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KRISTEN WATSON and JAMES WATSON IV, h/w 1962 Winsome Lane Adams, TN 37010, Plaintiffs v. 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, Defendants.	:	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: MIDDLESEX COUNTY** **DOCKET NO.** **CIVIL ACTION** **COMPLAINT**

Plaintiffs Kristen and James Watson IV, h/w, by and through their attorneys, Ross Feller Casey, LLP, based on information and belief, and for causes of action against the Defendants Johnson & Johnson, Ethicon, Inc., and Mentor Worldwide, LLC, and each of them, hereby allege as follows:

INTRODUCTION

1. Plaintiffs KRISTEN AND JAMES WATSON IV, h/w, bring this action against Defendants Johnson & Johnson, Ethicon, Inc. 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® Saline 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. Mentor is the only manufacturer whose breast implants are made in the United States. Over 20 years, more than 5 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's Saline 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

5. Plaintiff Kristen Watson is, and at all material times was, a resident of Tennessee.

6. Plaintiff James Watson IV is, and at all material times was, the husband of Plaintiff Kristen Watson and a resident of Tennessee.

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 Johnson & Johnson.

11. Defendant Mentor Worldwide LLC 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.

14. Mentor remains a leading supplier of medical products for the global aesthetic medicine market. The company develops, manufactures, and markets products for aesthetics medical procedures.

15. Defendant Mentor is a wholly-owned subsidiary of Defendant Johnson & Johnson.

16. Johnson & Johnson acquired Mentor Corporation in 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 Johnson & Johnson company.

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

18. 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.

19. 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® Saline 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 the Defendants' actions, Plaintiff Kristen Watson would not have suffered the severe injuries and harms which have resulted from implantation of Mentor® Saline Breast Implants into Plaintiff Kristen Watson's body.

20. 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, as well as Middlesex County, including the acts which caused or contributed to Plaintiffs' injuries.

21. 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.

22. The amount in controversy exceeds the prevailing local arbitration limits.

FACTS REGARDING MENTOR® SALINE BREAST IMPLANTS

General Information Relating To Breast Implants

23. 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.

24. 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.

25. Saline breast implants have a silicone outer shell that is filled with saline. They are available in various sizes and can have either a smooth or textured shell. Saline-filled breast implants are approved for breast augmentation in women age 18 or older and for breast reconstruction in women of any age.

26. 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).

27. 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").

28. 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.

29. 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.

30. 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.

A. Information Specific to Mentor® Saline Breast Implants

31. Pursuant to FDA action in the second half of 1999, the FDA required any manufacturer wishing to continue to market saline-filled implants in the U.S. to file an application for pre-market approval of such products by November 17, 1999. Mentor was among the three manufacturers of saline-filled breast implants whose PMA applications were accepted for filing and, in accordance with FDA regulations, each of the three applications was referred to an FDA Advisory Panel on general and plastic surgery.

32. The Advisory Panel met in open session on March 1-3, 2000 to consider the applications.

33. On May 10, 2000, the FDA announced that it had approved Mentor's application for PMA of its saline-filled breast implants for augmentation in women age 18 and older and for reconstruction in women of any age. These products were previously available in the U.S. marketplace as 510(k) devices.

34. As conditions of the 2000 approval, the FDA required Mentor to conduct post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Mentor® Saline Breast Implants included:

a. *10-year Post-Approval Studies*– To assess long-term clinical performance of the device. These studies were designed to follow women for 10 years after initial implantation.

b. *Retrieval Study*- To collect visual examination, physical, and histological data on explanted implants to determine the mode of failure of implants.

c. *Focus Group Studies* – To improve the format and content of the patient labeling.

d. *Mechanical Testing*

35. The FDA further stated that "[f]ailure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA."

36. The FDA continued – "Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

37. Thus, as a condition of its premarket approval, Mentor was required to provide data on the safety and effectiveness of the specific breast implant products.

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

39. 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.

40. 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.

41. 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 their product and breast cancer, Anaplastic Large-Cell Lymphoma ("ALCL") and/or Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL").

42. 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.

43. Specifically, Defendants' 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 [21 CFR §§803.50];

b. Monitoring the product and submitting reports to the FDA of any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 CFR §814];

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

f. Submitting postapproval reports annually including unpublished reports of data from any clinical investigations or nonclinical laboratory studies and reports in scientific literature concerning the device [21 CFR §814.39];

g. Reporting on any adverse reaction attributable to the device and device defects [21 CFR §814]

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

44. Defendants 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 Kristen Watson.

45. Defendants failed to fulfill these obligations, and, but for the Defendants' intentional failure to comply with their clearly-established post-market surveillance obligations, Mrs. Watson would have decided against implantation and her injuries would not have occurred.

46. 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® Saline 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.

47. Despite having knowledge and possession of evidence showing that the use of Mentor® Saline 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.

48. 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® Saline Breast Implants.

49. At relevant times, Defendants advertised, promoted and marketed their Mentor® Saline Breast Implants as safe for use by women as evidenced by their advertising and promotional efforts.

50. 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® Saline Breast Implants. Mentor refused or recklessly failed to do so.

51. 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.

52. The FDA publishes the adverse events in a public, searchable Internet database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

53. 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.

54. 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.

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

56. 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® Saline 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 Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL").

57. Specifically, Defendants knew or should have known that the new breast implants, specifically the textured design models, were associated with Anaplastic Large Cell Lymphoma.

58. 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 Anaplastic Large Cell Lymphoma.

59. Defendants also had a duty to exercise reasonable care in the manufacture, development, design, marketing, labeling, distributing, and sale of the product after it was approved for sale by the FDA in 2000, which does not impose duties or requirements materially different from those imposed by federal law. Defendants failed or refused to do so.

60. 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.

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

62. 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® Saline-Filled Breast Implants, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk.

63. 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.

64. 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.

65. 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® Saline Breast Implants, the public's knowledge of the risks associated with Mentor® Saline Breast Implants were seriously hampered and delayed. This endangered patient safety, including Plaintiff Kristen Watson's safety.

B. Breast Implant-Associated Anaplastic Large-Cell Lymphoma

66. 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%, and reconstructions after mastectomy rose 39%.

67. Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("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.

68. 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.

69. Upon information and belief, the first case of anaplastic large cell lymphoma (ALCL) in association with silicone breast implants was diagnosed in 1994 and reported in 1996.

70. In November 2008, 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.

71. 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.

72. 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."

73. 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*.

74. 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.

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

76. 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."

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

78. 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."

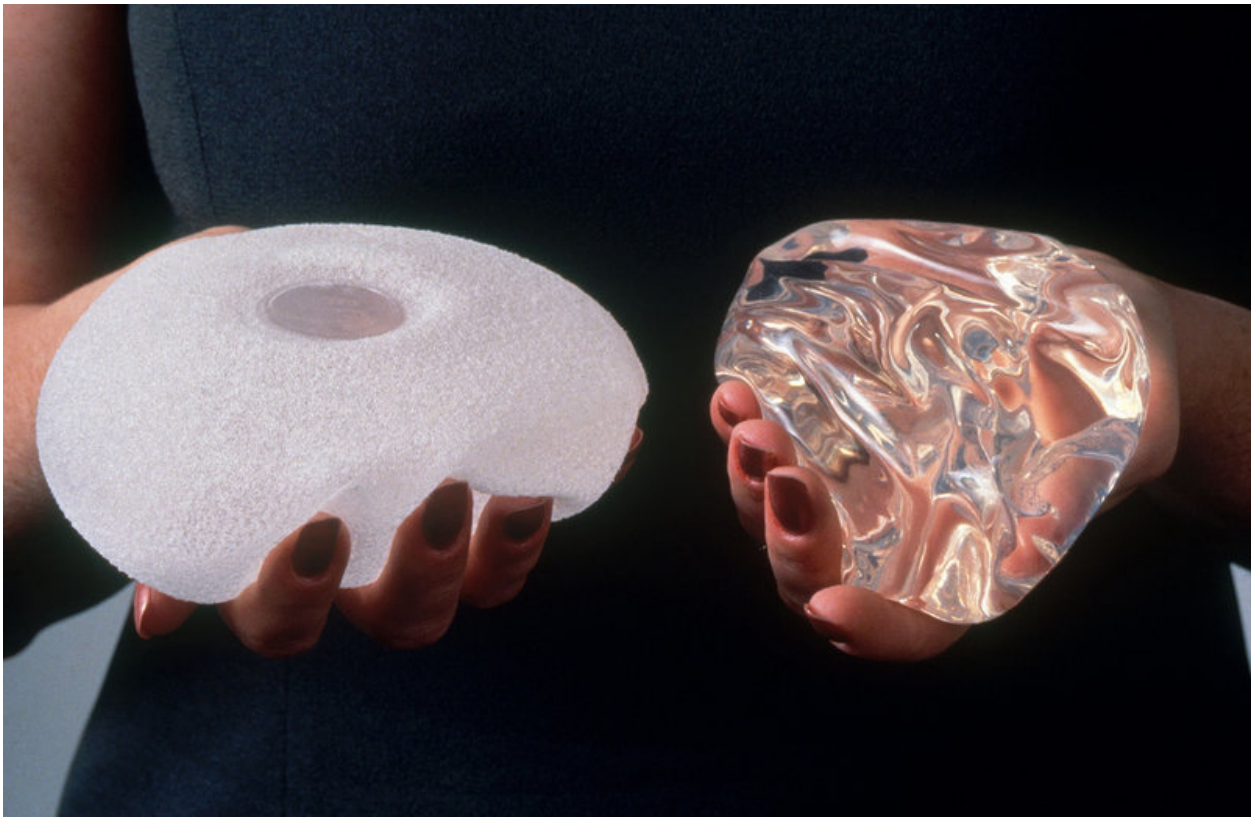
79. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including 9 deaths.

80. 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).

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

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

83. Upon information and belief, BIA-ALCL is mainly associated with textured breast implants, however, there have been cases of BIA-ALCL in women with smooth implants.



84. Despite knowledge on the part of the Defendants of an association between breast implants and ALCL dating back into the mid 1990's, Defendants purposefully failed to comply with their clearly-established post-market surveillance obligation and in doing so have exposed many hundreds of thousands of women to life-altering and avoidable cancer.

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

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

86. For example, a Johnson & Johnson 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, italics and underline added).

87. 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.

88. 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.

89. 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.

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

91. 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.*

92. The announcement also contained a link from J&J's website to the MemoryGel site.

93. 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 Johnson & Johnson banner (https://www.jnj.com/about-jnj/annual-reports).

FACTS SPECIFIC TO KRISTEN WATSON

94. On June 28, 2005, Kristen Watson underwent breast implantation surgery during which Mentor® Saline Breast Implants were implanted.

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

96. Mrs. Watson 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; or

f. The saline with which Mentor fills its implants contains many compounds and metals which are toxic to the human body.

97. After Defendant received approval of Mentor® Saline Breast Implants, but before Mrs. Watson's implantation procedure, Defendants became aware of defects in the Mentor® Saline Breast Implants and harm the product was causing, but did not respond in accordance with their obligations.

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

99. Had the medical community been made aware of the existence of the true frequency, severity and significance BIA-ALCL in Mentor® Saline 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.

100. During the summer of 2017, Mrs. Watson noticed a lump under her left armpit. Because she understood the Mentor® Saline Breast Implants to be stable and safe products, she did not associate the lump with the Products, nor did her treating medical professionals.

101. On September 29, 2017, Mrs. Watson's underwent an ultrasound and mammogram which were abnormal and revealed enlarged axillary lymph nodes.

102. On October 10, 2017, a tissue biopsy was taken of the left lymph node which was suggestive of a malignant neoplasm.

103. On October 19, 2017, Mrs. Watson's diagnosis was amended to that of Anaplastic Large-Cell Lymphoma.

104. On October 24, 2017, Mrs. Watson underwent surgery for the removal of the left axillary lymph node.

105. On October 26, 2017, Mrs. Watson was informed that she had anaplastic large cell lymphoma ("ALCL"). It was not until several weeks later that she learned that her ALCL was associated with her Mentor breast implants.

106. On November 20, 2017, Mrs. Watson began an aggressive chemotherapy regimen of chemotherapy for three days in a row, every 21 days, for a period of 6 months.

107. On June 12, 2018, Mrs. Waston underwent invasive explant surgery at which point her Mentor® Saline Breast Implants were removed along with the scar tissue capsules.

108. Thereafter, Mrs. Watson had to undergo physical therapy and occupational therapy. She also required vestibular therapy for dizziness and balance which has not been resolved. She will soon be treating with a neurologist.

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

110. Mrs. Watson exercised reasonable diligence at all times in investigating her injuries, and could not have discovered at any materially earlier time that her injuries were caused by Defendants' product.

111. Due to the Defendants' failures to comply with their post-approval surveillance obligation, Mrs. Watson did not suspect, nor did she have reason to suspect, that her injuries were caused by Mentor® Saline Breast Implants, or by Mentor's tortious conduct.

112. 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.

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

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

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

115. 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® Saline Breast Implants.

116. 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.

117. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Mentor® Saline 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. Watson, her medical providers and/or her health facilities, yet they failed to disclose the information to the public.

118. 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.

119. 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

120. 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.

121. 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® Saline Breast Implants.

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

123. At all times relevant hereto, Defendants knew of the defective nature of their Mentor® Saline Breast Implants, and continued to design, manufacture, market, label, and sell Mentor® Saline 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® Saline Breast Implants, including Plaintiff who did suffer such harm.

124. Defendants misled regulators, the medical community and the public at large, including Plaintiff, by making false and misleading representations about the safety of Mentor® Saline 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.

125. 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 - NEGLIGENCE AND NEGLIGENCE *PER SE*
(Against All Defendants)

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

127. At all material times, Defendants owed to Plaintiff Kristen Watson 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® Saline Breast Implants.

128. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor® Saline Breast Implants, including the devices which were implanted into Plaintiff Kristen Watson.

129. Plaintiff was implanted with Mentor® Saline Breast Implants which were

defective, dangerous and adulterated upon manufacture, and without adequate warnings, 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.

130. Defendants had parallel duties under state and federal law pursuant to the federal post-approval requirements, to exercise reasonable care in providing adequate warnings about the risks and dangers of Mentor® Saline Breast Implants, including the risk of developing BIA-ALCL, which was known or reasonably knowable to Defendants at the time of distribution, and that Defendants had come to know in light of adverse conditions and events experienced by patients in whom the Defendants' products were implanted.

131. Defendants breached their duty, pursuant to federal post-approval requirements, by failing to adequately warn Plaintiff Kristen Watson and her physicians, either directly or by not timely and accurately reporting to regulatory authorities the risks of serious defects, adulterations and life-altering complications, including the development of BIA-ALCL, experienced by patients in whom the products were previously implanted.

132. Defendants' specific actions which constitute breaches of these duties to Plaintiff include: failing to timely and accurately report adverse events regarding the Mentor® Saline Breast Implants; failing to report the Mentor® Saline Breast Implants' 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; receiving but failing to warn or report to the FDA and the medical community Mentor's knowledge and information regarding complaints and specific events about Mentor® Saline 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.

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

134. At all material times, Defendants knew and intended that the medical community and/or patients would rely upon Defendants' disseminated information in deciding whether to purchase and/or implant Mentor® Saline Breast Implants.

135. At all material times, Defendants knew and intended that patients who were implanted with Mentor® Saline Breast Implants would, in reliance on false information, be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Mentor® Saline Breast Implants, causing them to develop cancer requiring future removal surgeries and to suffer debilitating injuries and conditions, and emotional turmoil attenuated thereto.

136. Plaintiff and/or Plaintiff's physicians reasonably relied on Defendants' negligent misrepresentations and omissions, as Defendants intended, and would not have made the same decision(s) if provided the required information.

137. As a proximate and foreseeable result of the foregoing misrepresentations by Defendant, Plaintiff has suffered and will continue to suffer from BIA-ALCL and its

accompanying symptoms including, but not limited to, severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

138. For each of the statutes and regulations cited in this Complaint, Plaintiff Kristen Watson 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® Saline 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® Saline Breast Implants that are dangerous to the consuming public;

d. Designing, manufacturing, distributing and selling Mentor® Saline 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® Saline Breast Implants; and,

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

139. As a proximate and legal result of Defendants' failure to exercise reasonable care in the warning, design, manufacture, distribution and sale of the Mentor® Saline Breast Implants implanted into Plaintiff, Plaintiff has suffered and will continue to suffer severe from BIA-ALCL and its accompanying symptoms including physical injuries, pain and suffering, severe emotional distress, mental anguish, economic loss, future medical care and treatment, lost

wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Kristen Watson 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 – STRICT PRODUCTS LIABILITY: FAILURE TO WARN
(Against All Defendants)

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

141. At all material times, Defendants were engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Mentor® Saline Breast Implants.

142. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor® Saline Breast Implants, including those which were implanted into Plaintiff Kristen Watson.

143. Plaintiff was implanted with Mentor® Saline Breast Implants which were defective, dangerous and adulterated upon manufacture, and which were manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

144. At all material times, Defendants intended for the Mentor® Saline Breast

Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew the product would be surgically implanted into members of the general public, including Plaintiff.

145. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects, adulterations and life-altering complications faced by patients, including patients who had reported adverse, hazardous ailments and conditions, rendering the product defective and unreasonably dangerous.

146. Defendants also failed to revise its labeling to give warnings consistent with adverse event information which was known or available to Mentor at the time of distribution, and failed to warn Plaintiff of information which became known or available to Mentor after implantation into Plaintiff.

147. Plaintiff's Mentor® Saline Breast Implants were defective and adulterated at the time of sale and distribution, and at the time they left Defendant Mentor's possession, and Defendants failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and that the product was susceptible to causing ALCL and/or BIA-ALCL as suffered by Plaintiff Kristen Watson.

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

149. Despite the fact that Defendants knew or should have known that implantation of Mentor® Saline Breast Implants was unreasonably dangerous and was likely to seriously jeopardize the health of consuming patients, Defendants failed to identify, monitor and warn of the defects, adulterations, health hazards and increased risks associated with the product.

150. The defects, adulterations and increased risks inherent in Mentor® Saline Breast

Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the defects.

151. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants when she consented to the implantation of Mentor® Saline Breast Implants.

152. At all relevant times, Plaintiff's Mentor® Saline Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

153. The Mentor® Saline Breast Implants manufactured, designed, promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Plaintiff's physician without substantial change in the condition in which they were sold.

154. Defendants knew that Mentor® Saline Breast Implants would be used by the ordinary purchaser or user without inspection for defects and adulterations and without knowledge of the hazards involved in such use.

155. Mentor® Saline Breast Implants, which were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, and caused Plaintiff's injury of BIA-ALCL, which would not have occurred but for the use of Mentor® Saline Breast Implants.

156. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Mentor® Saline Breast Implants.

157. As a proximate result and/or substantial factor of Mentor® Saline Breast Implants' defective and adulterated condition at the time they were sold, Plaintiff suffered and

will continue to suffer severe physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Kristen Watson 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 3 – STRICT PRODUCTS LIABILITY
(Against All Defendants)

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

159. At all material times, Defendants were engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Mentor® Saline Breast Implants.

160. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor® Saline Breast Implants, including those which were implanted into Plaintiff Kristen Watson.

161. Plaintiff was implanted with Mentor® Saline Breast Implants which were defective, dangerous and adulterated upon manufacture, and which were manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements,

resulting in product failure and serious injury to Plaintiff.

162. At all material times, Defendants intended for the Mentor® Saline Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew the product would be surgically implanted into members of the general public, including Plaintiff.

163. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects, adulterations and life-altering complications such as the development of BIA-ALCL described in this Complaint, rendering the device defective and unreasonably dangerous.

164. Defendants also failed to revise the Product's labeling to give warnings consistent with adverse event information which was known or available to Defendants at the time of distribution, and failed to warn Plaintiff of information which became known or available to Defendants after implantation into Plaintiff.

165. Plaintiff's Mentor® Saline Breast Implants were defective and adulterated at the time of sale and distribution, and at the time they left Defendants' possession, and Defendants failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and that the product was susceptible to causing BIA-ALCL as suffered by Plaintiff Kristen Watson.

166. Defendants knew or should have known that there was a significant risk that its Mentor® Saline Breast Implants caused, and did in fact increase the risk of contracting, BIA-ALCL. Defendants deliberately refused to disclose this information to FDA, the medical community and the public.

167. Despite the fact that Defendants knew or should have known that implantation of Mentor® Saline Breast Implants was unreasonably dangerous and was associated with an

increased risk of serious injury to consuming patients, Defendants failed to monitor and warn of the defects, adulterations, health hazards and increased risks associated with the product.

168. The defects, adulterations and increased risks inherent in Mentor® Saline Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the defects.

169. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendant Mentor when she consented to the implantation of Mentor® Saline Breast Implants.

170. At all relevant times, Plaintiff's Mentor® Saline Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

171. The Mentor® Saline Breast Implants manufactured, designed, promoted, marketed, distributed, and sold by Defendant were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were sold.

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

173. Mentor® Saline Breast Implants, which were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, were a substantial contributing factor in bringing about Plaintiff's injuries, which would not have occurred but for the use of Mentor® Saline Breast Implants.

174. The defective and adulterated product was a substantial contributing factor in bringing about or did in fact cause the injuries to Plaintiff that would not have occurred but for

the use of Mentor® Saline Breast Implants.

175. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Mentor® Saline Breast Implants.

176. As a proximate result and/or substantial factor of Mentor® Saline Breast Implants' defective and adulterated condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Kristen Watson 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 4 - NEGLIGENT MISREPRESENTATION
(Against All Defendants)

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

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

179. Defendants falsely represented that the aforesaid product was safe and. These representations by Defendants were in fact false and the product was not safe for said purpose

and was in fact dangerous to the health of Plaintiff. Defendants concealed, omitted, or minimized the side effects of Mentor® Saline Breast Implants or provided misinformation about adverse reactions, risks and potential harms from Mentor® Saline Breast Implants and succeeded in persuading consumers and Plaintiff to purchase and implant Mentor® Saline Breast Implants despite the product's lack of safety and the risk of adverse effects, including ALCL and/or BIA-ALCL.

180. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and healthcare providers information about the propensity of their product to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of said product despite the lack of information regarding same.

181. Defendants' misrepresentations in promoting and marketing Mentor® Saline Breast Implants created and reinforced a false impression as to the safety of Mentor® Saline Breast Implants, thereby placing consumers at risk of serious and potentially lethal effects.

182. The aforesaid misrepresentations were made by Defendants with the intent to induce Plaintiff to use the product, to the detriment of Plaintiff.

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

184. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product. Plaintiff reasonably believed defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mentor® Saline Breast Implants.

185. 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 Kristen Watson 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 - FRAUDULENT MISREPRESENTATION
(Against All Defendants)

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

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

188. Defendants' fraudulently misrepresented information regarding their product including, but not limited to, its propensity to cause serious physical harm.

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

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

191. Defendants acted with deliberate intent to deceive and mislead Plaintiff.

192. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

193. 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 Kristen Watson 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 6 – FRAUDULENT CONCEALMENT
(Against All Defendants)

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

195. Prior to Plaintiff's use of the Mentor® Saline Breast Implants and during the period in which Plaintiffs actually used the Mentor® Saline Breast Implants, Defendants fraudulently suppressed material information regarding the safety and efficacy of the Mentor® Saline Breast Implants and the availability of an alternative feasible safer design. Furthermore, Defendants fraudulently concealed the safety information about the use of Mentor® Saline

Breast Implants. Plaintiffs believe the fraudulent misrepresentations and fraudulent concealment described throughout this Complaint were intentional so as to maintain the sales volume of the Mentor® Saline Breast Implants.

196. Defendants intentionally concealed safety issues with the Mentor® Saline Breast Implants in order to induce consumers, including Plaintiffs, to purchase Mentor® Saline Breast Implants, and to induce healthcare providers to utilize Mentor® Saline Breast Implants.

197. At the time Defendants concealed the fact that Mentor® Saline Breast Implants were not safe as designed and marketed, Defendants were under a duty to communicate this information to the general public in such a manner that the general public could appreciate the risks associated with Mentor® Saline Breast Implants, generally.

198. Plaintiff relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of Mentor® Saline Breast Implants.

199. As a direct and proximate result of Defendants' malicious and intentional concealment of material and information, Defendants caused or significantly contributed to Plaintiff's injuries.

200. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff and the public.

201. Defendants' acts before, during and/or after the act causing Plaintiff's injuries prevented Plaintiff from discovering the injury or cause thereof.

202. Defendants' conduct, as described in the preceding paragraphs and in the Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, needless and reckless, without regard to the consequences or the rights and safety of Plaintiff and the public.

203. As a direct and proximate result of Defendants' fraudulent concealment concerning Mentor® Saline Breast Implants, as described herein, Plaintiff suffered and continues to suffer from the damages for which she is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

WHEREFORE, Plaintiff Kristen Watson 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 7 – VIOLATION OF TENNESSEE CONSUMER PROTECTION ACT
(Against All Defendants)

204. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint. Plaintiffs plead all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the laws of Plaintiffs' resident State.

205. Plaintiff purchased and used Mentor® Saline Breast Implants and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws applicable to the laws of Plaintiffs' resident State.

206. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing Mentor® Saline Breast Implants have characteristics, ingredients, uses benefits or quantities that they do not have;

b. Advertising Mentor® Saline Breast Implants with the intent not to sell them as advertised;

c. Over-promotion of Mentor® Saline Breast Implants, including but not limited to over-promotion of their safety and efficacy;

d. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

207. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Mentor® Saline Breast Implants.

208. Defendants violated consumer protection laws, specifically the Tennessee Consumer Protection Act ("TCPA"), Tenn. Code Ann. § 47-18-101, *et seq*. or of other states, if those states law are deemed to apply.

209. Defendants uniformly communicated the purported benefits of Mentor® Saline Breast Implants while failing to disclose the serious and dangerous risk of developing BIA-ALCL related to the use of Mentor® Saline Breast Implants, and the true state of Mentor® Saline Breast Implants' safety, its efficacy, and its usefulness. Defendants made these representations to physicians, consumers, including Plaintiff, in the marketing and advertising described herein. Defendants' conduct in connection with Mentor® Saline Breast Implants was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Mentor® Saline Breast Implants.

210. As a direct and proximate result of Defendants' violation of consumer protection laws concerning Mentor® Saline Breast Implants, as described herein, Plaintiff suffered and continues to suffer from serious physical injury, pain, suffering, loss of income, loss of

opportunity, loss of family and social relationships, medical, hospital and surgical expenses for which Defendants are liable.

COUNT 8 – STRICT LIABILITY IN VIOLATION OF TENNESSEE PRODUCTS LIABILITY ACT
(Against All Defendants)

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

212. In the alternative, Defendants are liable under Tennessee's Products Liability ("TPLA") Act, Tenn. Code Ann. §§ 29-28-101, *et seq*.

213. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor® Saline Breast Implants, including the devices which were implanted into Plaintiff Kristen Watson.

214. At all material times, Defendants knew and intended for the Mentor® Saline Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and impliedly warranted, and falsely and negligently represented, the products to be of merchantable quality, safe and fit for use. These false representations and implied warranties were in fact false and the product was not safe for said purpose. Defendants concealed, omitted, or minimized the side effects of Mentor® Saline Breast Implants, including the risks of developing BIA-ALCL, and negligently misrepresented that the product was safe.

215. At all material times, Defendants' fraudulently suppressed material information regarding the safety and efficacy of the Mentor® Saline Breast Implants and the availability of an alternative feasible safer design. Furthermore, Defendants fraudulently concealed the safety information about the use of Mentor® Saline Breast Implants to maintain the sales volume of the

Mentor® Saline Breast Implants and to induce consumers and healthcare providers to utilize the product.

216. The Mentor® Saline Breast Implants manufactured, designed, promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were sold.

217. At all material times, Defendants owed to Plaintiff Kristen Watson 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® Saline Breast Implants.

218. At all material times, Defendants owed to Plaintiff Kristen Watson and the general public a duty to provide accurate and complete information regarding their product including the fact that the Mentor® Saline Breast Implants were not safe as designed and marketed.

219. Plaintiff was implanted with Mentor® Saline Breast Implants which were defective, dangerous and adulterated upon manufacture, sale, and distribution, and which were manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regularly requirements, resulting in product failure and serious injury to Plaintiff.

220. The Mentor® Saline Breast Implants were defective, dangerous and adulterated, and at the time they left Defendant Mentor's possession.

221. Defendants impliedly warranted, and negligently and fraudulently misrepresented, the safety of the product and failed to adequately warn of the risks of serious defects, adulterations and life-altering complications such as the development of ALCL and/or

BIA-ALCL as suffered by Plaintiff Kristen Watson.

222. Defendants intentionally concealed the safety issues of Mentor® Saline Breast Implants, including the risk of developing BIA-ALCL, in order to induce consumers and healthcare providers to use Mentor® Saline Breast Implants.

223. The defects, adulterations and increased risks inherent in Mentor® Saline Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the defects.

224. Plaintiff and Plaintiff's physician reasonably relied upon the implied warranties, false and fraudulent misrepresentations and concealments regarding the safety of Mentor® Saline Breast Implants when consenting and implanting the implants.

225. At all relevant times, Plaintiff's Mentor® Saline Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

226. Defendants knew or should have known that there was a significant risk that its Mentor® Saline Breast Implants caused, and did in fact increase the risk of developing, BIA-ALCL.

227. Such false, fraudulent and negligent misrepresentations and failure to warn 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.

228. Defendants had parallel duties under state and federal law pursuant to the federal post-approval requirements, to exercise reasonable care in providing adequate warnings about the risks and dangers of Mentor® Saline Breast Implants, including the risk of developing BIA-

ALCL, which was known or reasonably knowable to Defendants at the time of distribution, and that Defendants had come to know in light of adverse conditions and events experienced by patients in whom the Defendants' products were implanted.

229. Despite the fact that Defendants knew or should have known that implantation of Mentor® Saline Breast Implants was unreasonably dangerous and was 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.

230. Defendants breached their duty, pursuant to federal post-approval requirements, by failing to adequately warn Plaintiff Kristen Watson and her physicians, either directly or by not timely and accurately reporting to regulatory authorities, of the risks of serious defects, adulterations and life-altering complications, including the development of BIA-ALCL, experienced by patients in whom the products were previously implanted.

231. 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® Saline Breast Implants; failing to report Mentor® Saline 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® Saline 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.

232. Defendants' implied warranties and negligent and fraudulent misrepresentations and concealments in promoting and marketing Mentor® Saline Breast Implants created and reinforced a false impression as to the safety of Mentor® Saline Breast Implants, thereby placing consumers at risk of serious and potentially lethal effects. Such misrepresentations and concealments were made by Defendants with the intent to induce Plaintiff to use the product, to her detriment.

233. Defendants acted with deliberate intent to deceive and mislead Plaintiff.

234. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations and concealments when agreeing to the placement of Mentor® Saline Breast Implants.

235. Plaintiff and/or Plaintiff's physicians reasonably relied on Defendants' negligent and fraudulent misrepresentations and omissions, as Defendants intended and knew they would. Plaintiff and/or Plaintiff's physicians would not have made the same decision(s) if provided the required and accurate information of the product's risks.

236. At all material times, Defendants knew and intended that patients who were implanted with Mentor® Saline Breast Implants would, in reliance on false and concealed information and inadequate warnings, be placed in unnecessary, avoidable, and unreasonable

danger due to unwarranted exposure to Mentor® Saline Breast Implants, causing them to develop cancer requiring future removal surgeries and to suffer debilitating injuries and conditions, and emotional turmoil attenuated thereto.

237. As a proximate and foreseeable result of the foregoing implied warranties, negligent and fraudulent misrepresentations and fraudulent concealments by Defendant, Plaintiff has suffered and will continue to suffer from BIA-ALCL and its accompanying symptoms including, but not limited to, severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

238. For each of the statutes and regulations cited in this Complaint, Plaintiff Kristen Watson 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® Saline 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® Saline Breast Implants that are dangerous to the consuming public;

d. Designing, manufacturing, distributing and selling Mentor® Saline 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® Saline Breast Implants; and,

f. Failing to exercise reasonable care in the manufacturing, inspection, testing,

and quality control processes.

239. As a proximate result and/or substantial factor of Mentor® Saline Breast Implants' defective and adulterated condition at the time they were sold, and Defendants' implied warranties and negligent and fraudulent misrepresentations and concealments, Defendants' failure to exercise reasonable care in the warning, design, manufacture, distribution and sale of the Mentor® Saline Breast Implants implanted into Plaintiff, Plaintiff has suffered and will continue to suffer 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 wages and loss of future earning capacity, have been and will be kept from ordinary activities and duties and have and will continue to experience emotional and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue into the future.

240. Mentor® Saline 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® Saline Breast Implants and Defendants wrongful acts and omissions.

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

COUNT 9 - BREACH OF EXPRESS WARRANTY
(Against All Defendants)

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

242. Defendants in their manufacturing, design, distribution, marketing and promotion of Mentor® Saline Breast Implants voluntarily made express warranties that the Mentor® Saline Breast Implants were safe and effective for Plaintiff and members of the public generally.

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

244. Defendants further expressly warranted to Plaintiff and Plaintiff's physicians that their Mentor® Saline Breast Implants were safer and more effective than other breast implants, were safe and long-lasting.

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

246. Mentor® Saline Breast Implants do not conform to these express warranties and representations because Mentor® Saline Breast Implants are not safe or effective, nor are they safer or more effective than other breast implants available, and they may produce serious side effects, including among other things BIA-ALCL.

247. Plaintiff and Plaintiff's physician relied upon Defendants' voluntary express warranties that the Mentor® Saline Breast Implants were safe and effective for use. Instead, the use of Defendants' Mentor® Saline Breast Implants were not safe and caused Plaintiff to suffer 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 Kristen Watson 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 10 – LOSS OF CONSORTIUM
(Against All Defendants)

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

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

a. Perform all activities and upkeep around the house;

b. Support Kristen Watson by performing activities she previously performed for her own needs and maintenance;

c. Take over many of the activities which Kristen Watson previously commonly performed as a parent to Kristen Watson and James Watson IV's children.

250. As a result of Defendants' defective and adulterated Mentor® Saline Breast

Implants and the development of Kristen Watson's BIA-ALCL, Plaintiff James Watson IV effectively lost the companionship and accompaniment of his wife.

251. As a further result of Defendants' defective and adulterated Mentor® Saline Breast Implants and the injuries they caused to Kristen Watson and the resulting demands placed upon James Watson IV has suffered lost wages and income.

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

WHEREFORE, Plaintiff James Watson IV 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.

DEMAND FOR JURY TRIAL

The Plaintiffs demand trial by a jury on all of the triable issues of this Complaint, pursuant to New Jersey Court Rules 1:8-2(b) and 4:35-1(a).

Dated: October 9, 2018

Respectfully submitted,

ROSS FELLER CASEY, LLP

/s/ Brian J. McCormick, Jr.
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CERTIFICATION PURSUANT TO RULE 4:5-1

I certify that this dispute is not the subject of any other action pending in any other court or a pending arbitration proceeding to the best of my knowledge and belief. Also, to the best of my knowledge and belief no other action or arbitration proceeding is contemplated. Further, other than the parties set forth in this Complaint, Plaintiff knows of no other parties that should be made a part of this lawsuit. In addition, Plaintiffs recognize the continuing obligation to file and serve on all parties and the court an amended certification if there is a change in the facts stated in this original certification.

Dated: October 9, 2018

ROSS FELLER CASEY, LLP
Attorneys for Plaintiffs

/s/ Brian J. McCormick, Jr.
BRIAN J. MCCORMICK, JR.

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-005993-18

Case Caption: WATSON KRISTEN VS JOHNSON & JOHNSON
Case Initiation Date: 10/08/2018
Attorney Name: BRIAN J MC CORMICK JR
Firm Name: ROSS FELLER CASEY LLP
Address: ONE LIBERTY PLACE, 34TH FL 1650 MARKET ST
PHILADELPHIA PA 19103
Phone:
Name of Party: PLAINTIFF : WATSON, KRISTEN
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: Too many to list
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

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

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

If yes, is that relationship:

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

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

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

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

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

10/08/2018
Dated

/s/ BRIAN J MC CORMICK JR
Signed