THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

AMBER BROOKS and
JAMIE GALE,

Case No.: 2:19-cv-02088

Plaintiffs

-vs-

MENTOR WORLDWIDE, LLC,
a foreign limited liability company;

Defendant

_____/

COMPLAINT

Plaintiffs Amber Brooks and Jamie Gale sue Defendant, Mentor Worldwide, LLC, upon the following facts and causes of action.

PARTIES AND JURISDICTION

1. Plaintiff Amber Brooks is, and at all material times has been, a resident of Clay County, Missouri.

2. Plaintiff Jamie Gale is, and at all material times has been, a resident of Miami County, Kansas.

3. Defendant Mentor Worldwide, LLC ("Mentor") is a limited liability company incorporated under the laws of the state of Delaware, with its principal place of business located and headquarters in the state of California. Mentor is authorized to do business, and does business, in the state of Kansas.

4. Mentor manufactured the Mentor MemoryGel Silicone Implants that are the subject of this Complaint.

5. The Mentor MemoryGel Silicone Implants that are the subject of Plaintiff Amber Brooks' complaint were implanted in the state of Kansas.

6. The Mentor MemoryGel Silicone Implants that are the subject of Plaintiff Jamie Gale's complaint were implanted in the state of Kansas.

7. Subject matter jurisdiction is proper in this Court under 28 USC §1332, because each Plaintiff has suffered and claims damages of at least $75,000, exclusive of interest and costs, and because no Plaintiff is a citizen of the same state as the Defendant.

8. Personal jurisdiction over the Defendant exists in this Court because the Defendant does business in Kansas, committed tortious acts in Kansas, at all material times has had substantial contacts with Kansas, and manufactured, distributed, marketed and sold defective products in Kansas.

9. Venue is proper in this District under 28 USC §1391, because a substantial part of the events or omissions giving rise to each Plaintiff's claim occurred in Kansas.

10. All conditions precedent to bringing this action have occurred, or have been satisfied or waived.

FACTS SPECIFIC TO PLAINTIFF AMBER BROOKS

11. In the state of Kansas, Plaintiff Amber Brooks was implanted with Mentor MemoryGel Silicone Gel Breast Implants on or about March 4, 2016.

12. Soon after implantation and as a direct consequence of the implantation of Mentor MemoryGel Silicone Gel Breast Implants, Ms. Brooks developed a myriad of adverse symptoms and ailments, including:

- Muscle pain, in the extremities and trunk;
- Joint pain, in the neck, shoulders, thoracic spine, hips, hands, and ankles
- Sharp pins-and-needles-type pain in the fingers and toes;
- Fatigue

- Recurrent vaginal infections;
- Weakness;
- Burning thigh pain;
- Dry eyes, blurry vision, eye floaters;
- Weight loss;
- Malabsorption and nutrient deficiencies;
- Abdominal pain;
- Recurrent sore throats;
- Enlarged tonsils;
- Multiple rashes, lesions and bumps, of different types and at different locations;
- Intermittent fevers and chills;
- Cognitive dysfunction in the form of name recall, word recall, assimilation of new reading material, and confusion;
- Cracking, splitting, and slow growth of fingernails and toenails;
- Insomnia;
- Recurrent sinus congestion;
- Chest pain;
- Shortness of breath on exertion;
- Constipation;
- Headaches;
- Twitching of the eyes and facial muscles;
- Dizziness;
- Morning stiffness;
- Night sweats;
- Gait imbalance;
- Spider veins on the chest;
- Metallic taste;
- Hoarseness;
- Tinnitus;
- Thinning hair in the scalp and eyelashes;
- Odor and smell sensitivity;
- Headaches, dizziness, rashes, nausea on exposure to scents from candles, cleansers, gasoline, perfumes, and hairsprays, and from cosmetics during application;
- Temperature intolerance;
- Food sensitivities;
- Enlarged lymph nodes;
- Loss of sensation in both breasts;
- Deformity of left breast;

- Elevated metal levels in body, including barium, tin, mercury, strontium, aluminum and copper.

13. About six months after the Mentor MemoryGel implants were placed inside Ms. Brooks' body her breast augmentation surgery, Mrs. Brooks was hospitalized and was fortunate to recover from sepsis and a life-threatening severe staph infection.

14. On or about February 17, 2017, less than a year after the Mentor devices were placed inside Ms. Brooks' body, were surgically removed.

15. After the Mentor MemoryGel implants were explanted, it was discovered that silicone appears to exist in the tissues of Ms. Brooks' chest area.

16. Since the Mentor MemoryGel implants were explanted, some of Ms. Brooks' symptoms and conditions have improved or disappeared; many have not.

FACTS SPECIFIC TO PLAINTIFF JAMIE GALE

17. In the state of Kansas, Plaintiff Jamie Gale was implanted with Mentor MemoryGel Silicone Gel Breast Implants on or about September 11, 2009.

18. After implantation and as a direct consequence of the implantation of Mentor MemoryGel Silicone Gel Breast Implants, Ms. Gale developed:

- Skin rashes that continuously worsened and spread over the body, including blisters, intense itching, cracking and thickening skin, and discolored patches, and extreme sensitivity of the hands;
- Inflammation over the body, most acute around the eyes, hands and feet;
- Fatigue;
- Brain fog that increased over time;
- Constant aching of the neck and shoulders;
- Weight gain;
- Hypothyroidism;
- Hair loss at the scalp, eyebrows and eyelashes;
- Uncontrollable gastrointestinal issues;
- Rising blood pressure;
- Food and chemical sensitivities and allergies;

- Severe hearing loss, necessitating hearing aids at age 53 to 54;
- Elevated lead and heavy metal levels;
- Dry eyes;
- Joint pain in both feet, more severe in the mornings;
- Excessively dry skin, body-wide, cracking at heels.

19. On or about May 24, 2017, an MRI showed extracapsular silicone around both implants.

20. On or about July 25, 2017, the Mentor devices that were placed inside Ms. Gale's body were surgically removed.

21. After the Mentor MemoryGel implants were explanted, it was discovered that silicone had escaped from both of the devices.

22. Immediately after Mentor MemoryGel implants were explanted, many of Ms. Gale's symptoms and conditions greatly improved or disappeared; some have not.

FACTS SUPPORTING ALL COUNTS

A. FDA Regulation of Silicone Breast Implants

23. During the 1950s and 1960s many different materials were used for the purpose of augmenting the female breast which included direct injection of silicone oil, vegetable oil, bee's wax, rubber and Terylene wool. These all led to critical health problems in patients and were rejected as appropriate augmentation materials.

24. In 1961 the first silicone gel prosthesis was developed by American plastic surgeons Thomas Cronin and Frank Gerow and manufactured by the Dow Corning Corporation with the first augmentation mammoplasty being performed in 1962.

25. "Silicone" refers to a group of polymers based on the element silicon. Silicone polymers may be produced in a variety of forms, including oil, gels, or elastomers (rubber).

26. When an elastomer shell is not properly filled it can cause the implant to fold or crease in a woman's body which can also lead to degradation and ultimate rupture of the implant.

27. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic ("FDCA"). At the time that the MDA was enacted, certain medical devices[1], including breast implants[2], were already being sold in the United States.

28. Under the MDA, medical devices[1], such as the subject breast implants[2], are subject to three classifications and regulated accordingly. Class I devices require the least and most general oversight. 21 U.S.C. § 360c(a)(1)(A). Class II devices are reviewed according to more stringent "special controls," such as performance standards. *Id*. § 360c(a)(1)(B). Finally,

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[1] Under Federal law, term "device" includes any "implant… which is…

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321.

Kansas law is materially identical, as the term "device" includes any "implant… which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,
(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or
(c) Intended to affect the structure or any function of the body of humans or other animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes. F.S. 499.003(15).

[2] A breast implant is a prosthesis product used to change the size, shape, and contour of a woman's breast. The silicone implants contain a silicone elastomer shell filled with silicone gel and covered with a patch to seal the implant. On information and belief many implants by Mentor have a label on the implant imprinted by a laser.

Class III devices receive the most oversight and require rigorous premarket review and approval. *Id.* §360c (a)(1)(C)(ii).

29. The FDA originally classified silicone gel-filled breast implants as Class II devices. However, because of reports of adverse events, the FDA re-classified silicone gel-filled breast implants as Class III devices.[3] Accordingly, the FDA required that manufacturers meet certain requirements to allow these medical devices to remain on the market.

30. Subsequently, on April 10, 1991, the FDA published a final regulation under Section 515(b) of the FDCA requiring that manufacturers of silicone gel-filled breast implants submit pre-market approval applications ("PMAs") with data showing a reasonable assurance of safety and effectiveness of the implants by July 9, 1991.

31. On August 22, 1991, the FDA determined that the PMAs submitted by the manufacturers of silicone gel-filled breast implants, including Mentor, did not contain sufficient data.

32. In November of 1991, the FDA convened a panel to consider whether the PMA data regarding silicone gel-filled breast implants was sufficient to establish that they were safe and effective.

33. On January 6, 1992, the FDA called for a voluntary moratorium on the use of silicone gel-filled breast implants until new safety information could be thoroughly reviewed.

34. Additional information on silicone gel-filled implants was reviewed by the FDA panel on February 18, 1992, including case reports of autoimmune diseases, and evidence that some implants had leaked excessively.

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[3] A more detailed explanation of the FDA's regulation of breast implants can be accessed at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064461.htm (Regulatory History of Breast Implants in the U.S.) (Last accessed March 30, 2018).

35. On April 16, 1992 the FDA announced that there was not sufficient data to support approval of the sale of silicone gel-filled breast implants and that it would allow implantation of silicone gel-filled breast implants only under controlled clinical studies for reconstruction after mastectomy or correction of congenital deformities (reconstruction), or replacement of ruptured silicone gel-filled implants due to medical or surgical reasons (revision). The FDA expressly denied applications to use silicone gel-filled breast implants for breast augmentation.

36. The FDA further ordered that any silicone gel-filled implants used for reconstruction or revision would be considered to be "investigational devices," and that women who received these implants should be followed through clinical studies.

B. Mentor Application for FDA Approval of its Silicone Gel-filled Implants

37. In order to eventually seek pre-market approval for its MemoryGel Silicone gel-filled breast implants, Mentor was required to first provide the FDA with sufficient information regarding the safety and efficacy of that medical device.

38. As part of this process, Mentor requested that it be allowed to use the medical device for clinical testing pursuant to an investigational device exemption ("IDE"). See, 21 U.S.C. § 360j (g). Mentor was prohibited from conducting research concerning the device on human subjects without prior approval by the FDA. See, 21 CFR § 812.20.

39. Investigational devices are subject to complex and comprehensive regulations and detailed procedures intended to ensure that the devices are safe and effective.

40. In connection with Mentor's IDE, the FDA approved the following studies: "Adjunct Study" for reconstruction and revision patients only (July of 1992); "Core Study"

(August of 1992[4]); and, "IDE" study (August 2, 2000).

41. The FDA also sent a letter to Mentor and other companies seeking approval for the sale of silicone gel-filled implants and discussing the type of information needed for core studies (IDE studies) of silicone gel-filled breast implants on January 11, 1996.

C. Mentor Manufacturing Issues prior to FDA approval

42. During the time period prior to Mentor's FDA approval, Mentor's silicone gel-filled breast implants were manufactured at a facility in Irving, Texas operated by Mentor Texas, Inc. ("Mentor Texas") a wholly owned subsidiary of Mentor.

43. Based on whistleblower complaints and other information, an investigation was initiated by the United States into the manufacturing process for the silicone gel-filled breast implants made at the Mentor Texas plant.

44. As a result of the information gathered in that investigation, a complaint was filed on May 6, 1998, in the United State Court for the Northern District of Texas, *United States v. Mentor*, et al., 3:98-cv-01105-G seeking an injunction to prohibit Mentor and Mentor Texas from manufacturing silicone gel-filled breast implants in violation of the requirements of federal law.

45. On that same date, the parties to that case entered into a Consent Decree and Judgment of Permanent Injunction requiring that Mentor and Mentor Texas remedy the deficiencies identified and provide proof that their future manufacturing was done in compliance with Federal law and regulations.

46. Specifically, Mentor agreed to manufacture its breast implants in compliance with the FDA's Quality System Regulation, which is designed to ensure that medical devices are

[4] "In April 1992, the [FDA] moratorium was lifted but only for reconstruction and revision patients. Every patient implanted had to be part of an adjunct study, and had to be offered participation in a registry of gel-filled breast implant patients. In order to be implanted with gel-filled implants for augmentation, women had to be enrolled in a core clinical study." See Exhibit B, Core Gel Study, pg. 3.

consistently high in quality and are safe and effective.

47. The evidence supporting the claims made by the United States included sworn testimony from individuals who had been senior officials at the Mentor Texas facility.

48. John C. Karjanis, who from 1996 until 1998 was manager of product evaluation at Mentor Texas, testified that basic quality standards for implant manufacturing were never met while he served in that capacity. He further testified that he was instructed by his supervisors to destroy reports detailing the high rupture rates and poor quality of implants manufactured at that facility because the products "are in the customers."

49. He also testified that implants were sometimes contaminated with fleas and that employees at the Mentor Texas facility would sometimes store defective implant parts above ceiling tiles so managers and inspectors would not realize how often the plant failed to properly manufacture the implants.

50. Similarly, Cynthia Fain, the supervisor of the complaint unit, testified that Mentor greatly underreported rupture rates for its implants to federal authorities and suppressed a report finding that some implant models had a high failure. Mentor also was cited for other manufacturing deficiencies prior to the date that Plaintiffs received their implants. These include, but are not limited, to a Form 483[5] issued to Mentor on October 16, 1997 indicating that prior to February of 1997 no finished device testing was performed on any of its gel or saline filled mammary devices and that certain post sterilization testing was not done for an unknown time and these materials were used for gel implants.

[5] An FDA Form 483 is issued when an investigation establishes that a drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health or when an investigator has observed conditions that may constitute violations of the FDCA or related Acts. The purpose of the Form 483 is to notify the company of the objectionable conditions and to allow the company to propose a plan to correct these conditions.

51. Upon information and belief, a Mentor chemist of 15 years reported to the FDA that Mentor's implants are more likely to break than the company reported. It has also been reported that the silicone is more likely to leak, even when the implants are intact, and that the materials used in the implants are more dangerous than reported.

52. Mentor knew of these risks associated with its implants, but covered them up by terminating studies, sponsoring only self-serving research it could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

D. Mentor Silicone Implant FDA Approval

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

54. 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.

55. 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 10 years; (c) Conduct a device-failure study in concert with its large post-approval study to further identify the modes and causes of failure of explanted devices over the 10-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 5-year post-implant evaluations.

56. Mentor failed to ensure that these mandated studies were preformed 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.

57. 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 6 months post-operation, and annually one year to 10 years after surgery.

58. The FDA also stated that all non-MRI patients should have an MRI at years 6, 8, and 10, and that all patients who were explanted without replacement were to be evaluated through 10 years.

59. Mentor was further required to update the patient and physician labeling or its product to reflect the results of the 5 and 10-year Core Study findings and to report to the FDA significant new information regardless of when the information became available.

60. Although the actual follow-up rates for the "Core" study at 9 years post-implant were only 59 percent, Mentor reported that the follow-up rate at 10 years post-implant was 62 percent.

61. Furthermore, the FDA requirements specifically mandated evaluation through 10 years, but the core post-approval study report schedule illustrates that reporting was only done for 6 years.

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

63. 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.

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

65. 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.

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

67. The study also required physician evaluations at years 1, 4-6, 9 and 10 to collect data on complications.

68. Mentor was required to update its patient and physician labeling to reflect the 5-year and 10-year study findings, as well as at any other time if necessary to report significantly new information from the study.

69. 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.

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

71. 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% dropout rate, the study failed to collect data to demonstrate that use of the Mentor silicone gel implants was safe.

72. 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.

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

74. Mentor did not follow through with required data collection. The Year 1 follow-up rate of surgeon visit for study participants was 22.8%, leaving nearly 80% unaccounted for. Similarly, the Year 1, 2, and 3 follow-up rates were 21.4%, 24.3%, and 23.0%, respectively, leaving nearly 80% unaccounted for. At Year 7, the overall follow-up rate was 20.1%, leaving 79.9% of participants unaccounted for and did not have follow-ups for data collection. No follow-up rates were provided for the 10-year data collection.

75. 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.

76. 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 postapproval study."

77. 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.

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

79. 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.

80. 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.

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

82. 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.

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

84. 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 5 years. The data from this follow-up was to be reported as part of the annual reports required by the FDA.

85. 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.

86. The overall patient follow-up rates declined as follows: Year - 44%; Year 3 - 24.7%' and, Year 5 - 13.8%. 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.

87. In addition to Mentor's failure to follow up on the Post Approval Studies, from the time of the IDE until today, Mentor is solely responsible for designating the cause of an implant rupture, reporting a rupture, linking and/or designating any injuries as related to breast implants, and reporting any related injuries to the FDA and health care providers as required under both Kansas state and federal law. The details regarding this information remain solely in the hands of the Defendant.

88. On information and belief, Plaintiff allege that if ruptures had been properly reported, Plaintiff would have been notified of a rupture rate for Mentor MemoryGel Breast Implants that is significantly higher than reported in the product insert and disclosed to health

care providers.

89. On information and belief, Plaintiff allege that if the injuries of women who had been implanted with Mentor MemoryGel Breast Implants had been properly reported, Plaintiff would have been notified of the significant risk associated with the device, such as those suffered by Plaintiff.

90. During 2005 and 2006, additional whistleblowers reported to FDA and to watchdog agencies that Mentor was fraudulently reporting its test results and device failure rates.

91. Mentor is concealing, or has destroyed, substantial material evidence relating to the 2005 and 2006 whistleblowers.

COUNT 1
NEGLIGENCE AND NEGLIGENCE PER SE

92. The allegations of above paragraphs 1 through 91 are incorporated and realleged.

93. At all material times, Defendant had a duty to Plaintiffs to use reasonable care in formulating, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting its MemoryGel Silicone Gel Breast Implants.

94. Mentor formulated, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted its MemoryGel Silicone Gel Breast Implants, including the products that were implanted into Plaintiffs.

A. Negligent Failure to Warn

95. Defendant had a duty under Kansas law to exercise reasonable care to provide adequate warnings about the risks and dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendant at the time of distribution.

96. Defendant was negligent by not using reasonable care to warn about the dangers of which it was aware related to its silicone gel-filled breast implants, including the MemoryGel implants placed in Plaintiffs or facts that this product was likely to become dangerous after being implanted into their bodies.

97. Mentor knew or reasonably should have known that its silicone gel-filled breast implants, including the MemoryGel implants placed in Plaintiffs, were dangerous or were likely to be dangerous when used or misused in a reasonably foreseeable manner.

98. Defendant breached its duty under federal law, and its parallel state duty, in failing to warn the FDA, Plaintiffs and their physicians by failing to report and by inaccurately reporting the risks of serious defects and life-altering complications that Defendant knew or should have known were associated with Mentor's MemoryGel Silicone Gel Breast Implants prior to the time of Plaintiffs' implantations, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Plaintiffs.

99. Specifically, Mentor had a duty to report unanticipated adverse device effects (with evaluation) to the FDA, all IRBs, and investigators within 10 working days after notification by the investigator. 21 CFR 812.150(b). This duty is parallel to Mentor's state law duty to exercise reasonable care to provide adequate warning about the risks and dangers associated with its product.

100. Under both federal and state law, Mentor also had a continuing duty to monitor and report adverse events and risks associated with the use of its products.

101. The FDCA requires medical device manufacturers like Defendant to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for

reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

102. The FDA publishes this information in a public, searchable internet database called MAUDE (Manufacturer and User Facility Device Experience) 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.

103. This duty is parallel to the post-sale duty to warn under Kansas law and applies as Mentor gained knowledge, which it was under a duty to communicate to the FDA and physicians.

104. Under both federal and state law, Mentor had a duty to exercise reasonable care in adequately warning Plaintiffs and Plaintiffs' treating physicians about the dangers of Mentor MemoryGel silicone breast implants that were known or knowable to Defendant at the time of distribution or which became known thereafter.

105. Despite having knowledge and possession of information that showed the use of Mentor MemoryGel silicone breast implants was dangerous and likely to place consumers' health at serious risk, Mentor failed to adequately disclose and warn of the health hazards and risks associated with the product.

106. Instead, Mentor marketed, advertised, and promoted the product while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of Kansas law and applicable FDA regulations and requirements.

107. Mentor failed to report adverse events from the studies it was required to conduct, which would have led to adverse event reports revealing the product's contribution to serious injury.

108. Had Mentor complied with its obligation to report newly acquired information, true information about: instances of silicone toxicity; instances of adverse events; instances of adverse events requiring removal; instances of constellations of adverse symptoms; instances of chronic/persistent autoimmune-like complaints and inflammatory issues; rupture rates; and more, adequate information would have been provided to the FDA and would have been available to Plaintiffs' treating physicians, who would have communicated that information to Plaintiffs.

109. At all material times Mentor was responsible for maintaining the labeling of the product, and had the ability and duty under state and federal law, to directly warn healthcare providers and consumers by updating the labeling of Mentor MemoryGel silicone breast implants to reflect newly acquired safety information without advance approval by the FDA.

110. With pre-market approval for is MemoryGel Silicone Gel-Filled Implants, Mentor had a responsibility to file a "Special PMA Supplement – Changes Being Effected" ("CBE") by which Mentor could unilaterally update the product labeling to reflect newly acquired safety information without advance approval by the FDA. 21 CFR § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported

indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

111. Mentor breached its duties under Kansas and federal law to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

112. Mentor has the ability and the duty under Kansas law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product are not misbranded. KS Stat. §65-669.

113. Under parallel federal law, Defendant had the ability to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. 21 U.S.C. § 331 ("the following acts and the causing thereof are prohibited: (a) the introduction…of any device that is …misbranded, (b) the …misbranding of any …device…).

114. Had Defendant timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs' treating physicians, regarding the dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Defendant at the time of distribution and afterwards.

115. If Plaintiffs had been adequately warned of the serious risks and adverse events by Defendant Mentor, they would not have agreed to implantation of Mentor MemoryGel Silicone Gel Breast Implants.

116. Defendant was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action.

117. Defendant also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of Kansas law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

118. As a proximate and legal result of Mentor's failure to comply with its obligations under applicable Federal regulations, Mentor breached its duty of care and caused Plaintiffs to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

B. Negligent Manufacturing

119. Mentor had a duty under federal law, and a parallel duty under Kansas law, to exercise reasonable care in developing, manufacturing, testing, inspecting and selling its product to ensure that it was safe and further that it was made in conformity with the manufacturing and design specifications mandated by the FDA as part of Mentor's PMA.

120. Mentor was negligent under Kansas law, in the development, manufacture, testing, inspection and sale of its MemoryGel Silicone Gel Breast Implants by: (a) manufacturing MemoryGel Silicone Gel Breast Implants that differed from the specifications agreed to by the FDA; manufacturing MemoryGel Silicone Gel Breast Implants using materials and components which differed from those approved by the FDA; failing to follow good manufacturing practices

during the manufacture of its MemoryGel Silicone Gel Breast Implants; failing to properly meet the applicable standard of care by not complying with applicable federal regulations and failing to adhere to the manufacturing protocols approved by the FDA; carelessly and negligently selling and distributing its MemoryGel Silicone Gel Breast Implants in violation of the terms of the IDE and applicable federal law; negligently incorporating components and/or materials into its MemoryGel Silicone Gel Breast Implants that could not stand up to normal usage and/or which differed from those which were commercially reasonable and/or failing to use the components and/or materials approved by the FDA; failing to exercise reasonable care in inspecting and testing of the product; and, failing to exercise reasonable care in its manufacturing, quality control and quality assurance processes.

121. Mentor had a duty under Kansas law to exercise ordinary care in the manufacture of its MemoryGel Silicone Gel Breast Implants consistent with FDA specifications, the Mentor MemoryGel Silicone Gel Breast Implants IDE, and/or conditions of approval.

122. At all relevant times, Mentor was required to comply with the FDA's Quality System Regulations, the requirements under the PMA.

123. Mentor’s MemoryGel Silicone Gel Breast Implants contained a manufacturing defect when it left Mentor’s possession, in that Mentor’s manufacturing process did not conform to FDA's Quality System Regulations and design control requirements under 21 CFR 820.30.

124. Upon information and belief, prior to the date that the subject implants were manufactured Mentor has received several Form 483 notifications and otherwise was aware that its manufacturing process was deficient and that the implants being produced did not comply with applicable Federal requirements.

125. Mentor failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of its MemoryGel Silicone Gel Breast Implants.

126. Mentor failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of its MemoryGel Silicone Gel Breast Implants.

127. Mentor failed to adequately inspect, test, and validate its MemoryGel Silicone Gel Breast Implants after completion of assembly.

128. Mentor failed to comply with the requirements imposed by the FDA and other applicable federal requirements for the manufacture of its MemoryGel Silicone Gel Breast Implants.

129. Because Mentor failed to follow specifications, regulations, and required by the FDA, Plaintiffs' MemoryGel Silicone Gel Breast Implants were defective and were further vulnerable to degradation, deterioration, rupture and leakage.

130. Upon information and belief, when the MemoryGel Silicone Gel Breast Implants placed into Plaintiffs were manufactured, Mentor had the technological capability to manufacture its MemoryGel Silicone Gel Breast Implants in a reasonably safe manner.

131. Mentor was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both Kansas law and the requirements under 21 CFR § 800.100(a)(6)(7).

132. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of Kansas law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions,

hazards, adverse effects, interfering substances or devices, warnings and precautions."

133. Upon information and belief, Plaintiffs was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the FDA requirements, resulting in product failure and serious injury to her.

134. The injuries Plaintiffs suffered are expected to result from defective manufacture of the devices. Plaintiffs and their treating physicians were unaware that the product was defective at the time of implant and for years thereafter.

135. Plaintiffs are within the class of persons the cited statutes and regulations were designed to protect, and Plaintiffs injuries are of the type of harm these statutes and regulations are designed to prevent.

136. Mentor's violations of these statutes and regulations proximately caused Plaintiffs' injuries.

137. As a proximate and legal result of Mentor's failure to exercise reasonable care and the resulting defective condition of its MemoryGel Silicone Gel Breast Implants implanted into Plaintiffs, they suffered damages and will continue to suffer damages in the future including severe physical injuries, severe emotional distress, mental anguish, economic loss, past medical expenses, future medical expenses, and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendant for the full amount of their damages, plus interest, costs, and such other relief as may be just and equitable.

COUNT 2
STRICT PRODUCTS LIABILITY
FAILURE TO WARN

138. The allegations of above paragraphs 1 through 91 are incorporated and realleged.

139. At all material times, Mentor was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling MentorMemoryGel Silicone Gel Breast Implants.

140. At all material times, Mentor intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiffs, and knew or should have known that the product would be surgically implanted into members of the general public, including Plaintiffs.

141. Defendant failed to warn Plaintiffs and their physicians of the risk of serious defects and life altering complications that rendered the devices defective and unreasonably dangerous.

142. Mentor also failed to revise the product labeling or otherwise communicate the true rate of occurrence of adverse events to the FDA, the IRB or to physicians based upon the adverse event information available to it through, among other things, the studies which it was required to conduct and the reports of adverse events and effects which it received.

143. Plaintiffs' Mentor MemoryGel Silicone Gel Breast Implants were defective at the time of sale and distribution and at the time they left the possession of Mentor in that Mentor failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and other injuries associated with Mentor MemoryGel Silicone Gel Breast Implants.

144. The MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous when they left the possession of Mentor in that they contained warnings insufficient to alert physicians and consumers, including Plaintiffs, of the dangerous risks and complications associated with the MemoryGel Silicone Gel Breast Implants, including but not limited to, their propensity to cause injury, through leakage of the silicone gel into the tissues of the user's body, thereby introducing toxic metals and chemicals into those tissues, resulting in serious, dangerous and harmful side effects and complications all to the detriment of the health and well-being of the users of its product.

145. Defendant knew, or should have known, the gel contained in the implants contained metals and toxic chemicals in such quantities that would be extremely harmful to users of its product if the gel were allowed to escape its shell and "bleed" into the user's body.

146. Mentor also knew, or should have known, that there was a significant risk of rupture or seepage of the gel through the shell and into the tissues of the user's body.

147. Mentor failed to adequately warn physicians and patients implanted with the product, including Plaintiffs, of these potential serious and harmful risks.

148. Mentor failed to provide follow-through post-approval studies required by the FDA’s necessary in order to market and sell the product, and thus failed to report to, and warn, the FDA and the IRB of the risks described above.

149. The accurate rate of occurrence for these and other injuries associated with Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiffs and Plaintiffs’ treating physicians, as a result of Mentor’s conduct.

150. Mentor MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Mentor knew or

should have known that the products created a serious risk of degradation, deterioration, ruptures, and leakage, and other injuries that could, and did, harm consumers, including Plaintiffs, and Mentor failed to adequately warn consumers of said risks - including Plaintiffs and Plaintiffs' treating physicians - in accordance with Federal requirements and Kansas law.

151. Mentor's MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous due to inadequate warnings and instructions because Mentor knew or should have known that Mentor MemoryGel Silicone Gel Breast Implants created, among other things, a higher than expected risk for adverse events, and Mentor failed to adequately warn of those risks, to monitor those risks, report them, test for them, and update its labeling and the information provided to the FDA and IRB regarding such risks when the information became available.

152. Mentor failed to keep required records and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both Kansas law and the requirements under 21 CFR § 800.100(a)(6)(7).

153. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of Kansas law and its duty under 21 CFR § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

154. At all relevant times, Plaintiffs Mentor MemoryGel Silicone Gel Breast Implants were used and implanted into them as intended by Mentor and in a manner reasonably foreseeable to Mentor.

155. Mentor's MemoryGel Silicone Gel Breast were expected to, and did, reach Plaintiffs and Plaintiffs' implanting physician without substantial change in the condition in which they were sold.

156. Despite the fact that Defendant knew, or should have known, that the use of Mentor MemoryGel Silicone Gel Breast Implants were unreasonably dangerous and likely to place users at serious risks to their health, Defendant failed to monitor and warn of the defects, health hazards, and risks associated with Mentor MemoryGel Silicone Gel Breast Implants.

157. Plaintiffs Mentor MemoryGel Silicone Gel Breast Implants were also defective at the time of sale and distribution, and at the time the devices left the possession of Mentor, in that the devices differed from Mentor's intended result and design specifications as approved by the FDA.

158. Upon information and belief, Plaintiffs was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the specifications and requirements approved and mandated by the FDA, resulting in product failure and serious injury to Plaintiffs.

159. The injuries Plaintiffs suffered are expected to result from defective manufacture. Plaintiffs and their treating physicians were unaware that the product was defective at the time of implant and for years thereafter.

160. Mentor violated Federal regulations and Kansas law, by placing the Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

161. Mentor was, at all times, responsible for maintaining the labeling of the product, and had the ability under federal law, and the duty under state and federal law, to directly warn

healthcare providers and consumers by updating the labeling of Mentor MemoryGel silicone breast implants to reflect newly acquired safety information without advance approval by the FDA.

162. During the IDE process, Mentor was under a duty to advise the FDA, IRB and study investigators of all significant new information, including the duty to monitor, evaluate and report all unanticipated adverse device effects and to terminate the investigation, or portions of it, if that effect presents an unreasonable risk to subjects. See, 21 CFR 812.46.

163. Mentor was specifically required to report all unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. See, 21 CFR 812.150(b).

164. Kansas imposes a parallel duty to warn and advise product users.

165. Once Mentor applied for pre-market approval for is MemoryGel Silicone Gel-Filled Implants, it had additional duties and responsibilities.This included the responsibility to file a "Special PMA Supplement – Changes Being Effected" ("CBE") by which Mentor could unilaterally update the product labeling to reflect newly acquired safety information without advance approval by the FDA. 21 CFR § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

166. Mentor breached its duties under federal law and state law, including Kansas law, to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

167. The FDCA requires medical device manufacturers like Defendant to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 CFR § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 CFR § 820.198(a).

168. Specifically, 21 CFR § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury, or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

169. The FDA publishes this information in a public, searchable Internet database called MAUDE (Manufacturer and User Facility Device Experience) 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.

170. Despite the fact that evidence existed that Mentor MemoryGel Silicone Gel Breast Implants were dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with Mentor MemoryGel Silicone Gel Breast Implants.

171. Mentor MemoryGel Silicone Gel Breast Implants had a manufacturing defect when they left Mentor's possession in that Mentor's manufacturing process did not comply with the FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 CFR 820.30.

172. The defects inherent in Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' implanting physician.

173. Plaintiff could not, in the exercise of reasonable care, have discovered the product defects and perceived their true danger.

174. Plaintiffs and/or Plaintiffs' implanting physician reasonably relied upon the skill, superior knowledge, and judgment of Mentor, including Defendant Mentor, when they consented to the implantation procedure using Mentor MemoryGel Silicone Gel Breast Implants.

175. At all relevant times, Plaintiffs' Mentor MemoryGel Silicone Gel Breast Implants were used and implanted as intended by Mentor and in a manner reasonably foreseeable to Mentor.

176. Had Plaintiffs and/or Plaintiffs' physician received adequate warnings regarding the risks the risks of Mentor MemoryGel Silicone Gel Breast Implants, they would not have used them.

177. Had Mentor complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Plaintiffs' treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which

Plaintiffs was experiencing were related to its Mentor MemoryGel Silicone Breast Implants. Had that occurred, Plaintiffs would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured.

178. Mentor's MemoryGel Silicone Gel Breast Implants were expected to, and did, reach Plaintiffs and Plaintiffs' implanting physician without substantial change in the condition in which they were sold.

179. Mentor knew that its MemoryGel Silicone Gel Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

180. At all times relevant to this action, the dangerous propensities of Mentor MemoryGel Silicone Gel Breast Implants were known to Mentor or were reasonably and scientifically knowable to Mentor, through appropriate research and testing by known methods, at the time it distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to implant Mentor MemoryGel Silicone Gel Breast Implants for their patients.

181. Mentor was required to provide adequate warnings to consumers and the medical community under federal and Kansas law, but failed to do so in a timely, truthful, accurate and responsible manner.

182. Had Mentor timely and adequately reported adverse events to the FDA and IRB, there would have been effective warnings to physicians, including Plaintiffs' treating physicians, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' treating physicians, regarding the

dangers of Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to Mentor at the time of distribution.

183. Had Mentor complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Plaintiffs' treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which Plaintiffs was experiencing were related to their Mentor MemoryGel Silicone Breast Implants. Had that occurred, Plaintiffs would have been able to undergo the explantation surgery at an earlier date and would have been less severely damaged and injured.

184. Because Mentor failed to follow specifications, regulations, and required the FDA and applicable Federal regulations and requirements, the Mentor MemoryGel Silicone Gel Breast Implants implanted in Plaintiffs were vulnerable to degradation, deterioration, ruptures, and leakage.

185. Mentor's MemoryGel Silicone Gel Breast Implants were manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendant, and this was a substantial contributing factor in bringing about Plaintiffs' injuries, which would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

186. The defective warnings and failures to provide truthful, accurate and complete information as required under the IDE and other applicable Federal regulations and requirements were a substantial contributing factor in bringing about the injuries to Plaintiffs that would not have occurred but for the use of Mentor MemoryGel Silicone Gel Breast Implants.

187. As a proximate result and/or substantial contributing factor of Mentor MemoryGel Silicone Gel Breast Implants' defective condition at the time they were sold, Plaintiffs has suffered damages and will continue to suffer damages in the future including severe physical injuries, severe emotional distress, mental anguish, economic loss, past medical expenses, future medical expenses, and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs prays for judgment against Defendant for the full amount of their damages, plus interest, costs, and such other relief as may be just and equitable.

COUNT 3
STRICT PRODUCTS LIABILITY
MANUFACTURING DEFECT

188. The allegations of above paragraphs 1 through 91 are incorporated and realleged.

189. At all material times, Mentor was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel Breast Implants.

190. At all times material times, Mentor intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiffs, and knew or should have known that the product would be surgically implanted into members of the general public.

191. Mentor manufactured, tested, marketed, promoted, advertised, distributed, and sold the Mentor MemoryGel Silicone Gel Breast Implants that were implanted into Plaintiffs.

192. At all times relevant, Mentor placed Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce, and did so in a manner in which the Mentor MemoryGel Silicone Gel Breast Implants were defective in their manufacturing process did not comply with the FDA's Quality System Regulations and design control requirements under 21 CFR 820.30.

193. Mentor violated Federal regulations and requirements and Kansas law by placing the Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

194. Mentor failed to keep required records and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both Kansas law and the requirements the IDE approval process under 21 CFR § 800.100(a)(6)(7).

195. Mentor also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of Kansas law and its duty to describe all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions.

196. Mentor's MemoryGel Silicone Gel Breast Implants implanted during Plaintiffs' surgery contained a manufacturing defect. The rupture, leakage, and bleeding of silicone of the Mentor MemoryGel Silicone Gel Breast Implants implanted into Plaintiffs, due to porous or weak containment in the Implant shell, is inconsistent with specifications and conditions of the FDA's Quality System Regulations and design control requirements under 21 CFR 820.30, and therefore constitutes a manufacturing defect.

197. Mentor knew that the defects in its product were such that they would not be discovered through reasonable inspection by the users of the product, including Plaintiffs and Plaintiffs' implanting physician.

198. Mentor knew that its MemoryGel Silicone Gel Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the

hazards involved in such use.

199. Plaintiffs and their implanting physicians, foreseeable users and ultimate consumers of the Mentor's product, were unaware of these defects when Plaintiffs consented to have the product implanted in their bodies.

200. As a direct and legal result of the manufacturing defects contained in Plaintiffs' MemoryGel Silicone Gel Breast Implants, Plaintiffs was injured in their health and well-being.

201. As a proximate result and/or substantial contributing factor of Mentor MemoryGel Silicone Gel Breast Implants' defective condition at the time they were sold, Plaintiffs has suffered damages and will continue to suffer damages in the future including severe physical injuries, severe emotional distress, mental anguish, economic loss, past medical expenses, future medical expenses, and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendant for the full amount of their damages, plus interest, costs, and such other relief as may be just and equitable.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury as to all claims which are so triable.

Respectfully submitted,

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