IN THE CIRCUIT COURT OF COOK COUNTY
ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

CATHERINE GRAVITT and TRAVIS GRAVITT,

Plaintiffs

v.

MENTOR WORLDWIDE, LLC, a foreign corporation,

Defendant

_____/

2017L006329
CALENDAR/ROOM X
TIME 00:00
Product Liability

Case. No. _____

JURY TRIAL DEMANDED

FILED
2017 JUN 22 PM 3:05

COMPLAINT AT LAW

NOW COME the Plaintiffs, Catherine Gravitt and Travis Gravitt, by and through Seidman Margulis & Fairman, LLP, and Dogali Law Group, P.A., and for their Complaint against Defendant, Mentor Worldwide, LLC, assert the following facts and claims.

1. Plaintiffs bring this action against Defendant Mentor Worldwide, LLC ("Mentor"), in relation to the design, manufacture, marketing, and distribution of Mentor's MemoryGel Silicone Breast Implants, the refusal or reckless failure to abide by Premarket Approval Application ("PMA") requirements established by the Food & Drug Administration ("FDA"), and the failure to warn consumers of known dangers and known adverse events.

PARTIES, JURISDICTION AND VENUE

2. Plaintiff Catherine Gravitt ("Casey Gravitt") is, and at all material times was, a resident of Will County, Illinois.

3. Plaintiff Travis Gravitt is, and at all material times was, the husband of Plaintiff Casey Gravitt and a resident of Will County Illinois.

4. Defendant Mentor is a California corporation which does business within this county and throughout the state of Illinois.

5. Mentor markets itself as the United States and worldwide leader in aesthetic medicine, particularly in relation to breast aesthetics. For more than 30 years, Mentor's products have been implanted into millions of women's breast regions. Mentor purports to be the only breast implant manufacturer which makes its products in the United States of America.

6. Mentor MemoryGel Breast Implants are filled with Mentor's uniquely formulated silicone gel which is said to be neither liquid nor semi-liquid. Instead, it is a cohesive gel that allegedly holds safely and uniformly together to deliver a natural feel that closely resembles breast tissue.

7. At all relevant times, Mentor, individually and in concert with its affiliates and agents, which also do business within this county and throughout the state of Illinois, conveyed false and misleading information concerning Mentor's MemoryGel Silicone Breast Implants, and concealed from Plaintiffs, the public, physicians, and other healthcare providers risks which Mentor knew to be associated with the devices. But for the Defendant's actions, Plaintiff Casey Gravitt would not have suffered the severe injuries which have resulted from implantation of Mentor's MemoryGel Silicone Breast Implants into her body.

8. This Court has personal jurisdiction over Defendant Mentor. Mentor is, and at all material times was, authorized to conduct business in, and conducting business in, the state of Illinois, and such business has caused or contributed to the harm giving rise to this action. In addition, at all material times Defendant maintained continuous contacts within this jurisdiction and transacted business for financial gain within this jurisdiction.

9. The substantial facts relating to Defendant's actions toward Plaintiffs and to Plaintiffs' injuries arising from such actions occurred within the state of Illinois.

10. Venue is proper in this county.

FACTS REGARDING MENTOR AND MEMORYGEL SILICONE BREAST IMPLANTS

11. 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.

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

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

14. Aspects of the design and/or manufacture of a silicone breast implant may result in a phenomenon known as gel bleed. Gel bleed is the microscopic diffusion of silicone gel through the shell of the implant.

15. 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 silicone-filled breast implants 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). In 1988, in response to growing safety concerns, the FDA re-classified breast implants as Class III devices. Upon final publication of the FDA's new regulations in 1991, manufacturers were

required to obtain PMA for new silicone gel-filled breast implants.

16. 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.

17. 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.

18. 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.

19. In January of 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that the manufacturers stop supplying them and that surgeons stop implanting them while the FDA engaged in a further review of the devices' safety and effectiveness. In April of 1992, the FDA determined that insufficient data existed to support PMA for silicone breast implants. From that time, use of the devices in the United States was limited to reconstruction and revision patients.

20. In December of 2003, Mentor submitted another PMA for its MemoryGel Silicone Breast Implants. On or around November 17, 2006, the PMA was granted, marking the first time in fourteen years that the devices were available for augmentation.

21. In connection with the 2006 approval, Mentor was required to conduct six post-approval studies, and was required to address specific issues which had not been encompassed by the PMA and the clinical trials. The studies required as conditions of approval are described by the FDA as follows:

- *Core Post-Approval Studies (Core Studies)* – To assess long-term clinical performance of breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

- *Large Post-Approval Studies (Large Studies)* – To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10-years.

- *Device Failure Studies (Failure Studies)* – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

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

- *Annual Physician Informed Decision Survey (Informed Decision Study)* – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

- *Adjunct Studies* – To provide performance and safety information about silicone

gel-filled breast implants provided to U.S. women from 1992-2006, prior to approval, when implants could only be used for reconstruction and replacement of existing implants.

22. Primary responsibility for timely and accurately communicating safety information related to the medical devices rests with the manufacturer, which has superior and often exclusive access to such information, including post-market complaints. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report to the FDA, the healthcare community, and consumers. The manufacturer must also precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

23. These duties establish that time is of the essence for Mentor when reporting on adverse events. Delayed reporting will prevent the healthcare community and the public from timely learning of risks which must inevitably play a part in their decision-making regarding treatments and procedures.

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

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

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

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

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

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

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

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

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

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

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

25. Mentor failed to fulfill these obligations, and but for such failure, Plaintiff's injuries would not have occurred.

26. Under applicable common law, Mentor had a duty to exercise reasonable care in adequately warning Plaintiff and/or Plaintiff's treating medical professionals about the dangers of Mentor's MemoryGel silicone breast implants, and about adverse events of which Mentor became aware. Also under the common law, Defendant had a post-market duty to monitor and report adverse events and risks associated with the device. Despite having knowledge and possession of evidence showing that the use of Mentor MemoryGel silicone breast implants was dangerous and likely to place consumers' health at serious risk, Mentor refused or recklessly

failed to disclose and warn of the health hazards and risks associated with the product, and about adverse events which were known to Mentor. Instead, Defendant marketed, advertised and promoted the product while at the same time refusing or recklessly failing to monitor, warn, or otherwise ensure the safety and efficacy of users of the MemoryGel devices.

27. Mentor had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its MemoryGel products. Mentor refused or recklessly failed to do so.

28. At all material times, Mentor was required to promptly report any information suggesting that one of its devices 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.

29. 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.

30. As described above, the 2006 approval of Mentor's MemoryGel Silicone Breast Implants required Mentor to perform several different studies in connection with its products.

a. **Core Post-Approval Study**

1) 1008 patients were enrolled in the Mentor Core Study, which was to continue until all patients had completed their 10-year evaluations, in order to assess the long-term clinical performance of the Mentor devices. Mentor was required to collect data at least through physicians' annual examinations. During the period of the Core Study, changes to the post-approval process included the addition of a requirement that all patients without MRIs should have MRIs at years 6, 8, and 10, and all patients who were explanted without replacement were to be evaluated

through 10 years. Mentor was also required to update its patient and physician labeling to reflect the findings of the 5 and 10-year Core Study and to report to the FDA significant new information regardless of when the information became available.

2) Nine years post-implant, the Core Study follow-up rate was no more than 59 percent.

3) In addition, while the FDA required evaluations through 10 years, the report schedule illustrates that reporting was only done for six years. The reported findings of the Core Study lack statistical reliability in the sub-groups (cohorts) which are called: primary augmentation, revision augmentation, primary construction, and revision reconstruction.

4) In the primary augmentation cohort, Mentor reported the reasons for reoperation in only 36% of the samples, and did not disclose why only about one-third of the sample was included in this aspect of the study.

5) In the revision augmentation cohort, the reoperation rate was 43%. Mentor reported the most common reason for reoperation, which was capsular contraction, at 30.4%. Mentor failed to disclose other significant reasons why women in this category needed reoperation.

6) In the primary construction cohort, Mentor reported reoperation rates at 49%. Mentor reported that of that group, 53% needed reoperation because of asymmetry, capsular contraction, rupture, and breast mass. Mentor failed or refused to document the reasons the remaining 47% of patients in this category needed reoperation.

7) In the revision reconstruction cohort, reoperation was performed on 50.7% of the

women surveyed. The most frequently reported reasons were capsular contraction and breast mass, totaling 36% of reoperations. Other reported reasons, including connective tissue, neurologic disorders and gel bleed were downplayed even though they were significant given the small sample studied.

b. Large Post-Approval Study

1) Mentor's Large Study was to be consistent with a protocol submitted to the FDA by Mentor on September 26, 2006. The protocol required patient enrollment within 90 days of issuance of the PMA. The Large Study was separate from the Core Study and was to include 900 Mentor silicone gel patients and 1,000 saline-filled breast implant patients as the control group. The purpose of the Large Study was to address specific issues which the Core Study was not designed to fully address, including a real-world assessment of long-term local complications, 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. Data was to be collected through annual patient questionnaires completed via the Internet, mail or telephone. The Large Study also required physician evaluations at years 1,4,6,9 and 10, to collect data on complications. Mentor was required to update its patient and physician labeling to reflect the 5 and 10-year Large Study findings, as well as at any other time, if necessary to report significant new findings or information.

2) At the outset, 41,451 patients were enrolled, over 500 patients fewer than the PMA requirements. Of those patients, 113 did not provide important information. At year three, Mentor's overall follow-up rate was only 21%, with no data

obtained for 79% of the patients. At year seven, the rate had declined to 20.1% (8,331 participants), leaving 79.9% of the desired statistics unavailable for evaluation. With such a high rate of non-follow-up, Mentor's study failed to even arguably demonstrate that Mentor's MemoryGel Silicone Breast Implants were performing safely. The impact of Mentor's under-reporting is made even worse by the fact that the study was to include a reason for reoperation which was previously unevaluated – MRI results for rheumatologic or neurological symptoms.

3) In addition to Mentor's follow-up rate of only 21% at three years and 20% at seven years, Mentor reported no follow-up rate at all at ten years.

c. <u>Device Failure Post-Approval Study</u>

1) In order to ascertain the reasons for and frequency of device failure, the FDA specifically required that "Mentor must continue preclinical studies to characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large post-approval study." This study was designed to address several specific issues: "(1) further evaluation of iatrogenic failures to address issues...; (2) the characterization of when surgical instrument damage occurs; (3) further evaluation and characterization of failures due to localized shell stress; and (4) any correlation between surgical factors (e.g., incision size) and device rupture." Mentor was also required to update its patient and physician labeling to reflect any relevant findings from this study.

2) Mentor's Device Failure Study report of summary findings to the FDA did not list sample size, did not provide results or findings (no clinical data and no visual inspection data), did not provide safety data or findings, did not provide

recommendations for follow-up on any data, and did not list any changes to labeling.

3) For the Device Failure Study, Mentor merely filed a skeletal report with minimal information to create evidence that it was following reporting protocol, even though it was not doing so in substance.

d. <u>Focus Group Post-Approval Study</u>

4) Mentor's Focus Group Study was intended to encompass augmentation and reconstruction patient groups. An independent group was to obtain responses from patients on the adequacy of the format and content of the approved labeling. Upon completion of the Focus Group Study, Mentor was to provide a report of the findings and a revised patient and physician labeling based on those findings.

5) Mentor used only 35 women to evaluate how its universe of patients understood Mentor's safety and labeling brochures. Among the infinitesimal focus group, some respondents concluded that the true purpose of the brochure was to protect Mentor, rather than to inform patients about the risks of breast implant surgery. Respondents reported that the label information did not help them understand the risks and complications associated with breast implants. Respondents also felt the brochure did not provide information on the benefits of breast implants and did not acknowledge the deeply personal benefits of body image and self-esteem, especially for women who had lost their natural breasts to cancer.

6) The recommendations for labeling changes included adding information clearly describing differences between restoration, replacement, reconstruction, and revision early in the main body of the brochure; adding information on potential complications based on the likelihood of occurrence; providing more information

about benefits; and providing more qualitative information to help women make more informed decisions. Despite the long list of recommendations for labeling changes, nothing further was done.

e. Informed Decision Post-Approval Study

1) The Informed Decision Study required Mentor to distribute its approved patient labeling to all physicians intending to use the silicone gel products. Both the physician and the patient were intended to sign designated sections in order to best assure that each patient had obtained the labeling sufficiently in advance of surgery to read it and understand the risks and other information associated with the Mentor device. Mentor was to conduct the survey by randomly selecting 50 physicians on an annual basis, collecting the results, and providing a summary of the findings to the FDA. In addition, Mentor was to provide training on this process as part of its physician training program.

2) The summary of findings filed by mentor did not list the sample size of patients enrolled. It provided insight for only one year (2011) and disclosed little information which might have been helpful. For example, the report did not disclose the efforts which went into the survey, or which points were assessed.

f. Adjunct Post-Approval Study

1) The final study which was imposed by the FDA as a condition of product approval was the Adjunct Study, for which Mentor was to continue prior efforts. The study was originally designed to serve a public health need for reconstruction and revision patients, but in light of the PMA the study was revised so that Mentor was required to: (1) cease new patient enrollment into the study, and (2) continue to follow up on currently-enrolled Mentor Adjunct Study patients

through five years. The data from the follow-up study was to be reported as part of Mentor's annual PMA reports.

2) In addition to addressing the health needs of reconstruction and revision patients, the study was to gather data regarding short-term implant complications. After completion of the study, Mentor reported on only 36.8% of the patients in the reconstruction cohort; 49.7% revision- reconstruction cohort; and approximately 33% of the revision-augmentation cohort. Ultimately, Mentor blamed its under-reporting on "poor patient compliance."

31. The objective of all six of these studies was long-term safety. Mentor's poor follow-up rates and inadequate data confirm Mentor's reckless disregard for this objective. Halfway through the ten-year prospective post-marketing studies mandated by the FDA, well over 50% of the 80,000 women in the study groups were dropped or otherwise eliminated from the studies. Of the patients who were accounted for, significant numbers reported systemic ailments which could only be attributed to gel bleed introducing known toxins including silicone, heavy metals and chemicals into their bodies. Mentor was aware, or should have been aware, that the gel contained chemicals and metals toxic to the human body and was prone to seep into women's bodies, but Mentor refused or recklessly failed to report this information to the FDA, and to thus warn Mentor's patients of the grave threat presented by Mentor's devices, and of patient negative patient experiences and events of which Mentor was aware.

32. 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 had reported. It has also been reported that the 13 silicone is more likely to leak, even when the implants are intact and that platinum used in the implants is more dangerous than reported. Mentor knew of these risks associated with its implant devices, but covered up the information by terminating studies,

sponsoring only self-serving research Mentor could control, and misrepresenting the risks presented by its products to users, physicians, and regulatory agencies.

33. To protect the Mentor MemoryGel Silicone Breast Implant brand, Mentor consciously and deliberately concealed its knowledge of known safety risks from the FDA and public.

34. Defendant also has a duty under Illinois law to law 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 2006. Defendant Mentor failed or refused to do so.

35. At material times, Mentor 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 devices;

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 Mentor's 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 Mentor's reporting to its manufacturing processes as a potential cause of product failures relating to finished devices 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 Mentor's sampling methods for finished device testing;

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

j. Deficiencies in Mentor's environmental monitoring control procedures; and

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

36. These deviations and more were cited by the FDA's Office of Regulatory Affairs in reports dated: May 10, 2000, following inspections from May 1, 2000 to May 10, 2000; April 23, 2001 following inspections from April 16, 2001 to April 23, 2001; February 15, 2002, following inspections from February 4, 2002 to February 15, 2002; April 22, 2003, following inspections from April 16, 2003 to April 22, 2003; April 30, 2004, following inspections from April 13, 2004 to April 30, 2004; and December 7, 2007, following inspections from November 7, 2007 to December 7, 2007.

37. Mentor's Product Insert Data Sheet regarding the implants states that "[s]mall quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell. Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact MemoryGel Breast Implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supposes that the extremely low level of gel bleed is of no clinical consequence."

38. Residual arsenic, antimony, barium, chromium, cobalt, copper, mercury, molybdenum, nickel, selenium, tin, titanium, vanadium, and zinc are contained in Mentor's silicone gel implants and/or are present in the implants as a result of Mentor's manufacturing processes. Absent gel bleed far beyond Mentor's claimed "extremely low level [which] is of no clinical consequence," unnaturally elevated levels of metals would not be present in the bodies of Mentor's victims, including Plaintiff.

39. The nature and extent of Plaintiff's injuries evidence a significant gel bleed, as opposed to a bleed of small quantities of gel or extremely low levels of gel bleed.

40. Mentor failed to warn consumers, healthcare providers, and the FDA that a significant gel bleed was a potential risk of MemoryGel Silicone Gel Breast Implants, and that patients had suffered negative experiences and events as a result of such risk.

41. The risk of a significant gel bleed was not disclosed or discussed in what Mentor calls its "Directions for Use" or in its consumer labeling, despite the availability of substantial evidence that significant gel bleed was a substantial risk of use, even in a properly manufactured product.

42. In a FDA report on Mentor's breast implants entitled FDA Update on the Safety of Silicone Gel-Filled Breast Implants, the FDA advised that since Mentor began post-approval studies in 2007, Mentor found 43.5% of implants retrieved from patients participating in the large post-approval study had ruptures, and 25% of 97 implants that were explanted and returned to Mentor for evaluation from August 2000 to August 2009 in the Core Study had ruptured.

43. Mentor knew of multiple risks associated with implants, and responded by terminating studies in favor of self-serving research that it could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

FACTS SPECIFIC TO CASEY GRAVITT

44. In 2008, Casey Gravitt gave birth to a healthy daughter. Following her post- natal weight loss and a period of breastfeeding, Casey Gravitt suffered severe loss of breast volume. Her physician advised the condition could be corrected with breast augmentation surgery.

45. In December of 2009, Casey Gravitt underwent saline breast implantation surgery. The 2009 surgery was followed by a period of complications, including the failure to develop scar tissue and associated dropping of the implants.

46. During 2010, Casey Gravitt underwent revision or curative implantation surgery, during which textured-surface Mentor MemoryGel Silicone Breast Implants were implanted.

47. At the time the Mentor MemoryGel implants were placed into Casey Gravitt's body, she was not advised, nor did she have any independent knowledge, that the devices were anything other than safe, life-long devices. Nor was she advised that the materials incorporated into the manufacture of the devices contained anything other than inert, non-toxic materials. She was not advised, and had no independent knowledge that:

a. A significant risk of implant rupture existed; or

b. A significant risk of implant leakage or seepage existed; or

c. She might need future surgery to prevent rupture, leakage or seepage; or

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

e. She might need future imaging procedures to check for, or evaluate, ruptures, leakage or seepage; or

f. The silicone gel with which Mentor fills its MemoryGel implants contains many compounds and metals which are toxic to the human body; or

g. In the event of rupture, leakage or seepage, silicone and other toxic elements and compounds would travel throughout Casey Gravitt's body; or

h. If the silicone gel with which Mentor fills its MemoryGel implants should escape the implant and travel throughout the body, grave injuries will occur.

48. If Casey Gravitt had been advised that exposure to rupture and to future surgery was a meaningful risk, she would not have proceeded with implantation of the Mentor devices.

49. Over the years following implantation of the Mentor MemoryGel devices, Casey Gravitt began to experience an array of unfamiliar conditions and disorders. Because she understood the Mentor MemoryGel implant devices to be stable and inert products, she did not

associate her conditions with the implants, nor did her treating medical professionals. Conditions which caused her extreme suffering, from the time the Mentor MemoryGel devices were implanted, include:

a. Severe and random skin rashes and random acne;

b. Blackouts and periods of disorientation, to the extent that Casey Gravitt stopped driving, fearing for the safety of others and herself;

c. Severe memory decline, to the point that she was required to stop her schooling, and to forsake her planned future career;

d. Muscle soreness;

e. Extreme fatigue;

f. Abnormal thyroid levels;

g. Drowsiness; and

h. Anxiety and depression with the above-described injuries and conditions which were caused by the Mentor devices.

50. During these years following implantation of the Mentor MemoryGel devices, Casey Gravitt's treating medical providers administered many tests and attempted many treatments for the above-described conditions.

51. Some of the tests which were administered showed elevated levels of bromine and other toxins and metals.

52. Treatments included laser procedures for the skin conditions, chelating pills for elevated toxin levels, prescription medications for her thyroid and other conditions, and more. None of the tests or treatments led to improvement of her conditions.

53. In 2011, Casey Gravitt gave birth to a son who was born with a severe heart

defect, coarctation to the aorta and ventricular septal defect. Her son underwent open-heart surgery when he was six days old.

54. In 2013, Casey Gravitt gave birth to a daughter who was born with a severe bladder and kidney defect. Her daughter underwent surgery for the condition when she was two years old.

55. As 2016 began, the above-listed conditions had progressed to an intolerable level. Casey Gravitt was unable to stay awake, even when sitting up. She was extremely weak and fatigued, having no energy to even play with her children. She continued to suffer memory lapses and disorientation, to the extent she would occasionally fail to respond to her own name or would forget sentences while saying them. She had frequent flu-like symptoms and continued to suffer skin rashes.

56. All of these conditions caused Casey Gravitt's children to frequently miss the support of their loving mother, and caused Travis Gravitt to miss considerable work, particularly during times when Casey Gravitt's condition effectively left her bedridden.

57. During 2016, Casey Gravitt experienced breast pain, at which time she found a lump at her right breast. Until that time, Casey Gravitt did not relate any of her conditions to the Mentor MemoryGel Silicone Breast Implants, which she always thought were stable, inert and safe devices. Also, none of Casey Gravitt's medical providers had advised her that any of her above-described conditions, symptoms, and test results might relate to her Mentor MemoryGel Silicone Breast Implants.

58. Following the breast pain which appeared in 2016 along with the lump in her breast, Casey Gravitt's physician performed an ultrasound examination and discovered a lump which appeared to be silicone which had leaked. A subsequent MRI confirmed that the breast

implant had ruptured.

59. Through the ensuing months, Casey Gravitt and Travis Gravitt attempted to save money toward the cost of corrective surgery. During this time, Casey Gravitt's above-described symptoms worsened. Ultimately, one of her physicians determined that Casey Gravitt's lymph nodes had become undermined, whereupon he deemed the breast implant removal surgery to be an emergency.

60. In October of 2016, Casey Gravitt underwent surgery and the Mentor MemoryGel implants were removed. Some lymph nodes were deemed to have been contaminated by silicone and were also removed.

61. Since the 2016 surgery, Casey Gravitt's breast region and armpits have been very swollen and painful. Follow-up imaging showed the presence of more silicone which is contaminating Casey Gravitt's lymph nodes. In June of 2017, her treating professionals advised her that removing more lymph node tissue would be life-threatening, so the silicone which is causing the swelling and pain in her lymph nodes will just have to remain.

62. Prior to her breast revision and correction procedure in December of 2009, Plaintiff enjoyed an active, full life, and did not experience the symptoms which arose after the Mentor MemoryGel Silicone Breast Implants were placed in her body.

63. Plaintiff Casey Gravitt 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 Defendant's product. She did not suspect, nor did she have reason to suspect, that her injuries were caused by the Mentor MemoryGel Silicone Breast Implants, or by Mentor's tortious conduct.

64. Defendant Mentor, through its misrepresentations and omissions including its refusals or reckless failures to report defects and significant events to the FDA as required by

law, concealed from Plaintiff and her healthcare providers the true and significant risks associated with the Mentor product.

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

CAUSES OF ACTION

COUNT 1 – NEGLIGENCE AND NEGLIGENCE PER SE

66. Plaintiff Casey Gravitt incorporates the allegations of paragraphs 1 through 65 above.

67. At all material times, Defendant Mentor owed to Plaintiff Casey Gravitt a duty to use reasonable care in formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Mentor MemoryGel Silicone Breast Implants.

68. Defendant Mentor formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor MemoryGel Silicone Breast Implants, including the devices which were implanted into Plaintiff Casey Gravitt.

69. Plaintiff was implanted with Mentor MemoryGel Silicone Breast Implants which were defective and dangerous 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.

70. Defendant had a duty under applicable law to exercise reasonable care to provide adequate warning about the risks and dangers of Mentor MemoryGel Silicone Breast Implants that were known or reasonably knowable to Mentor at the time of distribution, and that Mentor

had come to know in light of adverse conditions and events experienced by patients in whom the Mentor devices were implanted.

71. Defendant breached its duty by failing to warn Plaintiff Casey Gravitt and her physicians, either directly or by not timely and accurately reporting to regulatory authorities the risks of serious defects and life-altering complications which Mentor knew or reasonably should have known were associated with Mentor's MemoryGel Silicone Breast Implants, and about ailments and adverse conditions which had been experienced by Mentor patients in whom the devices were previously implanted.

72. Mentor's specific actions which constitute breaches of these duties to Plaintiff include: failing to timely and accurately report adverse events regarding the Mentor MemoryGel Silicone Breast Implants; failing to report the MemoryGel Silicone Breast Implant devices' 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 and information; failing and 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 MemoryGel Silicone Breast Implants, including complaints regarding:

a. Leaks, and frequencies of leaks;

b. Ruptures, and frequencies of ruptures;

c. Silicone toxicity and related injury conditions;

d. Adverse events requiring removal; and

e. Persistent and/or chronic inflammation or autoimmune impacts.

73. Mentor disseminated false information by deliberately engaging in false and misleading sales and marketing tactics touting the aesthetic beauty of breast augmentation and minimizing the risks, which reached physicians, the medical community, and the public.

74. At all material times, Mentor knew and intended that the medical community and/or patients would rely upon Mentor's disseminated information in deciding whether to purchase and/or implant Mentor's MemoryGel Silicone Gel Breast Implant devices.

75. At all material times, Mentor knew and intended that patients who were implanted with Mentor MemoryGel Silicone Breast Implants would, in reliance on false information, be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Mentor MemoryGel Silicone Breast Implants, causing them to undergo future removal surgeries and to suffer debilitating illnesses and conditions.

76. Plaintiff and/or Plaintiff's physicians reasonably relied on Defendant's negligent misrepresentations and omissions, as Defendant intended.

77. As a proximate and foreseeable result of the foregoing misrepresentations by Defendant, Plaintiff has suffered and will continue to suffer 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.

78. For each of the statutes and regulations cited in this Complaint, Plaintiff Casey Gravitt 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. Mentor's violations of the cited statutes and regulations give rise to negligence per se.

79. Defendant was negligent in its development, promotion, marketing, manufacture, distribution, and/or sale of Mentor MemoryGel Silicone Gel Breast Implants in one or more of the following ways:

a. Designing, manufacturing, distributing and selling Mentor MemoryGel Silicone Breast Implants that are dangerous to the consuming public;

b. Designing, manufacturing, distributing and selling Mentor MemoryGel Silicone

Breast Implants which differ from the specifications set forth in the PMA, its Supplements, and the Conditions of Approval;

c. Failing to conduct regular risk analyses of Mentor MemoryGel Silicone Breast Implants; and

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

80. As a proximate and legal result of Defendant's failure to exercise reasonable care in the design, manufacture, distribution and sale of the Mentor MemoryGel Silicone Breast Implants implanted into Plaintiff, Plaintiff has suffered and will continue to suffer severe 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 Catherine Gravitt prays for judgment in her favor and against Defendant Mentor Worldwide LLC for all damages due under applicable law, along with interest, costs and such other relief as this Court may deem just and appropriate.

COUNT 2 – STRICT PRODUCTS LIABILITY: FAILURE TO WARN

81. Plaintiff Casey Gravitt incorporates the allegations of paragraphs 1 through 65 above.

82. At all material times, Defendant Mentor was engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Mentor MemoryGel Silicone Breast Implants.

83. Defendant Mentor formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted

Mentor MemoryGel Silicone Breast Implants, including the devices which were implanted into Plaintiff Casey Gravitt.

84. Plaintiff was implanted with Mentor MemoryGel Silicone Breast Implants which were defective and dangerous 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.

85. At all material times, Defendant intended for the MemoryGel Silicone 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.

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

87. Defendant Mentor 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.

88. Plaintiff's Mentor MemoryGel Silicone Breast Implants were defective at the time of sale and distribution, and at the time they left Defendant Mentor's possession, and Defendant Mentor 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 injuries precisely like those suffered by Plaintiff Casey Gravitt.

89. Defendant knew or should have known the gel contained in the implants contained metals and toxic chemicals in quantities that would be extremely harmful to users of the product if the gel were allowed to escape its shell and "bleed" into the user's body. Defendant also knew or should have known that there was a significant risk of rupture of the shell, or of seepage of silicone through the shell, with resulting dangerous infiltration into the tissues of the user's body.

90. Despite the fact that Defendant knew or should have known that implantation of Mentor MemoryGel Silicone Breast Implants was unreasonably dangerous and was likely to seriously jeopardize the health of consuming patients, Defendant Mentor failed to monitor and warn of the defects, health hazards and risks associated with the product.

91. The defects inherent in Mentor MemoryGel Silicone 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.

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

93. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Breast Implants were used and implanted as intended by Defendant and in a manner reasonably foreseeable to Defendant.

94. Mentor MemoryGel Silicone Breast Implants manufactured, designed, promoted, marketed, distributed, and sold by Defendant were expected to, and did, reach Plaintiff's physician without substantial change in the condition in which they were sold.

95. Defendant knew that Mentor MemoryGel Silicone 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.

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

97. 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 MemoryGel Silicone Breast Implants.

98. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Breast Implants' defective 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 Catherine Gravitt prays for judgment in her favor and against Defendant Mentor Worldwide LLC for all damages due under applicable law, along with interest, costs and such other relief as this Court may deem just and appropriate.

COUNT 3 – STRICT PRODUCTS LIABILITY

99. Plaintiff Casey Gravitt incorporates the allegations of paragraphs 1 through 65 above.

100. At all material times, Defendant Mentor was engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Mentor MemoryGel

Silicone Breast Implants.

101. Defendant Mentor formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Mentor MemoryGel Silicone Breast Implants, including the devices which were implanted into Plaintiff Casey Gravitt.

102. Plaintiff was implanted with Mentor MemoryGel Silicone Breast Implants which were defective and dangerous 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.

103. At all material times, Defendant intended for the MemoryGel Silicone 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.

104. Defendant Mentor failed to warn Plaintiff and her physicians of the risk of serious defects and life-altering complications described herein rendering the device defective and unreasonably dangerous.

105. Defendant Mentor 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.

106. Plaintiff's Mentor MemoryGel Silicone Breast Implants were defective at the time of sale and distribution, and at the time they left Defendant Mentor's possession, and Defendant Mentor 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 injuries precisely like those suffered by Plaintiff Casey Gravitt.

107. Defendant knew or should have known the gel contained in the implants contained metals and toxic chemicals in quantities that would be extremely harmful to users of the product if the gel were allowed to escape its shell and "bleed" into the user's body. Defendant also knew or should have known that there was a significant risk of rupture of the shell, or of seepage of silicone through the shell, with resulting dangerous infiltration into the tissues of the user's body.

108. Despite the fact that Defendant knew or should have known that implantation of Mentor MemoryGel Silicone Breast Implants was unreasonably dangerous and was likely to seriously jeopardize the health of consuming patients, Defendant Mentor failed to monitor and warn of the defects, health hazards and risks associated with the product.

109. The defects inherent in Mentor MemoryGel Silicone 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.

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

111. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Breast Implants were used and implanted as intended by Defendant and in a manner reasonably foreseeable to Defendant.

112. Mentor MemoryGel Silicone 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.

113. Defendant knew that Mentor MemoryGel Silicone 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.

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

115. The defective product was a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Mentor MemoryGel Silicone Breast Implants.

116. 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 MemoryGel Silicone Breast Implants.

117. As a proximate result and/or substantial factor of Mentor MemoryGel Silicone Breast Implants' defective 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 Catherine Gravitt prays for judgment in her favor and against Defendant Mentor Worldwide LLC for all damages due under applicable law, along with interest, costs and such other relief as this Court may deem just and appropriate.

COUNT 4 – LOSS OF CONSORTIUM

118. Plaintiff Travis Gravitt incorporates the allegations of paragraphs 1 through 65 above.

119. As a result of the injuries and damages caused to Plaintiff Casey Gravitt by Defendant Mentor's tortious conduct, Casey Gravitt was unable to perform activities she had previously commonly performed for the household, for the family, and for her own support. Consequently, Plaintiff Travis Gravitt was required to:

a. Perform all activities and upkeep around the house;

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

c. Take over many of the activities which Casey Gravitt previously commonly performed as a parent to Casey Gravitt's and Travis Gravitt's children; and

d. Take over all family transportation needs, particularly after Casey Gravitt's injuries required her to stop driving.

120. As a result of Defendant's defective Mentor MemoryGel Silicone Breast Implants and the injuries they caused to Casey Gravitt, Travis Gravitt effectively lost the companionship and accompaniment of his wife.

121. As a further result of Defendant's defective Mentor MemoryGel Silicone Breast Implants and the injuries they caused to Casey Gravitt and the resulting demands placed upon Travis Gravitt, Travis Gravitt has suffered lost wages and income.

122. As a direct and proximate result of the injuries caused to Plaintiff Casey Gravitt by Defendant Mentor's tortious conduct, Spouse Plaintiff Travis Gravitt 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 Travis Gravitt prays for judgment in his favor and against Defendant for all economic, non-economic and compensatory damages due under applicable law, along with interest, costs and such other relief as this Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

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

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