnostic procedures to check for,

or evaluate ALCL and/or BIA-ALCL.

155. Defendants were aware of the defects in the Mentor® Breast Implants before Mrs. D'Addario's implantation procedure, and the potential for development of BIA-ALCL but did not respond in accordance with their obligations.

156. If Mrs. D'Addario had been advised that implantation was associated with even the slightest risk of developing ALCL and/or BIA-ALCL she would not have proceeded with implantation of the Implants.

157. Had the medical community been made aware of the existence of the true frequency, severity and significance BIA-ALCL in Mentor® Breast Implants, medical professionals and providers, including those who advised and served Plaintiff, would not have advised patients, including Plaintiff, to proceed with implantation of the Mentor products.

158. On July 20, 2017, Mrs. D'Addario had fluid aspirated from her right breast where a seroma had developed. The pathology results were positive for BIA-ALCL.

159. On August 10, 2017, Mrs. D'Addario underwent bilateral implant removal and total capsulectomy. A right breast axillary lymph node which was also involved was removed.

160. Mrs. D'Addario suffered tremendously from the pain of her explant surgery, symptoms of her disease, and recovery.

161. Prior to her development, diagnosis and treatment of ALCL, Mrs. D'Addario 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.

162. 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, 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 true and significant risks associated with Products.

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

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

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

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

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

167. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Mentor® Breast Implants. Defendants were under a duty to disclose the true character, quality and nature of the Products because this was non-public information over which they continue to have exclusive control. Defendants knew that this information was not available to Plaintiff Mrs. D'Addario, her medical providers and/or her health facilities, yet they failed to disclose the information to the public.

168. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purposes of marketing and promoting a profitable product, notwithstanding

the known or reasonably knowable risks.

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

PUNITIVE DAMAGES

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

171. 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 Mentor® Breast Implants.

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

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

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

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

175. 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 LIAIBILITY- MANUFACTURING DEFECT IN VIOLATION OF THE CONNECTICUT PRODUCT LIABILITY ACT Conn. Gen.Stat. §§ 52-572, *et seq*.

(Against All Defendants)

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

177. Defendants are strictly liable for manufacturing Defendants' Mentor® Breast Implants in a defective condition pursuant to Connecticut's Products Liability Act ("CPLA"), Conn. Gen.Stat. §§ 52-572, *et seq*. for failing to follow PMA requirements.

178. At all material times, Defendants' Mentor® Breast Implants were manufactured in a flawed manner that violated the FDA approved design standards and specifications. Such violation runs parallel to Plaintiffs' Connecticut based manufacturing defect claim.

179. Pursuant to the parallel state and federal obligations pursuant to the CPLA and 21 C.F.R § 803.50, Defendants owed Plaintiff Lory D'Addario a duty to warn her of the defective

and unreasonably dangerous conditions of its Mentor® Breast Implants that could cause serious injury or death and to timely and accurately report such adverse events to the FDA.

180. Plaintiff's breast implants were defective as they contained a graham-negative biofilm/endotoxin released from the surface of the textured surface which stimulates lymphocytes.

181. The Mentor® Breast Implants Mrs. D'Addario received were not the breast implants approved by the FDA as those did not contain graham-negative bacteria.

182. Mentor failed to adhere to the specifications imposed and intended by the FDA through the implants' PMA and thus manufactured defective implants containing bacteria stimulating lymphocytes which caused Plaintiff's BIA-ALCL.

183. Defendants' Mentor® Breast Implants were in a defective and unreasonably dangerous condition at the time of sale, beyond which would be contemplated by the ordinary consumer.

184. 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.

185. Defendants' Mentor® Breast Implants were expected to, and did reach, Plaintiff

without substantial change to their condition which was inherently unsafe and unable to be used without subjecting Plaintiff to an unreasonable risk of injury.

186. No ordinary consumer would have contemplated that the Mentor® Breast Implants they have chosen for reconstruction of their breasts post-mastectomy would cause them an additional cancer.

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

188. The defective manufacturing of Mentor® Breast Implants caused Plaintiff's injury.

189. Plaintiff brings this claim pursuant to Connecticut's Products Liability Act for violations of federal requirements including violations of the following: 21 C.F.R. §§ 814.82(a)(2), (a)(9), and (c), among others.

190. 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 Mentor® Breast 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.

191. Mentor® Breast Implants were manufactured with contaminants and/or bacteria that remained on the implants after manufacture such that they were in a defective condition and

unreasonably dangerous at the time they left Defendants' control and were implanted into Plaintiff Lory D'Addario.

192. At all material times, Defendants owed to Plaintiff Lory D'Addario a duty to use reasonable care, pursuant to the federal post-approval requirements, in conducting and reporting on post-approval studies, monitoring, testing, and adequately warning of the dangers, including the development of BIA-ALCL, related to Defendant Mentor's Mentor® Breast Implants.

193. 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.

194. 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.

195. Despite the fact that Defendants knew or should have known that Mentor® Breast Implants were defective and that implantation was unreasonably dangerous and associated with an increased risk of serious injury to consuming patients, Defendants failed to identify, monitor and warn of the defects, adulterations, health hazards, and increased risk of developing BIA-ALCL associated with the use of the product and outwardly misrepresented its safety.

196. Defendants breached their duty, pursuant to federal post-approval requirements, by providing defective breast implants to Plaintiff Lory D'Addario and her physicians.

197. Defendants' specific actions which constitute breaches of these duties to Plaintiff include: providing false, incomplete and misleading information regarding their product, concealing safety information, failing to timely and accurately report adverse events regarding the

Mentor® Breast Implants; failing to report Mentor® Breast Implant products' failure to meet performance specifications and expectations under the PMA and FDA requirements; failing to revise and update product labeling to reflect Mentor's current knowledge of BIA-ALCL through adverse event information; receiving but failing to warn Plaintiff of information which became known or available to Defendants after implantation into Plaintiff; failing to report to the FDA and the medical community Mentor's knowledge and information regarding complaints and specific events about Mentor® Breast Implants causing BIA-ALCL, and additional injuries including:

a. Adverse events requiring removal;

b. Persistent and/or chronic inflammation or autoimmune impacts;

c. suspected cancer linked to breast implants;

d. ALCL diagnoses linked to breast implants; and,

e. BIA-ALCL diagnoses linked to breast implants.

198. For each of the statutes and regulations cited in this Complaint, Plaintiff Lory D'Addario 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 development, promotion, marketing, manufacture, distribution, sale and/or post-market surveillance of Mentor® Breast Implants in one or more of the following ways:

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

b. Failing to warn of the risk of BIA-ALCL;

c. Designing, manufacturing, distributing and selling Mentor® Breast Implants that are dangerous to the consuming public;

d. Designing, manufacturing, distributing and selling Mentor® Breast Implants which differ from the specifications set forth in the PMA, its Supplements, and the Conditions of Approval;

e. Failing to conduct regular risk analyses of Mentor® Breast Implants; and,

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

199. Mentor® Breast Implants, which were defectively manufactured, distributed, tested, sold, marketed, advertised, and represented by Defendants without adequate warnings of the risks of BIA-ALCL, and with false and implied warranties of the product's safety, were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Mentor® Breast Implants and Defendants wrongful acts and omissions.

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

COUNT 2 – NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

201. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Mentor® Breast Implants described herein, owed a duty to provide accurate and complete information regarding their product.

202. Defendants negligently misrepresented material information regarding their product including, but not limited to, its safety.

203. Defendants knew or should have known that their breast implants were not actually safe as they were manufactured in a defective condition.

204. At the time of Defendants' negligent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed relied upon them and believed them to be true.

205. Plaintiff relied on the Mentor® Breast Implants' FDA approval and relied on the warnings and representations provided to her.

206. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding their product.

207. Plaintiff reasonably relied upon Defendants' negligent misrepresentations and suffered severe and permanent injuries, namely the development of BIA-ALCL, as a result thereof.

208. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, 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.

WHEREFORE, Plaintiff Lory D'Addario 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.

COUNT 3 - BREACH OF EXPRESS AND IMPLIED WARRANTIES
(Against All Defendants)

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

210. As previously alleged, Mentor® Breast Implants were manufactured in a defective condition, not in accordance with FDA specifications.

211. Plaintiff brings this claim pursuant to Conn. Gen.Stat. §§ 52-572, *et seq*., Conn. Gen.Stat. §§ 41a-2-314 (implied warranty of merchantability), Conn. Gen.Stat. §§ 41a-2-315 (implied warranty of fitness for a particular purpose), and the Connecticut Unfair Trade Practices Act (CUTPA) Conn. Gen.Stat. §§ 42-110b which provide a damages remedy for violations of state laws and for violations of federal requirements including 21 U.S.C. § 360c(a)(3)(A).

212. Defendants, in their manufacturing, design, distribution, marketing and promotion of Mentor® Breast Implants voluntarily made implied and express warranties that the Mentor® Breast Implants were safe and effective for Plaintiff and members of the public generally and that they would" restore patients' appearance, self-esteem and quality of life."

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

214. Defendants breached the implied warranty of merchantability by selling products that were not of merchantable qualify, did not increase Plaintiff's quality of life, self-esteem or appearance, and were not safe and fit for their intended use.

215. Defendants breached the express warranties as described above in providing a product that was not safe as warranted.

216. Such affirmations and promises were made to induce Plaintiff, her physicians and the general public to purchase the products and did in fact induce Plaintiff's physician to recommend, and Plaintiff to select, Mentor® Breast Implants.

217. Plaintiff and Plaintiff's physician relied upon Defendants' voluntary express and implied warranties that the Mentor® Breast Implants were safe and effective for use.

218. Defendants breached its express warranty as the implants were placed into the stream of commerce by the Defendants with the express warranty that they were an FDA -approved class III device, which includes the reasonable assurance that the implants are safe and effective.

219. The requirements of truthful, accurate, and non-misleading warranties do not impose any different or additional requirements on defendants as required by federal law.

220. Mentor® Breast Implants do not conform to these implied or express warranties and representations because Mentor® Breast Implants are not safe or effective for their ordinary purpose, nor are they safer or more effective than other breast implants available, they were not manufactured in the specifications required by the FDA.

221. Defendants' breach of warranties directly caused and were the substantial factor in causing Plaintiff and Plaintiff's physician to choose Mentor® Breast Implants and develop BIA-ALCL and the profound injuries resulting therefrom.

222. 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 Lory D'Addario 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.

COUNT 4 – VIOLATION OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT (CUTPA)
(Against All Defendants)

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

224. The Defendants' acts and omissions previously set forth are in in violation of Conn. Gen.Stat. §§ 42-110b, et seq. which provides a damages remedy for violations of state laws and for violations of federal requirements including 21 U.S.C. § 360c(a)(3)(A).

225. Defendants, in their manufacturing, design, distribution, marketing and promotion of Mentor® Breast Implants, which is part of Defendants' primary trade, were involved in unfair and deceptive trade practices.

226. Such deceptive trade practices caused Plaintiff, a consumer, and her physician to choose Mentor® Breast Implants which were the direct cause of Plaintiff's BIA-ALCL.

227. Plaintiff could not reasonably have known or avoided such implants as she was unaware of the risks of developing BIA-ALCL from Mentor® Breast Implants.

228. 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 Lory D'Addario 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.

COUNT 5– LOSS OF CONSORTIUM
(Against All Defendants)

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

230. As a result of the injuries and damages caused to Plaintiff Lory D'Addario by Defendants' tortious conduct in violation of federal law and the post-approval requirements, Lory D'Addario was unable to perform activities she had previously commonly performed for the household, for the family, and for her own support. Consequently, Plaintiff Peter D'Addario was required to:

a. Perform all activities and upkeep around the house, including care of the barn and animals;

b. Support Lory D'Addario by performing activities she previously performed for her own needs and maintenance;

c. Take over many of the activities that Lory D'Addario previously commonly performed as a parent to Lory D'Addario and Peter D'Addario child.

231. As a result of Defendants' defective and adulterated Mentor® Breast Implants and the development of Lory D'Addario's BIA-ALCL, Plaintiff Peter D'Addario effectively lost the companionship and accompaniment of his wife.

232. As a further result of Defendants' defective and adulterated Mentor® Breast Implants and the injuries they caused to Lory D'Addario and the resulting demands placed upon Peter D'Addario has suffered lost wages and income.

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

JURY DEMAND

234. Plaintiffs demand a trial by jury on all of the triable issues within this pleading.

PRAYER FOR RELIEF

235. WHEREFORE, Plaintiffs request that the Court enter judgment in their favor and against Defendants, awarding Plaintiffs:

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.

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

Dated: July 19, 2019

Respectfully submitted,

ROSS FELLER CASEY, LLP

/s/ Brian J. McCormick, Jr.
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Joel J. Feller, Esquire
Brian J. McCormick, Jr., Esquire
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JS 44 (Rev. 07/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

LORY D'ADDARIO, and PETER D'ADDARIO, h/w

(b) County of Residence of First Listed Plaintiff Middlesex Co., CT
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*
Brian J. McCormick, Jr., Esquire, ROSS FELLER CASEY, LLP
One Liberty Place, 1650 Market St., Suite 3450, Phila., PA 19103
215-574-2000 bmccormick@rossfellercasey.com

DEFENDANTS

SEE ATTACHED LIST OF DEFENDANTS

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332; Diversity of citizenship

Brief description of cause:
Personal Injury; Health Care/Pharmaceuticals Personal Injury Product Liability

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ in excess of $75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 7/19/19

SIGNATURE OF ATTORNEY OF RECORD /s/ Brian J. McCormick, Jr..

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

LIST OF DEFENDANTS

JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933

ETHICON, INC.
U.S. ROUTE 22
SOMERVILLE, NEW JERSEY, 08876

MENTOR WORLDWIDE LLC
33 TECHNOLOGY DRIVE
IRVINE, CALIFORNIA, 92618