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Attorney for Plaintiff Thien Thanh Le

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

PORTLAND DIVISION

THIEN THANH LE,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.

-and-

TEVA WOMEN'S HEALTH, LLC f/k/a TEVA WOMEN'S HEALTH, INC.

-and-

Case No.: 3:21-cv-00635

COMPLAINT
Personal Injury Action (28 U.S.C. § 1332)
DEMAND FOR JURY TRIAL

TEVA BRANDED PHARMACUETICALS PRODUCTS R&D, INC.

-and-

COOPERSURGICAL, INC.,

-and-

THE COOPER COMPANIES, INC.,

Defendants.

Plaintiff Thien Thanh Le, by and through her undersigned attorneys, files this Complaint against Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., f/k/a Teva Women's Health, LLC, Teva Branded Pharmaceuticals Products R&D, Inc. (collectively referred herein as "Teva Defendants"), CooperSurgical, Inc., and the Cooper Companies, Inc., (collectively referred herein as "Cooper Defendants") both jointly and severally, the companies that designed, developed, manufactured, tested, performed safety surveillance, labeled, packaged, distributed, marketed and/or sold the Paragard® Intrauterine Device ("Paragard") implanted into Plaintiff and alleges as follows:

INTRODUCTION

1. Paragard is a temporary, non-hormonal, non-surgical birth control method that can remain in a woman's body for up to 10 years. It has a T-shaped plastic frame made of polyethylene and barium sulfate that is inserted into the uterus during a routine office visit. Defendants touted Paragard's simplicity and effectiveness, claiming that Paragard could be removed quickly and easily, and that immediately after removal, Paragard's contraceptive effect is reversed.

2. For decades, however, Defendants have known that Paragard regularly breaks inside the body, causing pieces of the Paragard to remain in a woman's body even after it is removed. During removal, the arms of the Paragard are supposed to fold upward at the joint, but often one or more of

the arms breaks. Paragard has also shown a propensity to break prior to removal, during the normal course of use. This dangerous breakage occurs spontaneously before or upon removal, even when the doctor carefully follows instructions without error. Often the Paragard pieces can then be removed only through hysterectomy or other surgical procedure—oftentimes destroying a woman's ability to ever conceive a child. Defendants never warned users, like Plaintiff, that surgery might be required because of a Paragard breakage.

3. Since Paragard was introduced to the market, Defendants (at their respective times as NDA holders) have received reports, studies, and otherwise learned new information about Paragard's breakage and the resulting injuries. Defendants, however, concealed this information and failed to take any action to inform patients, physicians, or the public about Paragard's propensity to break. This failure to act has resulted in life-altering consequences for Plaintiff, who was injured as a direct and proximate result of the breakage of the Paragard implanted in her body.

4. A woman's choice of birth control is a deeply personal decision, particularly when choosing a long-acting form of birth control like Paragard that can remain in a woman's body for up to 10 years.

5. For decades, women have relied on Defendants' representations that Paragard was a safe and dependable form of non-surgical and easily reversible birth control. It is of the utmost importance that women know all risks associated with a particular type of birth control given that a women's choice of birth control can have long-term consequences on her fertility and potential childbearing timeline. That is particularly true here, where Defendants intentionally marketed Paragard as a form of birth control that could easily be reversed when a woman wanted to conceive.

6. Women and their doctors depended on Defendants, the manufacturers and distributors of Paragard, to be forthcoming about the safety and risks of Paragard. And this reliance

on Defendants was warranted. The regulatory scheme that governs Paragard is premised on a system whereby the manufacturer is responsible for reporting relevant safety information to the public. A drug manufacturer oftentimes has exclusive access to post-market safety information, including the reporting of adverse events and complaints. The onus is on the manufacturer to come forward with any safety risks because the public and the U.S. Food and Drug Administration ("FDA") otherwise have no insight into these events.

7. As part of the manufacturer's duty, the manufacturer must vigilantly monitor and closely evaluate the post-market drug experience and report any issues to the FDA, and by extension, the healthcare community and consumers.

8. Defendants, however, failed to address Paragard's safety issues, even though over 2000 adverse event reports did alert or should have alerted them to a product defect causing the device to break inside the body, causing injuries. And, upon information and belief, this number is a gross understatement because Defendants also failed to maintain a systematic reporting system for complaints, as required by law. Defendants therefore likely underreported adverse events of Paragard breaks to the FDA.

9. Even though Defendants had knowledge of Paragard's defect, Defendants failed to timely update the Paragard warning label to adequately warn of Paragard's propensity to break—a label change that is permitted by the FDA under a "changes being effected" (CBE) warning supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review. 21 C.F.R. §§ 314.70(c)(3), (c)(6). Defendants failed to ever do this.

10. Despite having years of knowledge and information about the product's propensity to break inside a woman's body and cause injury, it was not until 2019 that Defendants used the prior approval supplement process to update the Paragard label to the Physician Labeling Rule

format, which added references to Paragard breakage. Even now, however, the current label is still inadequate.

11. Defendants had a duty to act as reasonable manufacturers. They had a duty to continually monitor their product, including, but not limited to, its design, manufacturing, performance, safety profile, and labeling. They had a duty to continually test their product and ensure it was safe and would perform as intended. And they had a duty to undertake stability testing to verify expiration dates. Yet Defendants breached their duties and Plaintiff was injured.

12. Even though Defendants were aware of the Paragard's propensity to break, including, but not limited to during routine removal, and the significant injuries that could result, Defendants continued to market Paragard as safe and safer than alternative forms of birth control. Over the years, Defendants have undertaken a concerted marketing campaign that has overstated the safety of Paragard, downplayed its risks, and portrayed Paragard as the safest form of long-lasting, non-surgical, non-permanent birth control.

13. Defendants intentionally concealed the risks, including, but not limited to, the severity and frequency of the risks associated with Paragard's removal, telling women the "contraceptive effect is reversed" as soon as Paragard was removed. In other words, Defendants not only shirked their reporting responsibilities to the FDA and the public at large but also undertook affirmative steps to misrepresent the safety profile of Paragard in order to increase sales.

14. Unfortunately for Plaintiff, Defendants chose greed and profits over the safety of users of Paragard, and Plaintiff suffered injuries as a consequence.

15. If Defendants had timely disclosed the propensity and severity of Paragard's risks, Plaintiff's injuries could have been avoided. Yet, Defendants did nothing and for that Plaintiff

seeks redress both to compensate her for her horrific losses and to strongly deter future, similar misconduct.

PARTIES

A. Plaintiff Thien Thanh Le

16. Plaintiff Thien Thanh Le is an adult citizen and resident of the State of Oregon.

17. In September 2017, Plaintiff Thien Thanh Le was implanted with a Paragard IUD by her gynecologist.

18. On July 21, 2020, following complaints of pain, Plaintiff's physician attempted to remove the Paragard IUD as instructed by Defendants by grasping the Paragard by the forceps and pulling gently.

19. Despite following the instructions provided by Defendants, only a portion of the Paragard was retrieved with one arm missing.

20. In January and February 2020, X-ray and CT scans detected the missing arm inside of Plaintiff's body.

21. Plaintiff's physician recommended surgery to repair the damage caused by the breakage of the Paragard IUD.

22. Accordingly, on June 2020, Plaintiff underwent a laproscopic surgery and hysteroscopy. Unfortunately, the surgeon could not remove the missing arm because it was located in the sigmoid colon.

23. The missing Paragard arm is still embedded in Plaintiff's body and Plaintiff is exploring all additional options to have the arm removed.

24. Prior to implantation and removal of the Paragard IUD, Plaintiff and her doctors were provided with no warning from the Defendants of the risk of Paragard failure and injury, nor were Plaintiff and her doctors provided with adequate warning of the risk of removal of Paragard.

25. The breakage of Plaintiff's Paragard IUD directly and proximately caused Plaintiff to suffer damages, 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.

B. Teva Defendants

26. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 400 Interpace Parkway, in Parsippany, New Jersey. For diversity of citizenship purposes, Defendant Teva USA is a citizen of Delaware and New Jersey.

27. Defendant Teva Women's Health, LLC is a Delaware limited liability company with its principal place of business located at 5040 Duramed Road, in Cincinnati, Ohio and is and/or was a wholly owned subsidiary of Defendant Teva USA. Teva Women's Health, LLC's sole member is Barr Pharmaceuticals, LLC formed under Delaware law with its principal place of business in New Jersey. The sole member of Barr Pharmaceuticals, LLC is Teva USA. For diversity purposes, Teva Women's Health, LLC is a citizen of Delaware and Ohio.

28. Teva Women's Health, LLC is the product of an entity conversion pursuant to Del. Code Ann. tit. 8, § 266. In August 2017, Teva Women's Health, Inc., a corporation, converted into Teva Women's Health, LLC and continues to operate as a limited liability company. Teva Women's Health, LLC sold all of its assets, including Paragard, to Cooper Defendants in November 2017. Teva Women's Health, LLC, became a holdings company with no tangible assets.

29. 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. 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 is not a dissolution and no wind 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. Teva Women's Health, LLC and Teva Women's Health, Inc. are referred to collectively hereinafter as "Teva Women's Health."

30. Defendant Teva Branded Pharmaceuticals Products R&D, Inc. ("Teva R&D") is a Delaware corporation with headquarters located at 41 Moores Road in Malvern, Pennsylvania. For diversity purposes, Teva R&D is a citizen of Pennsylvania and Delaware.

31. Defendants TPI Ltd., Teva USA, Teva Women's Health, and Teva R&D are referred to collectively herein as the "Teva Defendants."

C. Cooper Defendants

32. Defendant The Cooper Companies, Inc. ("CooperCompanies") is a Delaware corporation with its principal place of business located at 6101 Bollinger Canyon Road, in San Ramon, California. For diversity of citizenship purposes, Defendant CooperCompanies is a citizen of Delaware and California. CooperCompanies purchased the assets, global rights, and businesses of Paragard on November 1, 2017 for $1.1 billion, including the sole Paragard manufacturing facility in North Tonawanda, New York.

33. Defendant CooperSurgical, Inc. ("CooperSurgical") is a Delaware corporation with its principal place of business located at 75 Corporate Drive in Trumbull, Connecticut. CooperSurgical is a subsidiary of Defendant CooperCompanies. Defendant CooperSurgical is a citizen of Delaware and Connecticut for diversity of citizenship purposes.

34. Defendants CooperCompanies and CooperSurgical are referred to collectively hereinafter as "Cooper Defendants."

JURISDICTION & VENUE

35. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). There is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

36. Venue is proper in this district under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this district, in that the claims arise from injuries caused by the implant and removal of Plaintiff's Paragard IUD in the District of Oregon and the Paragard IUD was distributed and sold for use in the District of Oregon.

37. This Court has personal jurisdiction over Defendants because Plaintiff's claims against each Defendant arises out of contacts between the Defendants and Plaintiff in the Oregon, which established a close relationship between Defendants, the State of Oregon, and this litigation.

FACTUAL ALLEGATIONS

A. The Development, Manufacture, and Distribution of Paragard

38. Paragard is a non-hormonal intrauterine drug that Defendants marketed as providing long-term but non-permanent, non-surgical, and easily reversible birth control.

39. Paragard is a T-shaped plastic frame made of polyethylene and barium sulfate that is inserted into the uterus by a healthcare provider. Copper wire coiled around the frame is intended to produce an inflammatory reaction that interferes with sperm transport and fertilization of an egg. A monofilament polyethylene thread is tied through the tip, resulting in two white threads, which are intended to aid in the easy detection and non-surgical removal of the Paragard.

40. The Population Council ("TPC") developed Paragard in the 1970s, and in the early 1980s submitted to the FDA a new drug application ("NDA") for Paragard, pursuant to § 505(b) of the Federal Food, Drug, and Cosmetic Act.

41. On November 15, 1984, the FDA approved Paragard's NDA. As approved in 1984, the Paragard had an expiration date (or shelf life) of four years.

42. Based upon information and belief, following Paragard's FDA-approval, several companies marketed Paragard for distribution, including FEI Women's Health, LLC; GynoPharma, Inc. f/k/a GynoMed; and Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil," a subsidiary of Johnson & Johnson).

43. In the early 1990s, TPC sought an extension of the expiration date for Paragard from four to seven years. The FDA denied the application because TPC did not meet the specifications for flexibility in its approved new drug application.

44. Although the expiration date was eventually extended, no stability testing was conducted that supported this extension.

45. In fact, upon information and belief, Defendants undertook stability testing on Paragard's raw plastic T without testing Paragard with its other component parts. Defendants failed to undertake any stability testing of Paragard with the copper sleeves on each side of the Paragard arm, which inhibits the flexibility of the arms when force is applied to the arms.

46. Based upon information and belief, in or around 2003, TPC sold the Paragard NDA to FEI Women's Health, LLC, and FEI Women's Health, LLC, who acquired the right to market Paragard in the United States from Ortho-McNeil. After those acquisitions, FEI Products, LLC, manufactured and sold Paragard in the United States.

47. On or around November 9, 2005, Duramed Pharmaceuticals, Inc. ("Duramed"), a subsidiary of Barr Pharmaceuticals, Inc., acquired FEI Women's Health, LLC, including the Paragard NDA. Duramed thereafter manufactured and sold Paragard in the United States.

48. On December 23, 2008, Defendant TPI Ltd. acquired Barr Pharmaceuticals, Inc. As a result of that transaction, Duramed became an indirect wholly owned subsidiary of Teva USA, and Teva USA became the owner of Paragard. During this transaction, TPI Ltd. and Teva USA also acquired Duramed's manufacturing facilities, sales force, and responsibility for maintaining and updating the labeling for Paragard.

49. Teva USA manufactured Paragard through Duramed, which held the Paragard NDA, and designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and sold Paragard through September 2009.

50. In or around September 2009, Teva USA changed the name of Duramed to Teva Women's Health, Inc., which continued to operate as a wholly owned subsidiary of Teva USA. A new entity was not created and no entities were dissolved.

51. From September 2009 to August 2017, Teva Women's Health, Inc. held the Paragard NDA and designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and sold Paragard throughout the United States.

52. In or around August 11, 2017, Teva Women's Health, Inc. was converted into Teva Woman's Health, LLC.

53. From August 11, 2017 to November 1, 2017, Teva Women's Health, LLC held the Paragard NDA and designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and sold Paragard throughout the United States.

54. On September 11, 2017, CooperCompanies announced that CooperSurgical, Inc. had entered into an agreement to acquire Paragard from Defendant TPI Ltd.

55. On November 1, 2017, Cooper Defendants purchased Teva Women's Health, LLC, including the Paragard asset, from TPI Ltd.

56. From November 1, 2017 through the present, Cooper Defendants have held the Paragard NDA and design, develop, manufacture, test, label, package, distribute, market and sell Paragard throughout the United States.

57. Defendants (at their respective times as NDA holders) were or are involved in regulatory communications and medical communications, including but not limited to communications with the FDA, physicians, and other medical personnel.

58. Paragard is currently sold only in the United States.

B. Paragard Is Defective and Defendants Knew or Should Have Known of Such Defect but Failed to Warn Plaintiff

59. Unlike other intrauterine products ("IUDs"), Paragard's arms have no curvature and are fixed, straight plastic arms bonded to the plastic vertical post and copper sleeves are slid on each arm.

60. Upon information and belief, the design is flawed because Paragard does not provide sufficient flexibility.

61. Upon information and belief, Paragard breaks more and has more arm breaks than any other IUD on the market in the United States.

62. Additionally, upon information and belief, sample Paragard raw plastic T units, before having the copper sleeves installed, failed to meet the minimum flexibility requirements within the approved expiration date (i.e., shelf life) of the product.

63. The Paragard design is thus flawed for the additional reason that it does not account for the long expiration date and use of the product to decay and lose flexibility over time on the shelf and in situ.

64. Defendants market and have marketed Paragard as being safe and effective, promising that Paragard results in fewer side effects than other birth control methods.

65. Defendants market and have marketed Paragard as providing "continuous pregnancy prevention for as short or long as [the user] want[s]—up to 10 years."

66. Defendants further market and have marketed Paragard as easily reversible, asserting that Paragard can be removed any time before its 10-year expiration if a woman wants to become pregnant and that she "may become pregnant as soon as Paragard is removed."

67. The relevant Defendants have heavily marketed Paragard as being "reversible," "non-surgical," and removable by a healthcare provider "during a routine office visit in just a few minutes."

68. These marketing materials intentionally convey to consumers that Paragard removal is easy and safe, with no risk of complication and do not otherwise relay the risks of Paragard.

69. To remove Paragard, healthcare providers are instructed to locate the strings and pull gently until the Paragard is expelled from the uterus.

70. The Paragard arms are supposed to fold upward to aid in removal, but frequently the arms are broken or will break at the joint during removal. This unanticipated breakage can cause serious complications and injuries, including but not limited to, surgery to remove the broken device (including hysterectomy), infertility, and pain.

71. The marketing and promotional efforts of Defendants and their advertisers and/or salesforce served to overstate the benefits of Paragard and minimize and downplay the risks. These promotional efforts and marketing statements were made while Defendants knowingly withheld important safety information from healthcare providers and the public.

72. Prior to Plaintiff using Paragard, the relevant Defendants knew and/or should have known that the drug was defective and unreasonably dangerous.

73. Defendants knew or should have known that Paragard can and does cause serious harm to individuals who use it, due to the risk of Paragard breaking in utero and/or upon removal. Defendants knew or should have known removing broken pieces of Paragard could require additional medical intervention, including but not limited to hysterectomy, and thus causing infertility.

74. Defendants knew of these risks from their post-marketing experience and complaints received from doctors and patients, third-party studies, and their own analysis of these studies. Yet, they took no action to adequately warn or remedy Paragard's defects and instead concealed, suppressed, and failed to disclose or fix this danger.

75. Over time, as Defendants sought further extension for Paragard's indicated period of use, Defendants received a growing number of substantially similar reports of Paragard breakages that required surgical removal of the broken pieces, including hysteroscopy, laparoscopy, laparotomy, and hysterectomy.

76. Defendants, however, failed to modify the warning for Paragard to adequately warn of Paragard's propensity to break inside the body, including, but not limited to, during routine removal requiring further medical intervention, or to disclose the frequency of the breakage based on Defendants' internal knowledge, causing injuries to Plaintiff.

77. The product warnings for Paragard are or were intentionally vague, confusing, incomplete, or otherwise wholly inadequate to alert patients and prescribing physicians to the actual risks associated with Paragard, including, but not limited to, the risk of breakage, the frequency of breakage, and that the risk may result in injury, including surgical intervention and loss of reproductive health and fertility.

78. Before 2019, the Paragard warning label failed to adequately warn that a Paragard breakage could require further medical intervention, including surgery. The warning label failed to warn that Paragard had a propensity to break during a routine removal procedure and non-surgical removal procedures. And the label failed to warn about the frequency with which breakages occurred.

79. Defendants' marketing and promotion, through their own websites, did not acknowledge the risks of Paragard but sought to reassure physicians and patients of Defendants' longstanding record of quality and safety.

80. On July 25, 2019, Defendant CooperSurgical received a letter from the FDA admonishing Defendants for making a "false or misleading representation[] about the risks associated with Paragard," stating: "[t]he TV ad misbrands Paragard within the meaning of the Federal Food, Drug and Cosmetic Act and makes its distribution violative. 21 U.S.C. §§ 352(n); 331(n); 21 C.F.R. §§ 202.1(d)(1); (e)(5). This violation is concerning from a public health perspective because it creates a misleading impression about the safety of Paragard."

81. The July 25, 2019 FDA letter also admonished Defendants for emphasizing that Paragard is "100% HORMONE FREE!" and "1 SIMPLE ACTIVE INGREDIENT" in that those representations gave the impression to consumers that Paragard was safer than other long-acting reversible contraceptives.

82. Defendants' statements that triggered the FDA's reproach were consistent with Defendants' marketing strategy to advertise Paragard as safer than Paragard's competitors when in fact Paragard posed significant risks to its users. Defendants have carried out this marketing strategy since Paragard's launch in the United States.

83. Defendants intentionally marketed Paragard to women—particularly younger women—as quick and easy to remove without the risk of complications such that a woman could use Paragard and then have it quickly removed when she wanted to conceive. As Defendants told women, "See how Paragard lets you own your story," suggesting that Paragard was risk-free and that by using Paragard, women could decide to get pregnant at any time.

84. Defendants intentionally downplayed the risks of breakage, including, but not limited to, during removal, and told women they could try to get pregnant the same day they had their Paragard removed. For instance, based on information and belief, from December 2016 through April 2018, Defendants included the excerpt below on the Paragard website:

85. Based upon Defendants' misrepresentations, upon which Plaintiff and their physicians relied, Plaintiff had the Paragard inserted, believing it would be safe, effective, and reversible, for the entire duration it was inserted and upon removal.

86. In September 2019, Cooper Defendants amended Paragard's warning label pursuant to the FDA prior approval process.

87. Although Cooper Defendants amended the warning label to add information about breakage, Defendants had possessed knowledge that Paragard had the propensity to break for years and should have acted sooner. Regardless, Cooper Defendants' amendment of the warning label shows that for years, Defendants could have updated the warning label based on "newly acquired information" but chose not to, resulting in injuries to Plaintiff.

88. Cooper Defendants amended the Paragard label to add a warning that "Breakage of an embedded Paragard during non-surgical removal has been reported." The label further includes that "Breakage or embedment of Paragard in the myometrium can make removal difficult."

89. But the new label is still inadequate. The warnings remain intentionally vague and confusing and fail to adequately warn about the propensity of the product to break in a woman's body, including, but not limited to, during routine removal, and cause serious injuries. Defendants could have but failed to warn of Paragard's risks including, but not limited to, the frequency of breakages, that surgical intervention could be required as a result of a "difficult" removal, that a non-embedded Paragard could break during removal, or that surgery could prevent a woman from conceiving children.

C. Defendants Made False Statements to Users and Consumers in the Labeling of the Paragard

90. As detailed *supra* ¶¶ 51-67 and *infra* ¶¶ 121-126, Defendants knew that Paragard was frequently prone to break before or during removal, but Defendants have misrepresented the safety and risks of Paragard to users, consumers, and physicians.

91. Plaintiff references federal law throughout this Master Complaint not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

92. The FDA approved the NDA for Paragard in 1984 and by 1988 it was being marketed for sale to physicians and directly to women in the United States.

93. Although Defendants marketed and market Paragard as containing no hormones or other drugs, it is regulated by the FDA as a "drug" and thus subject to the requirements of Title 21 of the Code of Federal Regulations: Food and Drugs.

94. A manufacturer is required to give adequate directions for the use of a drug such that a "layman can use a drug safely and for the purposes for which it is intended," 21 C.F.R. § 201.5, and conform to requirements governing the appearance of the label. *Id.* § 201.15.

95. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, *id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000), and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also for example advertising.

96. All drug manufacturers are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products." 21 C.F.R. § 211.166(a). Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted." *Id.*

97. The purpose of stability testing is, in part, to determine "the appropriate storage conditions and expiration dates." *Id.* And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use." *Id.* § 211.137(a). An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166." *Id.* § 211.137(b).

98. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is to account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use." 43 Fed. Reg. 45059 (Sept. 29, 1978).

99. The FDA expressly recognizes that the initial expiration date set at the time of approval is tentative and may need to be adjusted to an earlier expiration date based on information acquired from ongoing studies: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined." 21 C.F.R. § 211.166(b).

100. After a drug is approved, a manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of 21 C.F.R. § 314.70.

101. Under some circumstances, a manufacturer of an approved drug must obtain FDA approval before implementing a label change. *Id.* § 314.70(b).

102. But the FDA has long recognized a "changes being effected" (CBE) supplement that permits a manufacturer to make certain changes immediately, which after being made are subject to FDA review. *Id.* §§ 314.70(c)(3), (c)(6).

103. A manufacturer of an approved drug can use the CBE supplement to make an immediate "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess." *Id.* § 314.70(c)(6)(i). "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described." 65 Fed. Reg. 83042 (Dec. 29, 2000).

104. A manufacturer, therefore, need not seek FDA preapproval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use." 21 C.F.R. § 211.137(a).

105. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter." *Id.* § 314.70(c)(6)(iii)(A).

106. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the

description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form." *Id.* § 314.70 (d)(2)(ix).

107. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA." *Id.* § 314.70 (d)(2)(vi).

108. At no time did any Defendant include a warning on the label for Paragard that users may be injured because the Paragard could break before or during removal. At no time did any Defendant include a warning about the frequency of such breakages. The FDA never rejected such warnings.

109. At no time did any Defendant attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that the Paragard would not degrade, causing the product to be more susceptible to breakage once inside a woman's body. The FDA never rejected such a warning.

110. Defendants knew or should have known that that the Paragard could break before or during removal and/or that the expiration date was too long. Because they failed to include appropriate warnings or expiration dates on their products, Defendants made false statements in the labeling of their product.

111. Under FDA regulations, "misbranded" drugs may not be manufactured, distributed, or sold in the United States. *See* 21 U.S.C. §§ 331(a), 331(g), 351(a)(2)(B).

112. Among the ways a drug may be misbranded are:

a. "If its labeling is false or misleading in any particular." 21 U.S.C. § 352(a);

b. "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it

likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 352(c);

c. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users ." 21 U.S.C. § 352(f);

d. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j);

e. If the drug is advertised incorrectly in any manner, 21 U.S.C. § 352(n); or

f. If the drug's "packaging or labeling is in violation of an applicable regulation." 21 U.S.C. § 352(p).

113. As detailed herein, Paragard was misbranded in that its labeling failed to include an adequate warning reflecting scientifically significant information made known to Defendants after Paragard's approval regarding its propensity to break before or during removal.

D. Defendants' Warranties Regarding Paragard

114. Despite the fact that Defendants were on notice that Paragard was unreasonably dangerous and posed serious risks to its users, Defendants represented to consumers and healthcare providers that Paragard was a safe form of nonpermanent birth control and safer than its competitors.

115. Based upon information and belief, Defendants made these statements regarding the safety of Paragard through directed advertising and marketing materials as well as through seminar presentations and publications.

116. As detailed *supra* ¶¶ 56-63,72-77, Defendants also overstated the safety of Paragard to consumers and healthcare physicians through its advertisements emphasizing that—unlike its competitors—Paragard was a completely hormone-free birth control and could safely provide birth control for up to 10 years.

117. The marketing and promotional efforts of Defendants served to overstate the benefits of Paragard and confuse, minimize and/or downplay the risks.

118. Defendants undertook these concerted and directed promotional and marketing efforts while Defendants intentionally withheld important safety information from healthcare providers and the public.

E. Defendants Violated Their Duty to Report Adverse Event and Other Safety Information About Paragard to FDA

119. During the time that each Defendant manufactured and sold Paragard in the United States, the evidence showed that Paragard breakages exposed users to significant injury, including but not limited to, surgery to remove the broken product (including hysterectomy), infertility, and pain. Defendants failed to report these risks to the FDA.

120. Defendants concealed the risk of breakage from consumers in part by not reporting it to the FDA, which relies on manufacturers to bring new information about an approved drug like Paragard to the public's attention.

121. To ensure the safety of drugs sold in the United States, the FDA has established a regulatory system under which the manufacturer is primarily responsible for establishing and following procedures for proper complaint handling, including, but not limited to, timely communicating complete, accurate, and current safety and efficacy information related to its product(s). This is because the manufacturer has superior—and oftentimes exclusive—access to relevant safety and efficacy information including post-market complaints and data.

122. Surveillance of marketed medical products, such as Paragard, plays a key role in protecting and promoting the public health. Much of the information needed to identify safety issues is generated and/or collected by the manufacturer.

123. Requirements for reporting information to the FDA provide the agency, other firms, and the public with access to this information in a timely manner, allowing awareness and independent assessment of emerging safety of performance issues. It also enables the FDA to act when necessary to protect the public health.

124. To fulfill this responsibility, drug manufacturers must vigilantly monitor all available information regarding the safety of a drug and timely provide updated safety and efficacy information to the FDA.

125. Manufacturers of an approved drug are required to "promptly review all adverse drug experience information obtained or otherwise received by the [manufacturer] from any source, foreign or domestic, including information derived from commercial marketing experience, post-marketing clinical investigations, post-marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80. Manufacturers are also required to "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences pursuant to FDA." 21 C.F.R. § 314.80(b).

126. Adverse event reports are any adverse event associated with the use of a drug in humans, whether or not considered drug related. 21 C.F.R. §314.80(a).

127. Defendants were/are required under federal law to submit to the FDA adverse event reports. 21 C.F.R. § 314.80(c). These requirements place an affirmative obligation on a manufacturer to seek out and report information about their products.

128. When a manufacturer receives a complaint about a drug, that complaint must be maintained within a file and written procedures must be established (and followed) for the timely review of complaints, determination of need for investigation, and determination of whether the complaint is a "serious and unexpected adverse drug experience" that is required to be reported to the FDA. 21 C.F.R. § 211.198.

129. Despite these obligations, Defendants systematically failed to properly monitor and handle complaints, including, but not limited to, failing to establish procedures for proper complaint handling, failing to follow complaint handling procedures, failing to timely monitor and record complaint investigations, failing to investigate complaints, and failing to adequately communicate and submit adverse event reports or new information gleaned from adverse event reports about Paragard breakages and associated injuries. Defendants' failures with regard to their entire complaint handling system were a cause of Plaintiff's injuries.

130. Based upon information and belief, between 2009 and 2020, for example, the Teva Defendants received reports of over 2000 Paragard breaks, as documented by the FDA Adverse Event Reporting System (FAERS) database. Upon further information and belief, Defendants had received even more reports of breakage from patients and/or their doctors that were not properly handled in accordance with the regulations, including, but not limited to, not properly recorded, not properly investigated, and not properly submitted to the FDA. Defendants knew or should have known that complaints of breakage occurred at a disproportionately greater frequency than what would normally be anticipated. And Defendants knew or should have known that reports of breakage requiring medical or surgical intervention were reportable events, yet they failed to report such events.

131. The FAERS database houses, among other things, adverse event reports regarding drugs submitted by healthcare professionals, consumers, and manufacturers.[1]

132. Based upon information and belief, Defendants also received reports of Paragard breaks as documented by the FDA Manufacturer and User Facility Device Experience (MAUDE) database.

133. The FDA MAUDE database houses "medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers."[2]

134. Upon information and belief, as stated herein, Defendants received complaints about Paragard yet failed to properly handle and/or file those complaints, establish or follow established procedures for complaint handling and reporting, and report those complaints that qualified as adverse events to the FDA.

135. Despite Defendants coming into possession of new information, as evidenced by the reports to the FAERS and MAUDE databases, Defendants failed to take action to investigate the issue or to update the Paragard warning label to adequately warn of the Paragard's propensity to break before or during removal.

136. As recently as August 2019, the FDA issued a citation to CooperSurgical for instituting deficient written procedures for the handling of written and oral complaints related to drug products and for failing to adequately follow procedures for handling written and oral complaints related to drug products, all in violation of 21 C.F.R. § 211.198.

[1] *See* https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.
[2] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

137. Had Defendants established and followed proper complaint handling procedures, information about the propensity of Paragard to break and result in significant injury to women would have been made available sooner to the FDA, the medical community, and women such as Plaintiff.

F. Defendants Failed to Comply with Good Manufacturing Practices

138. Another way in which the FDA ensures the quality of drug products in the United States is through the drug manufacturers' compliance with the Current Good Manufacturing Practices ("CGMPs").

139. The CGMPs are intended to ensure that a drug product is safe for use, and a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with the CGMPs to ensure drugs meet safety, quality, purity, identity, and strength standards. 21 U.S.C. § 351(a)(2)(B).

140. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

141. The FDA's CGMP regulations are found in 21 C.F.R. Parts 210 and These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F);

packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K).

142. For example, to assure uniformity and integrity, "written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials" of each batch or lot. 21 C.F.R. § 211.110.

143. Section 211.182 requires equipment cleaning and use logs.

144. Section 211.192 requires that "[a]ll drug product production and control records . . . shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed." And any such investigation shall extend to other potentially associated batches.

145. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." "Complete records shall be maintained of any modification of an established method employed in testing." 21 C.F.R. § 211.194.

146. Any drug not manufactured in accordance with CGMPs is deemed "adulterated and/or misbranded" and may not be manufactured, distributed, or sold in the United States. *See* 21 U.S.C. §§ 331(a), 331(g), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

147. Among the other ways a drug may be adulterated are:

a. "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health," 21 U.S.C. § 351(a)(2)(A);

b. "if . . . the methods used in, or the facilities or controls used for, manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess," 21 U.S.C. § 351(a)(1)(B);

c. "its quality or purity falls below the standard set forth in such compendium," 21 U.S.C. § 351(b);

d. "if . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefore," 21 U.S.C. § 351(d).

148. Defendants failed to comply with established safety regulations, maintenance, quality control, and cleanliness standards, resulting in the mass production, shipment into circulation, and use of defective and dangerous Paragard.

149. Upon information and belief, Defendants failed to source plastic material that had sufficient flexibility to satisfy the flexibility specifications.

150. Upon information and belief, sourcing suitable plastic with sufficient flexibility has been an ongoing problem for Defendants, which has resulted in defective Paragard products entering the stream of commerce.

151. Upon information and belief, Defendants lack quality assurance and quality control procedures to ensure product conformity to Paragard's design specifications.

152. Upon information and belief, a high percentage of Paragard were deemed defective at the time of final packing due to copper corrosion or discoloration, among other issues. Copper discoloration means that the metal is rotting.

153. Upon information and belief, this percentage exceeded Defendants' written quality controls. Instead of following their own quality objectives, Defendants deviated from their written policy.

154. Upon information and belief, Defendants failed to comply with their Standard Operating Procedure (SOP) on good manufacturing practices training by, for example, performing training less than required by the SOP.

155. Defendants' failures also include, but are not limited to:

a. failing to maintain a quality control unit;

b. failing to establish and/or follow written procedures applicable to the quality control unit;

c. failing to have educated, trained, and/or experienced personnel for the particular operation(s) and function(s) the employee performs, including, but not limited to supervisors;

d. failing to conduct and/or require training on a continuing basis and with sufficient frequency to assure their personnel remain familiar with CGMP requirements applicable to them;

e. failing to ensure that any third-party consultants advising on any aspect of Paragard's manufacture has sufficient education, training, and/or experience to

advise on the subject for which they are/were retained and/or failing to maintain records stating the name, address, and qualifications of any such consultants and the type of service he/she/it provided;

f. failing to maintain and/or follow written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and/or approval or rejection of Paragard components;

g. failing to maintain and/or follow written procedures for the production and process control designed to assure Paragard has/had the identity, strength, quality, and purity Defendants purport or is represented to possess and/or failing to have these procedures drafted, reviewed, and approved by the appropriate organizational units and/or the quality control unit;

h. failing to follow and/or timely document performance of written production and process control procedures in the execution of the various production and process control functions and/or failing to record and justify any deviations from such procedures;

i. failing to maintain and/or follow proper packing and labeling controls;

j. failing to bear an expiration date determined by appropriate stability testing;

k. failing to maintain and/or follow proper laboratory controls;

l. failing to maintain and/or follow written procedures for the handling of all written and oral complaints regarding Paragard.

156. These failures, in whole or in part, were a cause of Plaintiff's injuries and damages.

EXEMPLARY / PUNITIVE DAMAGES ALLEGATIONS

157. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of Paragard's safety risks, including that injuries from Paragard's defect could lead to infertility. Nonetheless, Defendants deliberately crafted their label and marketing to mislead consumers.

158. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that Paragard was a safe form of birth control, that could be easily reversed when a woman wanted to conceive, and that full disclosure of the true risks of Paragard (including hysterectomy or infertility) would limit the amount of money Defendants would make selling Paragard, which at times was the only hormone-free intrauterine birth controls offered in the United States. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiff was denied the right to make an informed decision about whether to use Paragard, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

159. Accordingly, Plaintiff requests punitive damages against Defendants for the harms caused to Plaintiff.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(STRICT PRODUCTS LIABILITY: DESIGN DEFECT)

160. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

161. At all relevant times, Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold Paragard.

162. At all relevant times, Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold the Paragard used by Plaintiff.

163. Paragard is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectation of patients and/or their healthcare providers.

164. Paragard is defective because the product is prone to break while inside a woman's body, including, but not limited to, during routine removal during the course of ordinary use.

165. Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold a product that was not merchantable and/or reasonably suited to its intended use.

166. Defendants' failure to provide adequate warnings and instructions for Paragard renders the device unreasonably dangerous and defective.

167. Plaintiff was a foreseeable user of the Paragard.

168. At the time Paragard left Defendants' possession, the drug was in a condition that made it unreasonably dangerous to Plaintiff.

169. At the time Plaintiff used Paragard, the drug was in a condition that made it unreasonably dangerous.

170. At all relevant times, the Paragard used by Plaintiff was expected to and did reach Plaintiff without a substantial change in the condition in which the drug was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendants.

171. The Paragard inserted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the products would have expected at time of use.

172. The Paragard inserted in Plaintiff was defective in design, in that the Paragard's foreseeable risks exceeded the alleged benefits associated with its design.

173. At all relevant times, Defendants knew or had reason to know that Paragard was defective and inherently dangerous and unsafe when used in the manner instructed by Defendants.

174. Plaintiff and her healthcare providers used Paragard in a manner that was reasonably foreseeable to Defendants and in the manner in which Paragard was intended to be used.

175. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered Paragard's defective conditions or perceived its unreasonable dangers prior to insertion of the drug.

176. As a result of the foregoing design defects, Paragard created risks to the health and safety of its users that were 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 Paragard.

177. Defendants intentionally and recklessly designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold Paragard with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of Plaintiff and others.

178. Defendants knew or should have known that physicians and other healthcare providers began commonly using this product as a safe and effective drug for temporary contraception despite its defective condition.

179. At all relevant times, there was a practical, technologically feasible, and safer alternative design for Paragard.

180. The defects in Defendants' Paragard were substantial factors in causing Plaintiff's injuries.

181. As a direct and proximate result of Defendants' defective design of Paragard, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

SECOND CLAIM FOR RELIEF
(STRICT PRODUCTS LIABILITY: DEFECT DUE TO INADEQUATE WARNING)

182. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

183. Paragard is defective and unreasonably dangerous because Defendants failed to adequately warn or instruct consumers and prescribers of Paragard's dangerous characteristic, including the full extent of the risk of breakage the injuries that could result, including hysterectomy, pain, and infertility.

184. Paragard is also defective because Defendants failed to properly and adequately warn and instruct Plaintiff and/or her healthcare providers with regard to the inadequate research and testing of Paragard.

185. At all relevant times, Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, sold and/or otherwise released into the stream of commerce Paragard, including the Paragard inserted in Plaintiff, and in the course of same, directly advertised and marketed the drug to consumers and/or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Paragard.

186. At all relevant times, Paragard was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings provided did not accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to the consumer and/or physicians. Defendants' promotional activities further diluted or minimized the warnings given with the product.

187. Paragard was defective and unreasonably dangerous at the time of their release into the stream of commerce (and when it left the possessions of Defendants) due to the inadequate warnings, labeling, and/or instructions accompanying the product including, but not limited to, the failure to warn of the proclivity of the Paragard breaking, as described above.

188. The warnings that accompanied Paragard failed to provide the level of information that an ordinary consumer and/or healthcare provider, would expect when using the product in a manner reasonably foreseeable to Defendants.

189. Defendants downplayed the serious and dangerous side effects of Paragard to encourage sales of the product; consequently, Defendants placed their profits above Plaintiff's safety.

190. At the time Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold Paragard into the stream of commerce, Defendants knew or should have known of the risks associated with Paragard when put to its intended and reasonably anticipated use.

191. Plaintiff was a foreseeable user of Paragard.

192. At all relevant times, Plaintiff used Paragard in the manner in which the drug was intended to be used.

193. At the time Plaintiff used Paragard, the drug was defective and in a condition that made it unreasonably dangerous to Plaintiff.

194. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Paragard.

195. Paragard is dangerous when used by the ordinary user who used the drug as intended.

196. The risks associated with each Paragard are of such a nature that healthcare providers and users could not have recognized the potential harm.

197. Paragard is dangerous to an extent contemplated beyond the ordinary user and/or healthcare providers because the Paragard product is prone to break while in a woman's body, including, but not limited to, during routine removal.

198. The Paragard, when inserted in Plaintiff, was in the same condition as when designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendants.

199. During the time that they held the NDA, Defendants had a duty to warn of the risk of harm associated with the use of the drug and to provide adequate warnings concerning the risk the product could break, even if inserted properly and even if the drug remained properly in place.

200. Defendants had a continuing duty to warn consumers, including Plaintiff, her physicians, and/or the medical community of the dangers associated with Paragard, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

201. Had Plaintiff received proper or adequate warnings and/or instructions as to the risks of using Paragard, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative birth control.

202. Defendants' lack of adequate warnings and instructions accompanying Paragard were a substantial factor in causing Plaintiff's injuries.

203. As a direct and proximate result of Defendants' failure to provide adequate warnings of the risks of Paragard, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

THIRD CLAIM FOR RELIEF
(STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT)

204. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

205. At all relevant times, Defendants designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, sold the Paragard IUD that was inserted into Plaintiff.

206. The Paragard inserted in Plaintiff contained an unreasonably dangerous condition or conditions, described above, at the time the Paragard left Defendants' control and possession.

207. The Paragard inserted in Plaintiff deviated from Defendants' design, specifications, or intentions in that, *inter alia*, Paragard was made of plastic with insufficient flexibility, Paragard was not in conformity with Paragard's design specifications because Defendants lacked quality assurance and control procedures to ensure product conformity, and/or the Paragard copper had experienced corrosion or discoloration at the time of final packing.

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

209. Plaintiff and Plaintiff's healthcare providers used the Paragard in a manner consistent with and reasonably foreseeable to Defendants.

210. Paragard 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 Paragard because of Defendants' manufacturing defects, which include but are not limited to:

a. Failure to follow CGMPs, including 21 C.F.R. §§ 211.110, 211.182, 211.192, 211.194;

b. Upon information and belief, failure to adequately inspect and/or test the drugs during the manufacturing process;

c. Failure to implement procedures that would reduce or eliminate breakages in Paragard.

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

212. The manufacturing defects in Defendants' Paragard were a substantial factor in causing Plaintiff's injuries.

213. As a direct and proximate result of Defendants' defective manufacture of Paragard, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not

limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

FOURTH CLAIM FOR RELIEF
(NEGLIGENCE)

214. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

215. At all times relevant, Defendants were in the business of designing, developing, manufacturing, testing, labeling, packaging, distributing, marketing, and/or selling Paragard, including the Paragard IUD that was inserted into Plaintiff.

216. Defendants had a duty to exercise reasonable and ordinary care in the design, development, manufacture, testing, labeling, packaging, distribution, marketing, and/or sale of Paragard so as to avoid exposing others to foreseeable and unreasonable risks of harm.

217. Defendants breached their duty of care to Plaintiff and their physicians in the design, development, manufacture, testing, labeling, packaging, distribution, marketing, and sale of Paragard.

218. Paragard is defective because the product is prone to break while in a woman's body, including, but not limited to, during routine removal.

219. Defendants breached their duty in that they failed to warn Plaintiff and her physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Paragard prior to the time of Plaintiff's insertion.

220. Defendants also breached their duties by receiving and failing to warn of complaints or adverse events regarding Paragard breakages to the FDA, the public, and the medical community.

221. Defendants knew that the Paragard could break and failed to warn Plaintiff of this potential breakage.

222. Plaintiff was a foreseeable user of Paragard.

223. Defendants knew women like Plaintiff would use Paragard.

224. Defendants knew or should have known that Paragard's defective condition made the drug unreasonably dangerous or likely to be unreasonably dangerous when used in its intended or reasonably foreseeable manner.

225. At the time of the manufacture and sale of the Paragard, Defendants knew or should have known that the Paragard was designed and manufactured in such a manner so as to present an unreasonable risk of breakage.

226. At the time of the manufacture and sale of the Paragard, Defendants knew or should have known that the Paragard was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement and subsequent removal.

227. Paragard was unreasonably dangerous when used by Plaintiff, who followed the instructions provided by Defendants and used Paragard according to its common usage.

228. At the time Paragard left Defendants' possession, the drug was in a condition that made it unreasonably dangerous to Plaintiff.

229. At the time Plaintiff used Paragard, the drug was in a condition that made it unreasonably dangerous.

230. The Paragard used by Plaintiff was expected to and did reach Plaintiff without substantial change in the condition in which the drug was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendants.

231. At all relevant times, Plaintiff used Paragard in the manner in which was the drug was intended.

232. As designers, developers, manufacturers, inspectors, advertisers, packagers, distributors, and suppliers of Paragard, Defendants had superior knowledge of the product and owed a duty of care to Plaintiff.

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

a. Failing to design Paragard in a manner that protected Plaintiff from injury;

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 burden of taking measures to reduce or avoid harm;

c. 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 drugs available for the same purpose;

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

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

f. Failing to perform reasonable pre- and post-market testing of Paragard to determine whether the product was safe for its intended use;

g. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would recommend, use, insert, and remove Paragard;

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

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

j. Continuing manufacture and sale of Paragard with the knowledge that Paragard was dangerous and not reasonably safe, and failing to comply with the FDA's CGMPs;

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

l. Failing to establish an adequate quality-assurance program used in the manufacturing of Paragard;

m. Failing to establish and maintain an adequate post-marketing surveillance program for Paragard;

n. Failing to adequately and correctly report safety information relative to Paragard product resulting in inadequate warnings;

o. Failing to provide adequate and continuous warnings about the inherent danger of breakage of the Paragard;

p. Failing to warn Plaintiff and her physicians by not reporting the risk of serious defects and life-altering complications described above;

q. Failing to warn of or report complaints about Paragard breakages to the FDA or the public and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Paragard breakages;

r. Concealing from the FDA, the general medical community and/or physicians their full knowledge and experience regarding the full extent and frequency of risks associated with the product;

s. Promoting, marketing, and/or advertising Paragard in a misleading manner, given their knowledge and experience of potential harmful effects;

t. Failing to fulfill the standard of care required of a reasonable, prudent, drug manufacturer;

u. Failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of Paragard to be harmful to patients; and

v. Failing to respond, react, or report appropriately to reports of Paragard causing harm to patients, including breakage and removal surgery.

234. It was foreseeable that Defendants' misrepresentations, actions, and omissions would cause severe, permanent, and debilitating injuries to Plaintiff.

235. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

236. As a direct and proximate result of Defendants' negligence, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

FIFTH CLAIM FOR RELIEF
(FRAUD & DECEIT)

237. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

238. At all times relevant, Defendants intentionally or recklessly misrepresented the safety of Paragard for its intended use.

239. Defendants knew or were reckless in knowing that their representations were false.

240. 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 Paragard was safe when, in fact, Paragard was unreasonably dangerous in that the product is prone to break before or during removal when used as intended.

241. 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 Paragard had been appropriately tested and was found to be safe and effective.

242. The representations made by Defendants were, in fact, false. When 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 Paragard.

243. Defendants made these representations with the intent of defrauding and deceiving the medical community, Plaintiff, Plaintiff's physicians, and/or the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public to recommend, prescribe, dispense, and purchase Paragard 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.

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

245. Plaintiff and their physicians reasonably relied on facts provided by Defendants, who foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of Paragard.

246. Having knowledge based on 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 Plaintiff's healthcare providers and physicians, that Paragard was safe for use as a means of long-term birth control and was as safe or safer than other products and/or procedures available and/or on the market. As a result of Defendants' research and testing, or lack thereof, 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.

247. 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.

248. The information distributed to the public, the medical community, Plaintiff, and her physicians by 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 that were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of Paragard.

249. These representations, and others made by 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.

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

251. 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 Paragard.

252. 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 Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts about Defendants' misrepresentations at the time when Plaintiff used Paragard.

253. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Paragard, neither Plaintiff nor her physicians would have purchased, used, or relied on Defendants' representations and omissions concerning Paragard.

254. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

255. As a direct and proximate result of Defendants' fraud, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

SIXTH CLAIM FOR RELIEF
(FRAUD BY OMISSION)

256. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

257. At all times relevant, Defendants intentionally or recklessly misrepresented the safety of Paragard for its intended use.

258. Defendants knew or were reckless in knowing that their representations were false.

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

a. That Paragard 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 Paragard was higher than with other products and procedures available for birth control;

c. That Paragard was not adequately tested;

d. That the limited clinical testing for Paragard 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 Paragard in addition to and above and beyond those associated with other products and procedures available for birth control;

g. That Paragard 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 Paragard needed to be removed, the removal procedure had a very high failure rate and/or needed to be performed repeatedly;

i. That Paragard was manufactured negligently;

j. That Paragard was manufactured defectively; and

k. That Paragard was designed negligently and designed defectively.

260. Defendants were under a duty to disclose the foregoing issues to Plaintiff.

261. 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 Paragard, such as Plaintiff.

262. Defendants knew that Plaintiff could not determine the truth of this information.

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

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

265. Defendants knew and had reason to know that Paragard 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.

266. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

267. As a direct and proximate result of Defendants' fraudulent concealment and/or omissions, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

SEVENTH CLAIM FOR RELIEF
(NEGLIGENT MISREPRESENTATION)

268. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

269. Defendants had a duty to tell Plaintiff and the public the truth about the risks and harms associated with Paragard.

270. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, her healthcare providers, and the public that Paragard had been tested and found to be safe and effective for long-term birth control.

271. At relevant times, Defendants breached that duty by providing Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failing to disclose material information concerning Paragard, including, but not limited to, misrepresentations regarding the safety of Paragard.

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

273. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's healthcare providers; to falsely assure them of the quality of Paragard; and to induce the public and medical community, including Plaintiff and their healthcare providers, to request, recommend, prescribe, insert, purchase, and continue to use Paragard.

274. The representations made by Defendants were, in fact, false. Paragard was not safe for human use in its intended and reasonably foreseeable manner. Use of Paragard is dangerous, as there is a risk that it may break and cause serious injury.

275. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff, and Plaintiff's healthcare providers were induced to and did use Paragard, thereby causing Plaintiff to endure severe and permanent injuries.

276. Defendants knew and had reason to know that Plaintiff, Plaintiff's 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 Defendants.

277. Defendants had sole access to the material facts concerning the defective nature of Paragard and its propensity to cause serious injuries.

278. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff was inserted with Paragard, Plaintiff and their healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

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

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

281. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by Defendants, where they concealed and misrepresented facts that were critical to understanding the true dangers inherent in the use of Paragard.

282. Plaintiff and their healthcare providers would not have recommended and inserted Paragard in Plaintiff had the true facts not been concealed by Defendants.

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

284. Defendants knew, and had reason to know, that Paragard 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.

285. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

286. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

EIGHTH CLAIM FOR RELIEF
(BREACH OF EXPRESS WARRANTY)

287. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

288. Through Defendants' public statements, descriptions, and promises regarding Paragard, 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 the products were adequately tested and fit for their intended use.

289. At relevant times, Defendants were aware that consumers, including Plaintiff, would use Paragard, which is to say that Plaintiff was a foreseeable user of Paragard.

290. Plaintiff and/or her inserting physicians were, at all relevant times, in privity with Defendants.

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

292. Defendants breached various express warranties with respect to Paragard, including the following particulars:

a. 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 Paragard was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Paragard;

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

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

293. In reliance upon Defendants' express warranties, Plaintiff was inserted with Paragard as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

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

295. 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 Defendants in connection with the use, recommendation, description, and/or dispensing of Paragard.

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

297. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

298. As a direct and proximate result of Defendants' breach, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

NINTH CLAIM FOR RELIEF
(BREACH OF IMPLIED WARRANTY)

299. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

300. At relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold Paragard.

301. Plaintiff was a foreseeable user of Paragard.

302. At relevant times, Defendants intended that Paragard be inserted for the purposes, and in the manner, that Plaintiff or their physicians or surgeons used it, and Defendants impliedly warranted each Paragard to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

303. Defendants were aware that consumers, including Plaintiff or her physicians or surgeons, would insert Paragard in the manner described by the instructions for use and that Plaintiff was a foreseeable user of Paragard.

304. Defendants knew or had reason to know that Plaintiff would rely on Defendants' judgment and skill in providing Paragard for its intended use.

305. Plaintiff and/or her physicians and surgeons were at all relevant times in privity with Defendants.

306. Defendants' Paragard were expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians and surgeons, without substantial change in the condition in which they were manufactured and sold by Defendants.

307. Defendants breached various implied warranties with respect to Paragard, including the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical literature, and regulatory submissions that Paragard was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Paragard;

b. Defendants represented that Paragard was safe and/or safer than other alternative drugs or procedures and fraudulently concealed information that demonstrated that Paragard was not as safe or safer than alternatives available on the market; and

c. Defendants represented that Paragard was more efficacious than other alternative treatments and fraudulently concealed information regarding the true efficacy of Paragard.

308. In reliance upon Defendants' implied warranties, Plaintiff and/or her inserting physicians and surgeons used Paragard as prescribed in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

309. Defendants breached their implied warranties to Plaintiff and/or her inserting physicians and surgeons in that Paragard was not of merchantable quality, safe, and fit for its intended use, or adequately tested, in violation of common law principles.

310. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

311. As a direct and proximate result of Defendants' breach, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future

medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

TENTH CLAIM FOR RELIEF
(VIOLATION OF OREGON CONSUMER PROTECTION ACT: Or. Rev. Stat. §§ 646.605 et seq.)

312. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

313. Plaintiff purchased and used Paragard primarily for personal use, thereby suffering ascertainable losses from Defendants' actions in violation of consumer protection laws.

314. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for Paragard and would not have incurred related medical costs and injury.

315. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for Paragard that was inserted into Plaintiff and that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

316. Unfair methods of competition or deceptive acts or practices that were proscribed by law include the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

317. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians, and consumers, including Plaintiff and her physicians, was to create demand for and promote the sale of Paragard. Each aspect of Defendants' conduct combined to artificially create sales of Paragard.

318. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Paragard.

319. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for Paragard and would not have incurred related medical costs.

320. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of state and federal consumer protection statutes.

321. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of state and federal consumer protection statutes.

322. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of state and federal consumer protection statutes, which serve to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising. Defendants are the suppliers, manufacturers, advertisers, and sellers who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

323. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising by knowingly and falsely representing that Paragard was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

324. Defendants' deceptive, unconscionable, unfair and/or fraudulent misrepresentations and material omissions to Plaintiff constituted consumer fraud and/or unfair and deceptive acts and trade practices in violation of Or. Rev. Stat. §§ 646.605 et seq.

325. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

326. Defendants had actual knowledge of the defective and dangerous condition of Paragard and failed to take any action to cure such defective and dangerous condition.

327. Plaintiff and their inserting physicians and surgeons relied upon Defendants' misrepresentations and omissions in determining which product to use and/or procedure to undergo and/or perform.

328. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers constitute unfair and deceptive acts and practices.

329. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

330. Defendants' conduct was a substantial factor in causing Plaintiff's injuries.

331. As a direct and proximate result of Defendants' violation of the consumer protection statutes, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

ELEVENTH CLAIM FOR RELIEF
(PUNITIVE DAMAGES)

332. Plaintiff incorporates all allegations in the preceding paragraphs as if fully set forth herein and further alleges:

333. At times material hereto, Defendants knew or should have known that their Paragard, as designed, manufactured, assembled, sold, and/or distributed, was inherently dangerous.

334. At times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their Paragard.

335. Defendants' misrepresentations included knowingly withholding material information from the public and consumers alike, including Plaintiff, concerning the safety of Paragard.

336. At times material hereto, Defendants knew and recklessly disregarded the fact that their Paragard could cause serious, disabling, and permanent injuries to individuals such as Plaintiff.

337. Notwithstanding the foregoing, Defendants continued to aggressively market and promote their Paragard without disclosing the risks.

338. As a proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered

severe and permanent physical and emotional injuries, endured pain and suffering, and have suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

339. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future. Plaintiff will require additional medical and/or hospital care, attention, and services in the future.

PRAYER FOR RELIEF

Plaintiff demands judgment in his favor and seeks the following relief against Defendants, jointly and severally:

A. Compensatory damages in excess of $75,000, exclusive of interest and costs;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

C. Reasonable attorneys' fees as allowed by law;

E. Punitive damages in an amount to punish Defendants and encourage Defendants and others from similar conduct; and

F. Such other relief as this Court deems just and proper under the circumstances.

JURY DEMAND

In accordance with Federal Rule of Civil Procedure 38(b), Plaintiff demands a jury trial as to all issues triable by a jury.

Dated: April 27, 2021

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