

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

MARY BUNCH,

Plaintiff,

TEVA PHARMACEUTICALS USA, INC.;
TEVA WOMEN'S HEALTH, INC. d/b/a
TEVA WOMEN'S HEALTH, LLC; TEVA
WOMEN'S HEALTH, LLC; TEVA
BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC.; THE COOPER
COMPANIES, INC.; and
COOPERSURGICAL, INC.,

Defendants.

Case No.:

JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES

COMES NOW Plaintiff, Mary Bunch, by and through her counsel, files this Complaint against Defendants Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., doing business as Teva Women's Health, LLC, Teva Women's Health, LLC, Teva Branded Pharmaceutical Products R&D, Inc., The Cooper Companies, Inc., and Cooper Surgical, Inc. (collectively hereinafter "Defendants"), both jointly and severally, as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold ParaGard Intrauterine medical device (hereinafter "Paragard") that was implanted into Plaintiff, and throughout the United States. Accordingly, Plaintiff alleges and states as follows:

INTRODUCTION

1. Plaintiff's choice of birth control was 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.

2. Plaintiff 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, including the Plaintiff, 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.

3. Plaintiff and her 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.

4. 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.

5. Defendants, however, failed to address Paragard's safety issues, even though over 2000 adverse event reports did 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. Unfortunately for Plaintiff, Defendants chose greed and profits over the safety of users of Paragard, and Plaintiff suffered injuries as a consequence. Plaintiff had a Paragard implanted that later broke during surgery to remove the product.

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

GENERAL ALLEGATIONS

13. Plaintiff, Mary Bunch ("Plaintiff"), by and through Plaintiff's attorneys, Crumley Roberts, LLP, brings this action for personal injuries suffered as a result of using the defective and dangerous Paragard.

14. Paragard is prescribed to prevent conception, and at all times relevant hereto, is manufactured, designed, tested, packaged, labeled, marketed, advertised, promoted, distributed, and sold by Defendants. On information and belief, Plaintiff used Paragard, resulting in injuries.

THE PARTIES

15. At all times relevant to this action, Plaintiff, is an individual, citizen and resident of the state of North Carolina.

16. Plaintiff was implanted with ParaGard IUD in 2012. It was removed in 2018, resulting in injuries.

A. Teva Defendants

17. 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.

18. 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.

19. 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.

20. Upon information and belief, and for purposes of liability and interest, Teva Women's Health, Inc. is the same entity as Teva Women's Health, LLC. 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."

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

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

B. Cooper Defendants

23. 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.

24. Defendant CooperSurgical, Inc. ("CooperSurgical") is a Delaware corporation with its principal place of business located at 95 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.

25. Defendants CooperCompanies and CooperSurgical are referred to collectively hereinafter as “Cooper Defendants.”

JURISDICTION & VENUE

26. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). Complete diversity of citizenship exists between the Plaintiff and Defendants and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

27. A substantial part of the events, actions, or omissions giving rise to Plaintiff’s causes of action occurred in the state of North Carolina, including the Middle District of North Carolina.

28. At all times alleged herein, Defendants were authorized to conduct or engage in business within the state of North Carolina and supplied Paragard within the state of North Carolina. Defendants received financial benefit and profits as a result of designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling Paragard, either directly or through a subsidiary, within the state of North Carolina.

29. Defendants each have significant contacts in the state of North Carolina, and Defendants have derived revenue from the sale of Paragard in the state of North Carolina, such that personal jurisdiction is proper.

30. In addition, venue of this case is proper in the state of North Carolina pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff’s claims occurred in the Middle District of North Carolina.

FACTUAL ALLEGATIONS

A. The Development, Manufacture, and Distribution of Paragard

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

32. 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.

33. 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.

34. 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.

35. 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).

36. 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.

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

38. In fact, upon information and belief, Defendants only ever 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.

39. 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, 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.

40. 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.

41. On December 23, 2008, Teva Pharmaceutical Industries Ltd. ("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.

42. 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.

43. 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.

44. 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.

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

46. 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.

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

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

49. 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.

50. 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.

51. 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

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

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

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

55. 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.

56. 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.

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

58. 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.”

59. 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.”

60. 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.”

61. 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.

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

63. 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.

64. 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.

65. Prior to Plaintiff's use of Paragard, the relevant Defendants knew and/or should have known that the drug was defective and unreasonably dangerous.

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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.

73. 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.”

74. 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.

75. 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.

76. 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.

77. 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:

Here are some things to consider:

-  PARAGARD is over **99% effective** and **100% hormone free**
-  It helps prevent pregnancy for up to 10 years, but **your healthcare professional can remove it at any time**
-  As soon as PARAGARD is removed by your healthcare professional, **you can try to get pregnant the same day**
-  PARAGARD can be used **whether or not you have had a child**
-  **FDA approved** for over 30 years and used by millions of women

PARAGARD does not protect against HIV/AIDS or sexually transmitted diseases (STDs).

78. Based upon Defendants’ misrepresentations, upon which Plaintiff and her 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.

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

80. 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.

81. 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.”

82. 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

83. As detailed *supra* ¶¶ 52-68 and *infra* ¶¶ 122-127, 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.

84. Plaintiff references federal law throughout this 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.

85. 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.

86. 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.

87. 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.

88. "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.

89. 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.*

90. 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).

91. 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).

92. 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).

93. 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.

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

95. 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).

96. 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).

97. 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).

98. 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).

99. 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).

100. 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).

101. 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.

102. 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.

103. 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.

104. 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).

105. 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).

106. 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

107. 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 non-permanent birth control and safer than its competitors.

108. 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.

109. As detailed *supra* ¶¶ 57-64,73-78, 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.

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

111. 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

112. 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.

113. 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.

114. 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.

115. 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. 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.

116. 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.

117. 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).

118. 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).

119. 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.

120. 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.

121. 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.

122. 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.

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

124. 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.

125. 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

126. 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.

127. 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.

128. 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>.

129. 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

130. 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").

131. 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).

132. 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.

133. The FDA's CGMP regulations are found in 21 C.F.R. Parts 210 and 211. 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).

134. 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.

135. Section 211.182 requires equipment cleaning and use logs.

136. 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.

137. “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.

138. 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.

139. 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).

140. 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.

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

142. 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.

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

144. 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.

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

146. 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.

147. 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.

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

G. Plaintiff's Paragard Insertion and Subsequent Injuries

148. On information and belief, in or around 2012 Plaintiff had Paragard inserted by a physician.

149. Plaintiff, a young and healthy woman, wanted a Paragard because it was a as a form of non-permanent and non-hormonal birth control that would allow her to conceive in the future.

150. On or around April 6, 2017, Plaintiff went to have Paragard removed by Jodi Bell Tolley, WHNP at the UNC Family Medicine Center at Chapel Hill in Chapel Hill, North Carolina.

151. Jodi Bell Tolley, WHNP attempted to remove the Paragard as instructed by Defendants, by grasping the Paragard by the forceps and pulling gently. Despite following the instructions provided by Defendants, the strings of the Paragard began to fray and the device was unable to be retrieved.

152. On or around April 13, 2017, Jodi Bell Tolley, WHNP attempted to remove the Paragard again, but was successful.

153. On or around June 14, 2018, Plaintiff underwent a hysteroscopy performed by doctor Louise Langdon Highley, MD at Duke Obstetrics & Gynecology. Unfortunately, Plaintiff's Paragard broke upon removal, and Dr. Highley was unable to remove the inferior ball portion of the Paragard during the procedure. Based in information and belief, this fragment of the Paragard still remains inside the Plaintiff.

154. Prior to insertion of Plaintiff's Paragard, Defendants provided no warning to Plaintiff and/or her doctors about Paragard's propensity to break in the body before or during

removal and the risk of injury, including, but not limited to, further medical and/or invasive surgical intervention. As detailed *supra* ¶¶ 52-68, 122-127, this information was known or knowable to Defendants.

155. On information and belief, Plaintiff used the Paragard designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendants. The Paragard reached Plaintiff without substantial change in the drug's condition.

156. On information and belief, as a direct and proximate result of using Paragard, Plaintiff suffered serious and/or permanent adverse effects.

157. As a result of said adverse effects, and as a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including but not limited to, significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of reproductive health, loss of earnings and earning capacity, and have and will incur past and future medical expenses. Plaintiff's damage equals a sum in excess of the jurisdictional limits of the Court.

158. At all relevant times, each Defendant had knowledge that there was a significant increased risk of adverse events associated with Paragard including, but not limited to breakage, and despite this knowledge Defendants continued to manufacture, market, distribute, sell, and profit from sales of Paragard.

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

160. On information and belief, Plaintiff's prescribing physicians would not have prescribed Paragard to Plaintiff, would have changed the way they warned Plaintiff about the signs,

symptoms, and risks of serious adverse effects of Paragard, and would have discussed with Plaintiff the true risks and propensity of breakage in the body and resulting injuries and complications had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of Paragard.

161. Defendants maintained a duty to Plaintiff after Paragard was inserted and until it was removed.

162. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

TOLLING / FRAUDULENT CONCEALMENT

163. Plaintiff assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

164. The discovery rule applies to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

165. The nature of Plaintiff's injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until September 18, 2020, a date within the applicable statute of limitations for filing Plaintiff's claims.

166. Plaintiff brings this Complaint within the applicable statute of limitations. Specifically, Plaintiff brings this action within the prescribed time limits following Plaintiff's injuries and Plaintiff's knowledge of the wrongful cause. Prior to such time, Plaintiff did not know and had no reason to know of her injuries and/or the wrongful cause of those injuries.

167. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiff and defects associated with Paragard. Defendants affirmatively withheld and/or misrepresented facts concerning Paragard's safety. As a result of Defendants' misrepresentations and concealment, Plaintiff and Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Plaintiff had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

168. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known that Paragard was and is defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claim asserted herein.

EXEMPLARY / PUNITIVE DAMAGES ALLEGATIONS

169. 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.

170. 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.

171. Accordingly, Plaintiff requests punitive damages (where available) against Defendants for the harms caused to Plaintiff.

CAUSES OF ACTION

COUNT I **NEGLIGENCE**

172. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein.

173. 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 that were inserted into Plaintiff.

174. 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.

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

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

177. 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.

178. 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.

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

180. Plaintiff was a foreseeable users of Paragard.

181. Defendants knew women like Plaintiff would use Paragard.

182. 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.

183. 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.

184. At the time of the manufacturer 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.

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

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

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

188. 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.

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

190. 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.

191. Defendants failed to exercise reasonable and due care under the circumstances and therefore breached their duty of care to Plaintiff in the following ways:

192. 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.

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

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

195. 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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II
NEGLIGENCE—DESIGN & MANUFACTURING DEFECT

196. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein.

197. 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 that were inserted into Plaintiff.

198. 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.

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

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

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

202. Plaintiff was a foreseeable users of Paragard.

203. Defendants knew women like Plaintiff would use Paragard.

204. Defendants knew or should have known that Paragard's defective condition made the drug unreasonably dangerous.

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

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

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

208. 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.

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

210. 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.

211. Defendants failed to exercise reasonable and due care under the circumstances and therefore breached their duty of care to Plaintiff in the following ways:

- w. Failing to design Paragard in a manner that protected Plaintiff from injury;
- x. 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;
- y. 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;
- z. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;
- aa. 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;

- bb. Failing to perform reasonable pre- and post-market testing of Paragard to determine whether the product was safe for its intended use;
- cc. 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;
- dd. 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;
- ee. 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;
- ff. 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;
- gg. 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;
- hh. Failing to establish an adequate quality-assurance program used in the manufacturing of Paragard;
- ii. Failing to establish and maintain an adequate post-marketing surveillance program for Paragard;
- jj. Failing to adequately and correctly report safety information relative to Paragard product resulting in inadequate warnings;
- kk. Failing to provide adequate and continuous warnings about the inherent danger of breakage of the Paragard product;
- ll. Failing to warn Plaintiff and her physicians by not reporting the risk of serious defects and life-altering complications described above;
- mm. 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.

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

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

214. 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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III
NEGLIGENCE— FAILURE TO WARN

215. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein.

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

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

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

219. Plaintiff were foreseeable users of Paragard.

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

221. Defendants knew or reasonably should have known that Paragard was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

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

223. Defendants had a duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for breakage.

224. Defendants had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for breakage.

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

226. At the relevant times, Defendants knew or should have known that Paragard was designed and manufactured to have unreasonable and insufficient strength or structural integrity.

227. At the relevant times, Defendants knew or should have known that using Paragard for its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe injuries.

228. Defendants knew or reasonably should have known that consumers of Paragard would not realize the danger associated with using the drug for its intended use and/or in a reasonably foreseeable manner.

229. The Paragard did not include an adequate warning that the Paragard is prone to break and can cause serious injury to users.

230. Defendants failed to properly and/or adequately warn or instruct that Paragard is prone to break and can cause serious injury to users.

231. Defendants also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of Paragard.

232. Defendants breached their duty to Plaintiff by failing to warn of the risks and dangers of using Paragard as intended.

233. 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.

234. Had Plaintiff received proper or adequate warnings and instructions as to the risks of using Paragard, including but not limited to adequate warnings regarding Paragard's propensity to break, Plaintiff would have avoided the risk and could have obtained or used alternative birth control.

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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

237. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein.

238. 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.

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

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

241. 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.

242. 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.

243. 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.

244. 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.

245. 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.

246. 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.

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

248. 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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT V
BREACH OF IMPLIED WARRANTY

249. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein.

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

251. Plaintiff was a foreseeable users of Paragard.

252. At relevant times, Defendants intended that Paragard be inserted for the purposes, and in the manner, that Plaintiff or her 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.

253. 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 users of Paragard.

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

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

256. 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.

257. 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.

258. 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.

259. 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.

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

261. 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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV
VIOLATION OF CONSUMER PROTECTION LAWS

262. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein.

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

264. 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.

265. 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.

266. 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.

267. 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.

268. 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.

269. 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.

270. 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.

271. 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.

272. 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.

273. 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.

274. 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 consumer protection statutes, including but not limited to N.C. Gen. Stat. §§ 75-1.1 *et seq.*

275. 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.

276. 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.

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

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

279. 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.

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

281. 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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII
GROSS NEGLIGENCE

282. Plaintiff realleges and incorporates by reference paragraphs 1 through 170 of this Complaint as if each were set forth fully and completely herein.

283. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff seeks at the appropriate time under governing law, for the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they were false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

284. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

285. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

286. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VIII
UNJUST ENRICHMENT

287. Plaintiff realleges and incorporates by reference paragraphs 1 through 168 of this Complaint as if each were set forth fully and completely herein

288. Defendants have received significant revenues from sales of Paragard.

289. It is unjust to allow Defendants to earn revenues and retain the benefits and profits from the sale of Paragard when Plaintiff suffered serious injuries as a result of Paragard, including but not limited to severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, loss of comfort, and economic damages.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IX
PUNITIVE DAMAGES

290. Plaintiff realleges and incorporates by reference paragraphs 1 through 170 of this Complaint as if each were set forth fully and completely herein.

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

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

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

294. 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.

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

296. 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 has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

297. 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 may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

298. Pursuant to Federal Rule of Civil Procedure 38(b) Plaintiff hereby demand a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. exemplary and punitive damages sufficient to punish and deter Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. reasonable attorneys' fees as provided by law;
- e. costs and expenses of these actions;
- f. statutory damages, treble damages and other relief permitted by the laws of the states that will govern these actions; and
- g. any other relief the Court may deem just and proper.

Dated: June 9, 2021

Respectfully submitted,

By: /s/ Brian L. Kinsley

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