UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF
GEORGIA

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITICATION,	**MDL DOCKET NO. 2974** **No. 1:20-md-02974-LMM**
This document relates to: **STACY GUZMAN**	**Civil Action No. 1:20-md-**

COMPLAINT

COME(S) NOW, STACY GUZMAN, Plaintiff herein, complaining of TEVA PHARMACEUTICALS, USA, INC.; TEVA WOMEN'S HEALTH, INC., doing business as TEVA WOMEN'S HEALTH, LLC; THE COOPER COMPANIES, INC. and COOPERSURGICAL, INC., Defendants herein, both jointly and severally, as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold the ParaGard Intrauterine medical device that was implanted into Plaintiff, and throughout the United States, and for cause of action say:

Parties

1. Plaintiff Stacy Guzman, ("Plaintiff"), Plaintiff herein, is an individual residing in Navarre, Santa Rosa County, Florida, citizen of the State of Florida.

2. Defendant Teva Pharmaceuticals USA, Inc. (hereinafter "Teva Pharmaceuticals" or "Teva USA") is a Delaware corporation with headquarters located at 1090 Horsham Rd. in North Wales, Pennsylvania, a citizen of Delaware and Pennsylvania. At times relevant to this action, Teva USA designed, developed, manufactured and marketed the ParaGard IUD at issue. At times relevant to this action, Teva USA communicated with the United States Department of Health and Human Services, Food and Drug Administration (hereinafter "FDA") regarding the sale, use, and safety concerns related to ParaGard IUDs, which includes managing product recalls, investigating adverse events from ParaGard IUD users, and performing mandatory reporting to FDA regarding the ParaGard IUD. Defendant Teva Pharmaceuticals USA, Inc. may be served with process by serving its registered agent in Delaware, Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building, Ste. 104, Wilmington, DE 19810.

3. Defendant Teva Women's Health, Inc., is a Delaware corporation with headquarters located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Teva USA, and/or operated as a successor-in-interest to Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., and/or assumed Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., in a name change after its acquisition by Teva USA. Teva Women's Health, Inc. converted into Teva Women's Health, LLC in 2017 and continues to operate as Teva Women's Health, LLC. Teva Women’s Health, Inc. is a citizen of Delaware and Pennsylvania. Defendant Teva Women’s Health, Inc. may be served with process by serving its registered agent in Delaware, Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building, Ste. 104, Wilmington, DE 19810.

4. Defendant Teva Women's Health, LLC is a Delaware limited liability company with headquarters located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Defendants Teva Pharmaceuticals. Teva Women's Health, LLC is the product of an entity conversion pursuant to Del. Code Ann. Tit. 8, 266. Teva Women's Health, Inc., converted into Teva Women's Health, LLC and continues to operate as a limited liability company instead of an incorporation (Teva Women's Health, LLC formerly known as Teva Women's Health, Inc. collectively hereinafter "Teva Women's Health"). Upon information and belief, Plaintiff(s) allege(s) that Teva Women's Health is a citizen of Delaware and Pennsylvania. Defendant Teva Women's Health, LLC may be served with process by serving its registered agent in Delaware, Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building, Ste. 104, Wilmington, DE 19810.

5. Accordingly, Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., d/b/a Teva Women's Health Inc., (hereinafter "Duramed"), acquired FEI Women's Health in 2005 wherein the asset of Para Gard IUD was acquired in the deal. Duramed was acquired by Teva USA in 2008 wherein its name was changed to Teva Women's Health, Inc., a wholly-owned subsidiary of Teva USA. (Defendants Teva USA and Teva Women's Health collectively hereinafter "Teva Defendants").

6. Defendant Teva Branded Pharmaceutical Products R&D, Inc. ("Teva R&D") is a corporation with headquarters located at 41 Moores Rd. in Frazer, Pennsylvania (collectively Defendants Teva Pharmaceuticals, Teva Women's Heath and Teva R&D are referred herein as the "Teva Defendants"). At all times relevant to this action, Teva R&D designed, developed, manufactured and marketed the Paragard at issue. At times relevant to this action, Teva R&D communication with the United States Department of Health and Human Services, Food and Drug Administration ("FDA") regarding the sale, use, and safety concerns related to ParaGard IUDs.

7. Defendant The Cooper Companies, Inc., (hereinafter "Cooper Companies") is a

process by serving its registered agent for service, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808.

8. Defendant CooperSurgical, Inc., (hereinafter "Cooper Surgical") is a Delaware corporation with headquarters at 95 Corporate Dr. in Trumbull, Connecticut and a subsidiary of Defendant Cooper Companies (Defendants Cooper Companies and CooperSurgical collectively hereinafter "Cooper Defendants"). Defendant Cooper Surgical is a Citizen of Delaware and Connecticut. Defendant CooperSurgical, Inc. may be served with process by serving its registered agent for service, The Prentice-Hall Corporation System, Inc., 251 Little Falls Drive, Wilmington, DE 19808.

Jurisdiction

1. The amount in controversy is within the jurisdictional limits of this court.

2. Jurisdiction is proper in this court pursuant to 28 U.S.C. § 1332 as complete diversity of citizenship exists between Plaintiff and Defendants and the matter in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

3. This Court has jurisdiction over the non-resident Defendants because they have conducted business in the state of Georgia. Defendants have committed a tort in whole or in partin the state of Georgia and have regular and continuing contacts with Georgia.

4. This Court has jurisdiction over each Defendant because each Defendant maintained sufficient minimum contacts with the State of Georgia such that the exercise of jurisdiction by the Court over each Defendant would not offend traditional notions of fair play and substantial justice.

Venue

1. At all times relevant hereto and alleged herein, the Defendants conducted and continue to conduct substantial business within the state of Georgia, and within the Northern District of Georgia.

2. At times relevant hereto and alleged herein, the Defendants conducted and continue to regularly conduct substantial business within the state of Georgia, which included andcontinues to include, the research, safety surveillance, manufacture, sale, distribution and marketing of the ParaGard IUD, which is distributed through the stream of interstate commerce into the state of Georgia, and within the Northern District of Georgia.

3. At all times alleged herein, Defendants were authorized to conduct or engage in business within the state of Georgia and supplied the ParaGard IUD within the state of Georgia and the Northern District of Georgia. Defendants received financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing the ParaGard IUD within the state of Georgia, and the Northern District of Georgia.

4. Venue of this case is proper in the Northern District of Georgia pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs claims occurred in The Northern District of Georgia.

Statement of Facts Applicable to All Counts

1. This is an action for damages relating to the Defendants' design, manufacture, surveillance, sale, marketing, advertising, promotion, labeling, packaging, and distribution of ParaGard Intrauterine medical device (hereinafter "ParaGard IUD").

2. The ParaGard IUD is an intrauterine device, however, it is regulated as a drug. It is placed into the uterus to prevent conception.

3. The Para Gard IUD has a propensity to break at the arms upon explant resulting in serious injuries.

4. Plaintiff Stacy Guzman used the ParaGard IUD, and as a result of its use suffered injuries.

5. Plaintiff Stacy Guzman ("Plaintiff'), by and through her attorneys, brings this action for personal injuries suffered as a result of using the defective and dangerous ParaGard IUD.

6. The ParaGard IUD is prescribed to prevent conception, and at all times relevant hereto, were manufactured, designed, tested, packaged, labeled, marketed, advertised, promoted, distributed, and sold by Defendants.

7. On or about November 21, 2016, Juanita Wyatt Hathaway, placed a Paragard IUD into Plaintiff at Atlanta Women's Specialists, 5445 Meridian Mark Rd., #430, Atlanta, GA 30342. The ParagardIUD placed into Plaintiff is believed to have lot number 516002.

8. On or about July 29, 2020, William R. Lile, attempted to remove the Paragard IUD that had been placed into Plaintiff at Women's Health Clinic Pensacola, 5153 N 9th Ave, #205, Pensacola, FL 32504. The Paragard IUD was attempted to removed by grasping the Para Gard IUDand pulling gently, according to the Defendant's instructions. Instead, the Paragard IUD broke inside Plaintiff.

9. Plaintiff was told she would have to have her Paragard IUD removed surgically.

10. At times relevant to this action, Teva USA was involved in regulatory communications, and medical communications, including but not limited to communications with physicians, doctors, the FDA and other medical personnel, which led to activities giving

rise to failure to warn, negligence, gross negligence, common law fraud, negligent misrepresentation, breach of warranty, and a violation of consumer protection laws.

11. At times relevant to this action, Teva Women's Health, Inc. designed, developed, manufactured and marketed the ParaGard IUD at issue.

12. The ParaGard IUD is an intrauterine drug that can provide long term birth control, up to 10 years, without hormones.

13. The ParaGard IUD drug is a T-shaped plastic frame made of polyethylene and barium sulfate that is inserted into the uterus. Copper wire coiled around the IUD produces an inflammatory reaction that is toxic to sperm and egg. A monofilament polyethylene thread is tied through the tip, resulting in two white threads, which aid in the detection and removal of the drug.

14. At relevant times, Teva Defendants designed, researched, manufactured, labeled, packaged, promoted, marketed and/or sold the ParaGard IUD at issue after receiving New Drug Application approval from FDA.

15. In 2008, Teva USA became the owner of the ParaGard IUD when it acquired Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., through its purchase of Barr Pharmaceuticals, Inc.

16. Upon information and belief, when Teva USA acquired Duramed, a division of Barr Pharmaceuticals, Inc., it also acquired Duramed's manufacturing facilities, sales force and responsibility for maintaining and updating the labeling for ParaGard IUD.

17. Shortly thereafter, Teva USA changed the name of Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., to Teva Women's Health, Inc., a wholly owned subsidiary of Teva USA.

18. On August 31, 2009, Duramed Pharmaceuticals, Inc., filed with the Ohio Secretary of State a Certificate of Amendment to Foreign Corporation Application For License requesting a name change. A new entity was not created, and no entities were dissolved. Duramed's license number did not change. Instead, Duramed changed its name to Teva Women's Health, Inc.

19. Upon information and belief, Teva Women's Health, Inc. is simply a new name for Duramed.

20. Upon information and belief, and for purposes of liability and interest, Teva Women's Health, Inc., is the same entity as Teva Women's Health, LLC. Teva Women's Health, Inc., converted into Teva Women's Health, LLC under the laws of Delaware. Del. Code Ann. Tit. 8, 266. Pursuant to Del. Code Ann. Tit. 8, 266, a company that converts from one entity into another is deemed to be a continuation of the preexisting company. A conversion does not equate to a dissolution and no winding up takes place. Therefore, Teva Women's Health, Inc., did not dissolve, windup, or *cease to exist* and liability continues from the corporation to the Limited Liability Company.

21. Upon information and belief on August 11, 2017, Teva Women's Health, Inc., converted into Teva Women's Heath, LLC and sold off all of its assets.

22. On September 11, 2017, Teva Defendants sold the ParaGard IUD to Cooper Defendants.

23. ParaGard IUD is currently sold only in the U.S. and had earned revenues of approximately $168 million for the twelve-month period ending June 30, 2017.

24. The Cooper Defendants still manufacture and sell the ParaGard IUD in the U.S.

25. The ParaGard IUD was marketed heavily by Defendants as being safe and effective, and promising fewer side effects than other birth control methods.

26. The marketing and promotional efforts of Defendants, their advertisers, and sales force served to overstate the benefits of ParaGard IUD and minimize and downplay the risks. These promotional efforts were made while Defendants fraudulently withheld important safety information from health care providers and the public.

27. Prior to Plaintiff being implanted with the ParaGard IUD, Defendants knew and should have known that the drug was defective and unreasonably dangerous.

28. Defendants knew or should have known that ParaGard IUD can and does cause serious harm to individuals who use it, due to the risk of the ParaGard IUD's arm breaking upon removal.

28. Defendants knew of these risks from the trials they performed, their post-marketing experience and complaints, third party studies, and their own analysis of these studies, but took no action to adequately warn or remedy the defects and instead concealed, suppressed and failed to disclose or fix this danger.

29. The product warnings for ParaGard IUD were vague, incomplete or otherwise wholly inadequate to alert prescribing physicians and patients to the actual risks associated with ParaGard IUD.

30. Defendants' marketing and promotion, through its own website, sought to reassure physicians and patients of Defendants' longstanding record of quality and safety assurance.

31. Based upon these representations, upon which Plaintiff and her physician relied, Plaintiff had the ParaGard IUD implanted, believing it would be safe and effective, for the entire duration it was implanted and upon removal.

32. Since 2010, the FDA has received over 1600 reports of ParaGard IUD breakage, with over 700 classified as serious.

33. Defendants failure to adequately communicate and report to the FDA the injuries associated with ParaGard IUD resulted in inadequate warnings.

34. The Cooper Defendants are also liable as successors-in-interest; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

35. Plaintiff, a young and healthy woman, wanted a ParaGard IUD because it was a reversible form of birth control that would allow her to conceive in the future.

36. Prior to her procedures, neither Plaintiff nor her doctors were provided with any warning from the Defendants of the risk of ParaGard IUD failure and injury, nor were Plaintiff or her doctors provided with adequate warning of the risk of removal of ParaGard IUD. This information was known or knowable to the Defendants.

37. Plaintiff used the ParaGard IUD manufactured, packaged, marketed, sold and/or distributed by Defendants. The ParaGard IUD reached Plaintiff without substantial change in the drug's condition.

38. As a direct and proximate result of using the ParaGard IUD, Plaintiff developed serious and/or permanent adverse effects.

39. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

40. At all relevant times, each Defendant had knowledge that there was a significant increased risk of adverse events associated with ParaGard IUD including arm breakage, and

despite this knowledge Defendants continued to manufacture, market, distribute, sell, and profit from sales of ParaGard IUD.

41. The Cooper Defendants continue to manufacture, market, distribute, sell and profit from sales of Para Gard IUD.

42. Despite such knowledge, Defendants knowingly, purposely, and deliberately failed to adequately warn Plaintiff, patients, consumers, medical providers, and the public of the increased risk of serious injury associated with using ParaGard IUD.

43. On information and belief, Plaintiffs prescribing physicians would not have prescribed ParaGard IUD to Plaintiff, would have changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of ParaGard IUD, and discussed with Plaintiff the true risks of arm breakage and resulting injuries and complications had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of the ParaGard IUD.

44. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including, but not limited to, pain, suffering, and loss of reproductive health, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.

45. The Defendants maintained a duty to Plaintiff after the ParaGard IUD was implanted and until it was removed.

46. The Cooper Defendants are also liable as successors-in-interest.

47. As a direct result of Plaintiffs use of the ParaGard IUD, Plaintiff suffers from severe pain, causing her damage, including but not limited to pain, suffering, mental anguish, the loss of reproductive health, loss of enjoyment of life, medical expenses and other out of pocket

losses and loss of income. Additionally, Plaintiff will require surgery to have her Paragard IUD removed.

Alter Ego, Successor in Interest, Etc.

In support of piercing the corporate veil, Plaintiff says:

1. Plaintiff is unaware of the precise relationships between the Defendants.

2. The corporate veil between the Defendants, or any of them, should be disregarded for one or more of the following reasons, among others:

(a) the corporate form has been used as part of an unfair device to achieve an inequitable result;

(b) the corporate structure has been used to perpetrate a fraud;

(c) the corporate structure has been used to evade an existing obligation;

(d) the corporate structure has been used to create a monopoly;

(e) the corporate structure has been used to circumvent a statute;

(f) the corporate structure has been used to protect a crime;

(g) the corporate structure has been used to justify a wrong;

(h) A corporation was organized and operated as a mere tool or business conduit of another corporation.

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

4. The Cooper Defendants are liable as successors-in-interest; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

5. Upon reasonable belief, Duramed became Teva Women's Health, Inc., through a name change in 2008. Teva Women's Health, Inc., then became Teva Women's Health, LLC

through a conversion in 2017. Teva Women's Health, LLC then sold all of its assets including the ParaGard IUD to the Cooper Defendants in 2017. Teva Women's Health, LLC became a *holdings* company with no tangible assets.

6. The Cooper Defendants knew or should have known that the transfer and conversion of Teva Women's Health, Inc, was intended to thwart potential creditors from having a claim against Teva Women's Heath, Inc. or Teva Women's Health, LLC. Therefore, the Cooper Defendants are liable pursuant to the Federal Consumer Protection Acts.

7. The liability of these companies has passed on through various business instruments and now lies with both the Teva Defendants and the Cooper Defendants.

8. At times relevant and material hereto, Defendants were engaged in the business of, or were successors-in-interest to entities engaged in the business of, researching, developing, designing, formulating, licensing, manufacturing, testing, producing, processing, assembling, packaging, inspecting, distributing, selling, labeling, monitoring, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the state of Georgia, and within the Northern District of Georgia, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the ParaGard IUD, a drug used in the preventionof pregnancy, implanted in patients throughout the United States, including Plaintiff.

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

Count One – Negligence

For negligence cause of action against Defendants, jointly and severally, Plaintiff says:

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. At times relevant, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling and/or distributing the ParaGard IUD, including the one that was implanted into the Plaintiff.

3. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, safety surveillance and distribution of the ParaGard IUD so as to avoid exposing others to foreseeable and unreasonable risks of harm.

4. Defendants breached their duty of care to the Plaintiff and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, safety surveillance, and distribution of the ParaGard IUD.

5. Defendants knew that the ParaGard IUD could break upon removal and failed to warn Plaintiff or her physician of this potential injury.

6. Defendants had a duty to warn Plaintiff, Plaintiffs physician, and/or the medical community of the potential for breakage at the arms upon removal.

7. Defendants knew or reasonably should have known that the ParaGard IUD was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

8. At the time of the manufacture and sale of the ParaGard IUD, Teva Defendants knew or should have known that the ParaGard IUD was designed and manufactured in such a manner so as to present an unreasonable risk of the fracture of the arm of the drug upon removal.

9. At the time of the manufacturer and sale of the ParaGard IUD, Teva Defendants knew or should have known that the ParaGard IUD was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement and subsequent removal.

10. At the time of the manufacture and sale of the ParaGard IUD, Teva Defendants knew or should have known that using the ParaGard IUD for its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe injuries, including but not limited to additional surgeries and/or medical procedures in order to remove the fragmented drug, even leading to hysterectomy.

11. Upon acquisition of ParaGard IUD from Teva Defendants, Cooper Defendants are charged with the same knowledge that Teva Defendants knew or should have known regarding the risks associated with ParaGard IUD at the time of manufacture and sale, and therefore, all Defendants had a continuing duty to warn Plaintiff and her physicians or the general health care community of those reasonably known risks.

12. Defendants knew or reasonably should have known that neither the consumers of the ParaGard IUD nor their doctors would realize the danger associated with using the drug for its intended use and/or in a reasonably foreseeable manner.

13. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the ParaGard IUD in, among others, the following ways:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other drug available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiffs healthcare providers or the general health care community about the ParaGard IUD's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;

e. Failing to perform reasonable pre-and post-market testing of the ParaGard IUD to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the ParaGard IUD;

g. Advertising, marketing and recommending the use of the ParaGard IUD, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the ParaGard IUD;

h. Representing that the ParaGard IUD was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the ParaGard IUD with the knowledge that the IUD was dangerous and not reasonably safe, and failing to comply with the FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the ParaGard IUD so as to avoid the risk of serious harm associated with the use of the IUD;

k. Failing to establish an adequate quality assurance program used in the manufacturing of the ParaGard IUD;

l. Failing to establish and maintain an adequate post-marketing surveillance program for the ParaGard IUD;

m. Failing to adequately and correctly report safety information relative to the ParaGard IUD product resulting in inadequate warnings;

n. Failing to provide adequate and continuous warnings about the inherent danger of breakage with the ParaGard IUD upon removal;

o. Manufacturing an IUD with insufficient structural integrity to withstand the normal forces of implanting and removing;

p. Manufacturing an IUD that had a propensity to fracture upon insertion or removal, especially at the arms; and

q. Manufacturing an IUD with strings meant to be used to remove the IUD that lacked sufficient strength to be used to remove the IUD, and that broke during the attempted removal of the IUD.

14. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

15. Each and every one of the foregoing acts, omissions, or both, taken singularly or in any combination, proximately caused Plaintiffs' injuries and damages, more particularly set forth below.

Count Two – Strict Liability Design Defect

For strict liability design defect cause of action against Defendants, jointly and severally, Plaintiff says:

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. Plaintiff adopts by reference Count One of this Complaint as if fully copied and set forth at length herein.

3. The Paragard IUD was defectively designed in one or more of the following particulars, among others:

a. lacking sufficient structural integrity to withstand the normal forces of implantation and removal;

b. having a propensity to fracture upon insertion or removal;

c. containing strings intended to be used to remove the IUD that lacked sufficient strength to be used to remove the IUD, and that broke during the attempted removal of the IUD;

4. Because of the lack of structural integrity, propensity to fracture and/or and strings that lacked insufficient strength to be used to remove the IUD, the Paragard IUD broke during an attempt to remove it. Because Plaintiff's Paragard IUD broke, it will have to be removed surgically.

5. If the Paragard IUD placed into Plaintiff had sufficient structural integrity to withstand the normal forces of implantation and removal, did not have a propensity to fracture and/or contained strings with sufficient strength to be used to remove the IUD, the Paragard IUD would not have broken upon the attempted removal. Thus, the alleged defect in the Paragard IUD that had been placed into Plaintiff was a producing cause, and proximate cause, of Plaintiffs' injuries and damages, more particularly set forth below.

6. The Paragard IUD that had been placed into Plaintiff was unreasonably dangerous because:

(a) the utility of the Paragard IUD to the user and to the public as a whole was outweighed by the gravity and likelihood of injury from its use. The likelihood the Paragard IUD would break during attempted removal outweighed any utility of the Paragard IUD to the Plaintiff or to the public as a whole.

(b) a substitute product which would meet the same need and not be unsafe or unreasonably expensive was available. IUD's that did not break during attempted removal were available at the time Plaintiff received her Paragard IUD.

(c) Defendants had the ability to eliminate the unsafe character of the mesh without seriously impairing its usefulness or significantly increasing its costs. IUD's that did not break during attempted removal were available at the time Plaintiff received her Paragard IUD.

(d) Neither Plaintiff nor her surgeon were aware (and it could not be anticipated they would be aware) of the danger the Paragard IUD would

break during attempted removal; or, of how to prevent or avoid that danger. These dangers in the Paragard IUD were not general public knowledge or obvious.

(e) Neither Plaintiff nor her surgeon expected the Paragard IUD to break during attempted removal.

7. The above five factors considered holistically, with no single factor needing to be proven on its own, working together show that the Paragard IUD was unreasonably dangerous.

8. One or more of the following safer alternative designs for the product existed that would have prevented or significantly reduced the risk of Plaintiff's injury without substantially impairing the product's utility, and that was economically and technologically feasible at the time the product left Defendant's control by the application of existing or reasonably achievable scientific knowledge:

a. making the Paragard IUD with sufficient structural integrity to withstand the normal forces of implantation and removal;

b. making the Paragard IUD so that it did not have a propensity to fracture upon insertion or removal;

c. containing strings intended to be used to remove the IUD that had sufficient strength to be used to remove the IUD, and that did not break during the attempted removal of the IUD

9. The foregoing design defects, taken singularly or in any combination, was a proximate and producing cause of Plaintiffs' injuries and damages, more particularly set forth below.

Count Three – Strict Liability Manufacturing Defect

For strict liability manufacturing defect cause of action against Defendants, jointly and severally, Plaintiff says:

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. Plaintiff adopts by reference Count One of this Complaint as if fully copied and set forth at length herein.

3. The ParaGard IUD implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time the ParaGard IUD left Defendants' control and possession.

4. Plaintiff and Plaintiffs' health care providers used the drug in a manner consistent with and reasonably foreseeable to Defendants.

5. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.

6. The ParaGard IUD was defectively and/or improperly manufactured, rendering it defective and unreasonably dangerous and hazardous to Plaintiff.

7. As a result of the manufacturing defects, the ParaGard IUD creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the ParaGard IUD.

8. Defendants have intentionally and recklessly manufactured the ParaGard IUD with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

9. The Paragard IUD was defectively manufactured in one or more of the following particulars, among others:

a. lacking sufficient structural integrity to withstand the normal forces of implantation and removal;

b. having a propensity to fracture upon insertion or removal;

c. containing strings intended to be used to remove the IUD that lacked sufficient strength to be used to remove the IUD, and that broke during the attempted removal of the IUD.

10. Because of the lack of structural integrity, propensity to fracture and/or and strings that lacked insufficient strength to be used to remove the IUD, the Paragard IUD broke during an attempt to remove it. Because Plaintiff's Paragard IUD broke, it will have to be removed surgically.

11. If the Paragard IUD placed into Plaintiff had sufficient structural integrity to withstand the normal forces of implantation and removal, did not have a propensity to fracture and/or contained strings with sufficient strength to be used to remove the IUD, the Paragard IUD would not have broken upon the attempted removal. Thus, the alleged defect in the Paragard IUD that had been placed into Plaintiff was a producing cause, and proximate cause, of Plaintiffs' injuries and damages, more particularly set forth below. Thus, the alleged defect in the Paragard IUD that had been placed into Plaintiff was a producing cause, and proximate cause, of Plaintiffs' injuries and damages, more particularly set forth below.

12. The manufacturing defects, or any of them, rendered the Paragard IUD unreasonably dangerous by making it dangerous to an extent beyond that which would be contemplated by the ordinary consumer with the knowledge common to the community as to its characteristics. Neither a patient nor a surgeon would expect an IUD to break during attempted removal.

13. The foregoing manufacturing defects, taken singularly or in any combination, was a proximate and producing cause of Plaintiff's injuries and damages, more particularly set forth below.

Count Four – Strict Liability Marketing Defect

For strict liability marketing defect cause of action against Defendants, jointly and severally, Plaintiff says:

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. Plaintiff adopts by reference Count One of this Complaint as if fully copied and set forth at length herein.

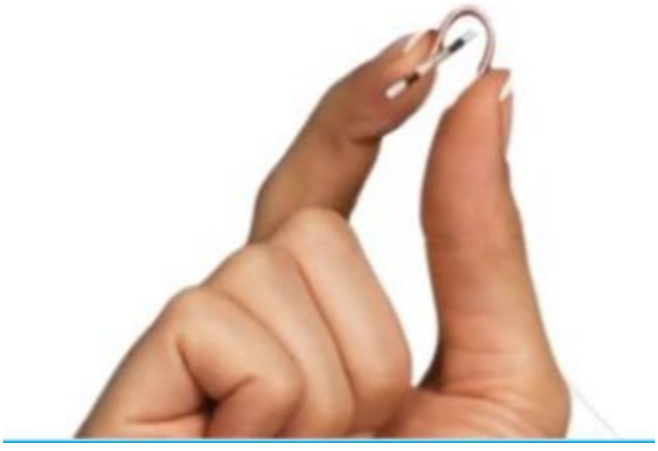
3. Defendants made the following representations regarding the Paragard IUD:

a. Paragard lasts up to 10 years, but can be removed at any time sooner. If you decide you want to get pregnant or stop using it, your healthcare provider can remove it. And because Paragard is hormone-free, it doesn't stop you from ovulating each month, so when it's removed your ability to get pregnant will return immediately;

b. that the Paragard IUD contains no hormones;

c. that the ParaGard IUD was safe for its intended use;

d. Paragard is smaller and more flexible than you may think. It's made primarily of soft, flexible plastic with a thin layer of copper around the arms and stem. Once in place, you shouldn't be able to feel it at all;



e. Paragard removal is nonsurgical and done by a healthcare provider during a routine office visit in just a few minutes.

4. The net impression of Defendants' representations regarding the Paragard IUD is to misleadingly suggest that the Paragard IUD does not have potential negative health effects.

5. There was an inherent risk the Paragard IUD would break during attempted removal.

6. Defendants knew or reasonably foresaw (or should have known or reasonably foreseen) the above risks. Thus, Defendants had a duty to warn Plaintiff's physician of the above risks.

7. Defendants failed to satisfy their duty to warn Plaintiff's physician of the Paragard IUD's potential risks by failing to provide an adequate warning to Plaintiff's surgeon, the learned intermediary. Defendants failed to warn Plaintiff's surgeon of one or more of the following, among other things:

a. Failing to warn or instruct Plaintiff, Plaintiffs healthcare providers or the general health care community about the ParaGard IUD's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;

b. Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the ParaGard IUD;

c. Advertising, marketing and recommending the use of the Para Gard IUD, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the ParaGard IUD;

d. Representing that the ParaGard IUD was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

e. Failing to adequately and correctly report safety information relative to the ParaGard IUD product resulting in inadequate warnings;

f. Failing to provide adequate and continuous warnings about the inherent danger of breakage with the ParaGard IUD upon removal; and

g. Failing to warn that the Paragard IUD was susceptible to breaking during removal.

8. If Plaintiff's physician had been warned of these risks, Plaintiff's physician would not have chosen to use the Paragard IUD. In the alternative, Plaintiff's physician would have informed Plaintiff of the above risks, and Plaintiff would not have consented to the use of the Paragard IUD. If the Paragard IUD had not been used on Plaintiff, the Paragard IUD would not have broken during the attempted removal.

9. The marketing defects, or any of them, rendered the Paragard IUD unreasonably dangerous by making it dangerous to an extent beyond that which would be contemplated by the ordinary consumer with the knowledge common to the community as to its characteristics. Neither a patient nor a surgeon would expect Paragard IUD to break during attempted removal.

10. The above marketing defects, taken singularly or in any combination, was a producing and proximate cause of Plaintiff's injuries and damages, more particularly set forth below.

Count Five – Common Law Fraud

For common law fraud cause of action against Defendants, jointly and severally, Plaintiffs say:

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. Plaintiff adopts by reference Count Four of this Complaint as if fully copied and set forth at length herein.

3. The Defendants have falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the

public that the ParaGard IUD had been appropriately tested and was found to be safe and effective.

4. The representations made by the Defendants were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the ParaGard IUD.

5. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiffs physicians, and/or the public, to recommend, prescribe, dispense, and purchase the ParaGard IUD for use as a form of long-term birth control, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

6. In representations to Plaintiff and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted the following material information:

a. That the ParaGard IUD was not as safe as other products and procedures available to aid in the long-term prevention of pregnancy;

b. That the risk of adverse events with the ParaGard IUD was higher than with other products and procedures available for birth control;

c. The ParaGard IUD was not adequately tested;

d. That the limited clinical testing for ParaGard IUD revealed a higher risk of adverse events, above and beyond those associated with other products and procedures available for birth control;

e. That Defendants deliberately failed to follow up on the adverse results from clinical studies and/or formal and informal reports from physicians and/or other healthcare providers and either ignored, concealed and/or misrepresented those findings;

f. That Defendants were aware of dangers in the ParaGard IUD in addition to and above and beyond those associated with other products and procedures available for birth control;

g. That the ParaGard IUD was defective, and that it caused dangerous and adverse side effects, including but not limited to unacceptable incidence of breakage upon removal;

h. That when the ParaGard IUD needed to be removed, the removal procedure had a very high failure rate and/or needed to be performed repeatedly;

i. That the ParaGard IUD was manufactured negligently;

J. That the ParaGard IUD was manufactured defectively; and

j. That the ParaGard IUD was designed negligently and designed defectively.

7. The Defendants were under a duty to disclose to Plaintiff and her physicians, the defective nature of the ParaGard IUD, including but not limited to, the risk of breakage prior to and upon removal, which could result in permanent injury.

8. The Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the ParaGard IUD, such as Plaintiff.

9. The Defendants' concealment and omissions of material facts concerning the safety of the ParaGard IUD were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiffs physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or dispense the ParaGard IUD; and/or to mislead them into reliance upon and cause them to use the ParaGard IUD.

10. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians, used the ParaGard IUD, Plaintiff and/or her physicians were unaware of the falsehood of these representations, and reasonably believed them to be true.

11. The Defendants knew and had reason to know that the ParaGard IUD could and would cause severe and grievous personal injury to the users of the product and was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

12. In reliance upon these false representations, Plaintiff and her physicians were induced to, and did use the ParaGard IUD, thereby causing severe and permanent personal injuries and damages to Plaintiff. The Defendants knew or had reason to know that the Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the ParaGard IUD, as described in detail herein.

13. Plaintiff and her physicians reasonably relied on facts provided by the Defendants which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent to the use of the ParaGard IUD.

14. Having knowledge based on the Defendants research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff, the public, and Plaintiffs healthcare providers and physicians, that the ParaGard IUD was safe for use as a means of providing long-term birth control and was as safe or safer than other product and/or procedures available and/or on the market. As a result of Defendants' research and testing, or lack thereof, these Defendants intentionally omitted, concealed and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff, her physicians, and the public at large.

15. The Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

16. The information distributed to the public, the medical community, Plaintiff and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of the ParaGard IUD.

17. These representations, and others made by the Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

18. The Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the ParaGard IUD to Plaintiff, her physicians and the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

19. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the ParaGard IUD.

20. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of the Defendants, nor would

Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when the ParaGard IUD was surgically implanted into her.

21. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the ParaGard IUD, neither Plaintiff nor her physician would not have purchased, used, or relied on Defendants' representations and omissions concerning the ParaGard IUD.

22. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been seriously injured, and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

Count Six – Negligent Misrepresentation

For negligent misrepresentation cause of action against Defendants, Plaintiff(s) say(s):

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. Plaintiff adopts by reference Count Five of this Complaint as if fully copied and set forth at length herein.

3. Defendants misrepresented that the Paragard IUD was safe for its intended use.

4. Defendants made the above representations in the course of its business, or in a transaction in which he had a pecuniary interest.

5. In making the above representation, or representations, Defendants supplied false information for the guidance of others.

6. Defendants failed to exercise reasonable care or competence in obtaining or communicating the above information.

7. At relevant times, Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning the ParaGard IUD, including, but not limited to, misrepresentations regarding the safety of the ParaGard IUD.

8. The information distributed by the Defendants to the public, the medical community, the Plaintiff and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of the ParaGard IUD.

9. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' health care providers; to falsely assure them of the quality of the ParaGard IUD and the induce the public and medical community, including Plaintiff and her healthcare provider to request, recommend, prescribe, implant, purchase and continue to use the ParaGard IUD.

10. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical drug manufacturers, Plaintiff, her healthcare providers and the public, that the ParaGard IUD had been tested and found to be safe and effective for long term birth control.

11. The representations made by the Defendants were, in fact, false. The ParaGard IUD was not safe for human use in its intended and reasonably foreseeable manner. Use of the ParaGard IUD is dangerous as there is a risk that it may fracture upon removal cause significant injury.

12. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiffs healthcare providers were induced to, and did use the ParaGard IUD, thereby causing Plaintiff to endure severe and permanent injuries.

13. Defendants knew and had reason to know that the Plaintiff, Plaintiffs healthcare providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

14. Plaintiff and her healthcare providers would not have recommended, and implanted ParaGard IUD had the true facts not been concealed by the Defendants.

15. Defendants had sole access to the material facts concerning the defective nature of the ParaGard IUD and its propensity to cause serious and dangerous side injuries.

16. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff was implanted with the ParaGard IUD, Plaintiff and her healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

17. The Defendants failed to exercise ordinary care in making representations concerning the ParaGard IUD while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the ParaGard IUD's high risk of unreasonable and dangerous adverse side effects.

18. The Defendants breached their duty to Plaintiff, her physicians, and the medical and healthcare community, by representing that the Para Gard IUD has no serious side effects different from older generations of similar products or procedures.

19. Plaintiff and Plaintiffs healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendants, where they concealed and

misrepresented facts that were critical to understanding the true dangers inherent in the use of the ParaGard IUD.

20. Plaintiff and Plaintiffs healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiffs injuries.

21. The Defendants knew, and had reason to know, that the ParaGard IUD had been insufficiently tested, or had not been tested at all, that the products lacked adequate and accurate warnings, that they created a high risk, and/or higher than acceptable risk, and/or higher than reported risk that they represented a risk of adverse side effects, including, pain and suffering, surgery to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

Count Seven – Breach of Express Warranty

For breach of express warranty cause of action against Defendants, Plaintiff(s) say(s): 1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts of this Complaint as if fully copied and set forth at length herein.

2. Plaintiff adopts by reference Count One of this Complaint as if fully copied and set forth at length herein.

3. At relevant times, Defendants intended that the ParaGard IUD be used in the manner that Plaintiff used it and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for long-term birth control, and that they were adequately tested and fit for their intended use.

4. At relevant times, Defendants were aware that consumers, including Plaintiff, would use the ParaGard IUD; which is to say that Plaintiff was a foreseeable user of the ParaGard IUD.

5. Plaintiff and/or her implanting physicians were, at all relevant times, in privity with the Defendants.

6. ParaGard IUD was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by the Defendants.

7. The Defendants breached various express warranties with respect to the ParaGard IUD including the following particulars:

a. The Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the ParaGard IUD was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the ParaGard IUD;

b. The Defendants represented to Plaintiff and her physicians and healthcare providers that the ParaGard IUD was as safe, and/or safer than other alternative procedures and drugs and fraudulently concealed information, which demonstrated that the ParaGard IUD was not safer than alternatives available on the market; and

c. The Defendants represented to Plaintiff and her physicians and healthcare providers that the ParaGard IUD was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the products.

8. In reliance upon the Defendants' express warranties, Plaintiff was implanted with the ParaGard IUD as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

9. At the time of making such express warranties, the Defendants knew or should have known that the ParaGard IUD does not conform to these express representations because the ParaGard IUD was not safe and had numerous side effects, many of which the Defendants did not accurately warn about, thus making the ParaGard IUD unreasonably unsafe for its intended purpose.

10. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of the Defendants in connection with use, recommendation, description, and/or dispensing of the ParaGard IUD.

11. The Defendants breached their express warranties to Plaintiff in that the ParaGard IUD was not of merchantable quality, safe and/or fit for its intended uses, nor was it adequately tested.

12. The breach of the above express warranty proximately caused Plaintiff(s) injuries and damages, more particularly set forth below.

Count Eight – Breach of Implied Warranty of Merchantability

For breach of the implied warranty of merchantability cause of action against Defendants, Plaintiff says:

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length herein.

2. Defendants sold the product.

3. The product was unmerchantable. It was unfit for ordinary purposes. It was unfit for ordinary purposes because it was constructed in such a way that made it unreasonably dangerous. It was unreasonably dangerous because it lacked sufficient structural integrity to

withstand the normal forces of implantation and removal, had a propensity to fracture during removal and/or contained strings intended to be used to remove the IUD that lacked sufficient strength to be used to remove the IUD. Because the IUD lacked sufficient structural integrity to withstand the normal forces of implantation and removal, had a propensity to fracture during removal and/or contained strings intended to be used to remove the IUD that lacked sufficient strength to be used to remove the IUD, the Paragard IUD that was placed into Plaintiff broke during attempted removal. Had the Paragard IUD placed into Plaintiff possessed sufficient structural integrity to withstand the normal forces of implantation and removal, did not have a propensity to fracture during removal and/or contained strings intended to be used to remove the IUD with sufficient strength to be used to remove the IUD, the Paragard IUD that was placed into Plaintiff would not have broken during attempted removal.

4. Plaintiff notified Defendant of the breach of this warranty before filing suit. Exhibit A.

5. The breach of warranty of merchantability proximately caused Plaintiff's injuries and damages more particularly set forth below.

Basis for Imposition of Punitive Damages

1. Defendant was grossly negligent in one or more of the following particulars, among others:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other drug available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiffs healthcare providers or the general health care community about the ParaGard IUD's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;

e. Failing to perform reasonable pre-and post-market testing of the ParaGard IUD to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the ParaGard IUD;

g. Advertising, marketing and recommending the use of the Para Gard IUD, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the ParaGard IUD;

h. Representing that the ParaGard IUD was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the ParaGard IUD with the knowledge that the IUD was dangerous and not reasonably safe, and failing to comply with the FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the ParaGard IUD so as to avoid the risk of serious harm associated with the use of the IUD;

k. Failing to establish an adequate quality assurance program used in the manufacturing of the ParaGard IUD;

l. Failing to establish and maintain an adequate post-marketing surveillance program for the ParaGard IUD;

m. Failing to adequately and correctly report safety information relative to the ParaGard IUD product resulting in inadequate warnings;

n. Failing to provide adequate and continuous warnings about the inherent danger of breakage with the ParaGard IUD upon removal;

o. Manufacturing an IUD with insufficient structural integrity to withstand the normal forces of implanting and removing;

r. Manufacturing an IUD that had a propensity to fracture upon insertion or removal, especially at the arms; and

s. Manufacturing an IUD with strings meant to be used to remove the IUD that lacked sufficient strength to be used to remove the IUD, and that broke during the attempted removal of the IUD.

2. Each and every one of the foregoing acts, omissions, or both, taken singularly or in any combination, when viewed objectively from Defendants' standpoint at the time of such conduct involved an extreme degree of risk (high probability) that the Paragard IUD would break upon attempt to remove it, requiring later surgery to remove it and causing severe pain.

3. Defendants, at the time of such conduct had actual, subjective awareness of the extreme degree of risk (high probability) that the Paragard IUD would break upon attempted removal, requiring subsequent surgery to remove it, and resulting in severe pain, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others.

4. Additionally, as alleged above, Defendants committed fraud.

5. Defendants are responsible and liable in exemplary damages for the above gross negligence because:

a. Defendants authorized the doing and the manner of such conduct;

b. The personnel of Defendants who engaged in such conduct were unfit and recklessly employed by Defendants;

c. The personnel who engaged in such conduct were employed as vice-principals in a managerial capacity and were acting within the course and scope of their employment; or

d. Defendants, or a vice-principal or manager of Defendants ratified or approved such conduct.

Damages Applicable to All Counts

1. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Amended Complaint as if fully copied and set forth at length herein.

2. Plaintiff hereby adopts by reference each and every Count of this Complaint as if fully copied and set forth at length herein.

3. Plaintiff suffered sustained and incurred, and in reasonable medical probability will suffer, sustain and incur, the following injuries and damages as a producing or proximate result (or both) of Defendant's conduct, the defective product, or both, among others:

(a) physical pain, past and future;

(b) mental suffering, past and future;

(c) physical impairment, past and future;

(d) physical disfigurement, past and future;

(e) reasonable and necessary medical bills, past and future;

(f) loss of earnings/earning capacity, past and future.

Jury Demand

Plaintiff requests trial by jury.

Prayer

Plaintiff prays that Defendant be cited to appear herein, and that upon final trial, Plaintiff has judgment against Defendants, jointly and severally, for the following, among other things:

1. Compensatory damages in an amount above the minimum jurisdictional limits of the Court;

2. Pre-judgment interest;

3. Post-judgment interest;

4. Costs of court;

5. Such other and further relief to which Plaintiff shows themselves justly entitled to receive.

Respectfully submitted,
By: */s/ William H. Barfield*

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