UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

KRISTIE B. DONOVAN,

Plaintiff,

-against-

BAYER HEALTHCARE PHARMACEUTICALS, INC.,

Defendant.

CASE NUMBER

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, **KRISTIE B. DONOVAN** (referred to as "Plaintiff"), by and through her undersigned counsel, on behalf of herself individually, hereby sues the defendant, **BAYER HEALTHCARE PHARMACEUTICALS, INC.** (hereinafter referred to as "Defendant") and upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. Venue in this District is appropriate on the basis that plaintiff resides within the geographical boundaries of the United States District Court for the Western District of New York and, more specifically, resides in Tonawanda, New York.

BACKGROUND

3. This is an action for damages suffered by Plaintiff, KRISTIE B. DONOVAN, who used the intrauterine device (hereinafter referred to as "IUD") MIRENA® (hereinafter referred to as "MIRENA®" or "the subject product").

4. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed MIRENA®.

5. When warning of safety and risks of MIRENA®, Defendant negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff and the public in general, that MIRENA® had been tested and was found to be safe and/or effective for its indicated use.

6. Defendant concealed their knowledge of MIRENA's® defects, from Plaintiff, the FDA, the public in general and/or the medical community specifically.

7. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, implant and/or purchase MIRENA® for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

8. Defendant negligently and improperly failed to perform sufficient tests, if any, on women using MIRENA® during clinical trials, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other contraceptives, which does not entirely and/or necessarily apply to the MIRENA® whatsoever.

9. Defendant was negligent in failing to adhere to and/or take into consideration warnings from the FDA, who determined that the Defendant was misleading the public in general, and the medical community in particular, through the use of advertisements which overstated the efficacy of MIRENA® and minimized the serious risks of the product.

10. As a result of the defective nature of MIRENA®, those persons who use and/or used and relied on MIRENA® have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff herein has sustained certain of the above health consequences due to her use of MIRENA®.

12. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiff seeks compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper, as a result of her use of the MIRENA®, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death,

early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

14. Plaintiff KRISTIE B. DONOVAN is a natural person and resident of Tonawanda, New York.

PARTY DEFENDANT

15. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is, and at all relevant times, was a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

16. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.

17. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. expected or should have expected that its acts would have consequences within the United States of America, and the State of New Jersey in particular and derived substantial revenue from interstate commerce.

18. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute MIRENA® as an intrauterine contraceptive system.

19. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of the approved New Drug Application ("NDA") for contraceptive device MIRENA®.

20. At all times alleged herein, Defendant includes and included any and all parents, subsidiaries, affiliates, division, franchises, partners, joint venturers, and organizational unites of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

21. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, MIRENA®.

FACTUAL ALLEGATIONS

22. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein, and further alleges as follows:

23. MIRENA® is an intrauterine contraceptive system made of flexible plastic that is inserted by a healthcare provider during an office visit.

24. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for MIRENA® in December 2000. Today, millions of women in the United States use MIRENA®. It has been used by more the 15 million women worldwide.

25. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendant admits "[i]t is not known exactly how MIRENA® works," but provided that MIRENA® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

26. The MIRENA® intrauterine system (IUS) is designed to be placed within seven (7) days of the first day of menstruation and approved to remain in the uterus for up to five years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

27. The package labeling recommends that MIRENA® be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after MIRENA® use.

28. MIRENA®'s label does not warn about spontaneous migration of the IUD, but only states that migration may occur if the uterus is perforated during insertion.

29. Defendant has failed to alter their product packaging to reflect the growing number of MedWatch Adverse Event reports related to embedment of and perforation through the uterine lining and/or migration of the IUD through the uterine lining after the period of insertion.

30. Defendant has a history of overstating the efficacy of MIRENA® while understating the potential safety concerns.

31. In or around March 2009, the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) issued a warning regarding Defendant's advertising materials for MIRENA® that constituted misbranding of the IUD in violation of the Federal Food, Drug and Cosmetic Act and FDA implementing regulations.

32. Specifically, DDMAC pointed out that Bayer failed to communicate any risk information, inadequately communicated MIRENA®'s indications, and overstated the efficacy associated with the use of MIRENA® in Bayer-sponsored on internet search engines.

33. DDMAC requested that Bayer immediately cease the dissemination of the violative materials.

34. Then, in or around December 2009, Defendant was again contacted by DDMAC regarding a consumer-directed program entitled "MIRENA® Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendant.

35. This Simple Style program represented that MIRENA® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined that these claims were unsubstantiated and, in fact, pointed out that MIRENA®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

36. The Simple Style program script also intimated that MIRENA® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that MIRENA® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

37. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on MIRENA®.

38. Finally, Defendant falsely claimed that Defendant's system required no compliance with a monthly routine in contradiction of patient instructions.

39. As a result of Defendant's violation of the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations and ordered Bayer to cease use of the violative materials.

CASE-SPECIFIC ALLEGATIONS

40. Plaintiff KRISTIE B. DONOVAN is 28 years old.

41. Plaintiff's medical provider at the Suburban Women's Healthcare inserted the MIRENA® on or about October 30, 2006. Plaintiff tolerated the procedure well and neither Plaintiff nor her medical provider had any reason to suspect that the MIRENA® perforated her uterus.

42. On or about December 4, 2006, Plaintiff presented to Suburban Women's Healthcare for a follow-up appointment and the Mirena IUD was in proper place.

43. On or about April 4, 2011, plaintiff presented to Suburban Women's Healthcare after testing positive with an in-home pregnancy test. Subsequent testing revealed that the Mirena IUD was no longer in her uterine cavity.

44. Plaintiff delivered a child on December 8, 2011 and thereafter was scheduled for radiographic testing to locate the misplaced Mirena IUD.

45. On or about January 24, 2012, an abdominal x-ray revealed the Mirena IUD in the Plaintiff's abdomen projecting over the left sacroiliac joint.

46. On March 20, 2012, plaintiff underwent operative laparoscopy, but no Mirena IUD was found. Plaintiff also suffered from a blood clot in the cerebral hemisphere. A CT scan was ordered revealing the Mirena IUD in the upper abdomen located next to the umbilicus in the anterior abdominal wall.

47. Plaintiff underwent a second laparoscopic surgery on May 1, 2012, to retrieve the Mirena IUD which was embedded in the omentum in the left upper quadrant of plaintiff's abdomen.

48. As alleged herein, as a direct and proximate result of the Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, Plaintiff suffered severe and permanent physical injuries, and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendant as alleged herein.

FEDERAL REQUIREMENTS

49. Defendants had an obligation to comply with the law in the manufacture, design and sale of MIRENA®.

50. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*

51. With respect to MIRENA®, Defendants, upon information and belief, failed to comply with federal standards applicable to the sale of prescription drugs including but not limited to one or more of the following violations:

a. MIRENA® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements.

b. MIRENA® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for MIRENA® and such deviations are not plainly stated on their labels.

c. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling is false or misleading.

d. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. MIRENA® is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe methods or duration of administration or application in such manner and form as are necessary for the protection of users.

f. MIRENA® is misbranded pursuant to U.S.C.§ 352 because it is dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

g. MIRENA® does not contain adequate directions for use pursuant to 21 C.F.R. § 201.5 because, among other reasons of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes or uses for which it is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in their oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application and/or (d) route or method of administration or application.

h. The Defendants violated 21 C.F.R. § 201.56 because the labeling was not informative and accurate.

i. MIRENA® is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated and new information became available that caused the labeling to become inaccurate, false or misleading.

j. The Defendants violated 21 C.F.R. § 201.57 by failing to provide information that is important to the safe and effective use of the device including the potential of MIRENA® to migrate through the uterine lining or wall not related to insertion and the need for regular and/or consistent monitoring to ensure that the device has not migrated.

k. The Defendants violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who used MIRENA®.

l. MIRENA® is mislabeled pursuant to 21 C.F.R.§ 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it and steps that should be taken if they occur.

m. MIRENA® is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the contraceptive device.

n. The Defendants violated 21 C.F.R. § 201.57 because the possibility that the device could migrate through the uterine lining and/or wall not associated with insertion is significantly more severe than the other reactions listed in the adverse reactions and yet the Defendants failed to list the risk of migration before the other adverse reactions on the labeling of MIRENA®.

o. MIRENA® violates 21 C.F.R. § 210.1 because the process by which it was manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing or holding of a contraceptive device to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

p. MIRENA® violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

q. MIRENA® violates 21 C.F.R. § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity and/or reproducibility of test methods have not been properly established and documented.

r. MIRENA® violates 21 C.F.R. § 211.165 in that it fails to meet established standards or specifications and any other relevant quality control criteria.

s. MIRENA® violates 21 C.F.R. § 211.198 because the written procedures describing the handling of all written and oral complaints were not followed.

t. MIRENA® violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

u. The Defendants violated 21 C.F.R. § 310.303 because they failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

v. The Defendants violated 21 C.F.R. §310.305 and § 314.80 by failing to report adverse events associated with MIRENA® as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse event report.

w. The Defendants violated 21 C.F.R. § 310.305 and § 314.80 by failing to conduct an investigation of each adverse event associated with MIRENA® evaluating the cause of the adverse event.

x. The Defendants violated 21 C.F.R. §310.305 and § 314.80 by failing to promptly investigate all serious, unexpected adverse experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

y. The Defendants violated 21 C.F.R. § 310.305 and § 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse experiences.

z. The Defendants violated 21 C.F.R. § 310.305 and § 314.80 by failing to identify the reports they submitted properly such as by labeling them as "15-day Alert report" or "15-day Alert report follow-up."

aa. The Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of MIRENA® or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers as well as reports from foreign regulatory authorities that have not already been reported to the agency by the sponsor.

bb. The Defendants violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse experience not already reported under the post-marketing 15-day alert report and/or (c) a history of actions taken since the last report because of adverse experiences (for example labeling changes or studies initiated).

cc. The Defendants violated 21 C.F.R. § 314.80 by failing to submit a copy of a published article from scientific or medical journals along with one or more 15-day alert reports based on information from the scientific literature.

1. Defendants failed to meet the standard of care set by the above statutes and regulations which were intended for the benefit of individual consumers such as Plaintiff making the Defendants liable.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

2. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

3. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of MIRENA® into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

4. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of MIRENA® into interstate commerce in that Defendants knew or should have known that using MIRENA® created a high risk of unreasonable, dangerous side effects, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

5. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing MIRENA® without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing MIRENA® without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not MIRENA® was safe for use; in that Defendants herein knew or should have known that MIRENA® was unsafe and unfit for use by reason of the dangers to its users;

d. Selling MIRENA® without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of MIRENA®;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, MIRENA®;

g. Failing to test MIRENA® and/or failing to adequately, sufficiently and properly test MIRENA®.

h. Negligently advertising and recommending the use of MIRENA® without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that MIRENA® was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that MIRENA® had equivalent safety and efficacy as other forms of birth control/contraception;

k. Negligently designing MIRENA® in a manner which was dangerous to its users;

l. Negligently manufacturing MIRENA® in a manner which was dangerous to its users;

m. Negligently producing MIRENA® in a manner which was dangerous to its users;

n. Negligently assembling MIRENA® in a manner which was dangerous to its users;

o. Concealing information concerning FDA warnings from the Plaintiff in knowing that MIRENA® was unsafe, dangerous, and/or non-conforming with FDA regulations; and

p. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of MIRENA® compared to other forms of contraception.

6. Defendants under-reported, underestimated and downplayed the serious dangers of MIRENA®.

7. Defendants negligently compared the safety risk and/or dangers of MIRENA® with other forms of contraception.

8. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of MIRENA® in that they:

a. Failed to use due care in designing and manufacturing MIRENA® so as to avoid the aforementioned risks to individuals when MIRENA® was used for contraceptive purposes;

b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of MIRENA®;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of MIRENA®;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning MIRENA®;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of MIRENA®;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of MIRENA®, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

h. Were otherwise careless and/or negligent.

9. Despite the fact that Defendants knew or should have known that MIRENA® caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell MIRENA® to consumers, including the Plaintiff.

10. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

11. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

12. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

13. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff may in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

14. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

15. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed MIRENA® as hereinabove described that was used by the Plaintiff.

16. At those times, MIRENA® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

17. At those times, MIRENA® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

18. MIRENA® is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

19. At all times material to this action, MIRENA® was expected to reach, and did reach, consumers in all States and Territories throughout the United States, including the Plaintiff herein, without substantial change in the condition in which it was sold.

20. At all times material to this action, MIRENA® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, MIRENA® contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to the risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences;

b. When placed in the stream of commerce, MIRENA® was defective in design and formulation, making the use of MIRENA® more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other contraceptive devices, medications and similar drugs on the market for the prevention of pregnancy;

c. The subject product's design defects existed before it left the control of the Defendants;

d. MIRENA® was insufficiently tested;

e. MIRENA® caused harmful side effects that outweighed any potential utility; and

f. MIRENA® was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants strictly liable to Plaintiff.

1. The Plaintiff was prescribed and used the subject product for its intended purpose.

2. Defendants created a product unreasonably dangerous for its normal, intended use.

3. Defendants knew, or should have known that at all times herein mentioned its MIRENA® was in a defective condition, and was and is inherently dangerous and unsafe.

4. Defendants, with this knowledge, voluntarily designed its MIRENA® in a dangerous condition for use by the public, and in particular the Plaintiff.

5. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

6. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

7. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

8. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT)

9. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

10. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed MIRENA® as hereinabove described that was used by the Plaintiff.

11. At those times, MIRENA® was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

12. At those times, MIRENA® was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

13. The contraceptive, MIRENA®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' MIRENA® was manufactured.

14. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

15. The Plaintiff was prescribed and used the subject product for its intended purpose.

16. The Plaintiff could not by the exercise of reasonable care, have discovered MIRENA®'s defects herein mentioned and perceived its danger.

17. At all times material to this action, MIRENA® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, MIRENA® contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The subject product was not made in accordance with the Defendants' specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of the Defendants.

1. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects

including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

2. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY - FAILURE TO WARN)

3. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

4. The contraceptive, MIRENA®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

5. MIRENA® was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the

Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

6. The Plaintiff was prescribed and used the subject product for its intended purpose.

7. The Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

8. The Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

9. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

10. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. The Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

12. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with the subject product.

13. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, MIRENA®.

14. Defendants' inadequate warnings of MIRENA® were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

15. That said defects in Defendants' product MIRENA® were a substantial factor in causing Plaintiff's injuries.

16. Had the Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

17. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

18. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY –
DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS)

19. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

20. The Defendants made representations regarding the safety of MIRENA®.

21. The subject product supplied by the Defendants was defective in that it did not conform to representations made by the Defendants regarding the safety of the subject product.

22. The Plaintiff and her healthcare providers justifiably relied upon all of the Defendants' representations regarding MIRENA® when they used and prescribed MIRENA®, respectively.

23. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and

infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

24. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY –
DEFECT DUE TO FAILURE OF ADEQUATELY TEST)

25. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

26. The Defendants repeatedly advised consumers and the medical community that MIRENA® contained the same safety profile as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

27. The Defendants failed to adequately test the safety of MIRENA® versus other hormonal contraceptives, intrauterine devices and other forms of birth control therapy

28. Had the Defendants adequately tested the safety of MIRENA® versus other hormonal contraceptives, intrauterine devices and other forms of birth control therapy and disclosed those results to the medical community and the public, the Plaintiff and her healthcare providers would not have undertaken birth control therapy with MIRENA®.

29. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences

30. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

31. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

32. Defendants expressly warranted that MIRENA® was safe and well accepted by users.

33. The contraceptive MIRENA® does not conform to these express representations because MIRENA® is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

34. Plaintiff did rely on the express warranties of the Defendants herein.

35. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of MIRENA® in recommending, prescribing, and/or implanting MIRENA®.

36. The Defendants herein breached the aforesaid express warranties, as their product MIRENA® was defective.

37. Defendants expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that MIRENA® was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of other hormonal contraceptives, intrauterine devices and other forms of birth control therapy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

38. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that MIRENA® was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

39. As a result of the foregoing acts and/or omissions the Plaintiff, was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects

including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

40. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' MIRENA® IUD.

41. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

42. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

43. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold MIRENA® for use in contraception.

44. At the time Defendants marketed, sold, and distributed MIRENA® for use by Plaintiff, Defendants knew of the use for which MIRENA® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

45. The Defendants impliedly represented and warranted to the users of MIRENA® and their physicians, healthcare providers, and/or the FDA that MIRENA® was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

46. That said representations and warranties aforementioned were false, misleading, and inaccurate in that MIRENA® was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

47. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

48. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether MIRENA® was of merchantable quality and safe and fit for its intended use.

49. The contraceptive MIRENA® was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

50. The Defendants herein breached the aforesaid implied warranties, as their product MIRENA® was not fit for its intended purposes and uses.

51. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

52. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

53. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

54. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, MIRENA®, had been tested and was found to be safe and/or effective for contraceptive purposes.

55. That representations made by Defendants were, in fact, false.

56. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

57. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, implant and/or purchase said product, MIRENA®, for use as a means of birth control, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

58. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used MIRENA®, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

59. In reliance upon said representations, the Plaintiff was induced to and did use MIRENA®, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

60. Said Defendants knew and were aware or should have been aware that MIRENA® had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

61. Defendants knew or should have known that MIRENA® had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

62. Defendants brought MIRENA® to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

63. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

64. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

65. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

66. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of MIRENA® for its intended use.

67. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the efficacy and risks associated with the use of MIRENA®.

68. Defendants knew or were reckless in not knowing that its representations were false.

69. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that MIRENA® was not as safe as other forms of contraception;

b. that the risks of adverse events with MIRENA® were higher than those with other forms of birth control, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

c. that the risks of adverse events with MIRENA® were not adequately tested and/or known by Defendants;

d. that Defendants were aware of dangers in MIRENA®, in addition to and above and beyond those associated with other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

e. that MIRENA® was defective, and that it caused dangerous side effects, including but not limited to perforation, migration, embedment, ectopic

pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause, in a much more and significant rate than other forms of birth control, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy;

f. that patients needed to be monitored more regularly than normal while using MIRENA®;

g. that MIRENA® was manufactured negligently;

h. that MIRENA® was manufactured defectively;

i. that MIRENA® was manufactured improperly;

j. that MIRENA® was designed negligently;

k. that MIRENA® was designed defectively; and

l. that MIRENA® was designed improperly.

1. Defendants were under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of MIRENA®, including but not limited to the heightened risks of perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause and infertility.

2. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used MIRENA®, including the Plaintiff, in particular.

3. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of MIRENA® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and their physicians, hospitals and healthcare providers into reliance, continued use of MIRENA®, and actions thereon, and to cause them to purchase, prescribe, and/or implant MIRENA® and/or use the product.

4. Defendants knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding MIRENA®, as set forth herein.

5. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

6. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

7. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

8. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

9. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, MIRENA®, had been tested and found to be safe and effective for birth control.

10. The representations made by Defendants were, in fact, false.

11. Defendants failed to exercise ordinary care in the representation of MIRENA®, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented MIRENA®'s high risk of unreasonable, dangerous side effects.

12. Defendants breached their duty in representing MIRENA®'s serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

13. As a result of the negligent misrepresentations of the Defendants set forth hereinabove, said Defendants knew and were aware or should have known that MIRENA® had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause, infertility as well as other severe and personal injuries which are permanent and lasting in nature.

14. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TWELFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

15. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

16. Defendants conducted research and used MIRENA® as part of their research.

17. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that MIRENA® was safe and effective for use as a means of providing birth control.

18. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

19. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

20. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

21. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' product MIRENA® was safe and effective for use as a form of birth control.

22. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' product MIRENA® carried the same risks, hazards, and/or dangers as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

23. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' product MIRENA® was more effective in treating the symptoms of heavy menstrual bleeding, encouraging the use of MIRENA® in circumstances other than those in which the product has been approved, over-promises the benefits and minimizes the risk associated with MIRENA®.

24. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that MIRENA® was not injurious to the health and/or safety of its intended users.

25. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that MIRENA® was as potentially injurious to the health and/or safety of its intended as other forms of other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

26. These representations were all false and misleading.

27. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that MIRENA® was not safe as a means of contraception and/or was not as safe as other means of contraception, including but not limited to other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

28. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of MIRENA®, specifically but not limited to MIRENA® not having dangerous and serious health and/or safety concerns.

29. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintiff, regarding the safety of MIRENA®, specifically but not limited to MIRENA® being as safe a means of birth control as other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

30. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of MIRENA® and induce the public, and/or the Plaintiff to purchase, request, implant, prescribe, recommend, and/or continue to use MIRENA®.

31. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that MIRENA® was fit and safe for use as birth control.

32. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that MIRENA® was fit and safe for use as birth control and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

33. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that MIRENA® did not present serious health and/or safety risks.

34. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that MIRENA® did not present health and/or safety risks greater than other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

35. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

36. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including their respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, implant, recommend, and/or prescribe MIRENA®.

37. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of MIRENA® to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and

defective and/or not as safe as other alternatives, including other hormonal contraceptives, intrauterine devices and other forms of birth control therapy.

38. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of MIRENA® by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of MIRENA®.

39. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on MIRENA® and/or that their respective healthcare providers would implant, prescribe, and/or recommend the same.

40. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

41. Defendants utilized direct to consumer adverting to market, promote, and/or advertise MIRENA®.

42. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of birth control and were thereby induced to purchase, use and rely on Defendants' product MIRENA®.

43. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of MIRENA®.

44. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

45. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of MIRENA®, Plaintiff would not have purchased, used and/or relied on Defendants' product MIRENA®.

46. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

47. As a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, perforation, migration, embedment, ectopic pregnancy, intrauterine pregnancy, cancer, adhesions, cysts, fetal injury, fetal death, early/premature menopause as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and a future of high risk pregnancies and infertility, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

48. As a result of the foregoing acts and omissions the Plaintiff requires and/or may require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRTEENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(VIOLATION OF GBL §§ 349 and 350)

49. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

50. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

51. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

52. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

53. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged herein.

54. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.

55. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Plaintiffs have suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

56. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350 and other various consumer protection statutes enacted in other states and the District of Columbia, Plaintiff has suffered damages, for which Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTEENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(PUNITIVE DAMAGES)

57. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

58. At all times material hereto, the Defendant knew or should have known that the subject product was inherently more dangerous than alternative methods of birth control.

59. At all times material hereto, the Defendant attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

60. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff herein, concerning the safety of the subject product.

61. At all times material hereto, the Defendant knew and recklessly disregarded the fact that MIRENA® causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

62. Notwithstanding the foregoing, the Defendant continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative methods of birth control.

63. The Defendant knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by MIRENA®.

64. Defendant intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff herein, the potentially life threatening side effects of MIRENA® in order to ensure continued and increased sales.

65. The Defendant's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the subject product against its benefits.

66. As a direct and proximate result of the Defendant's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has

incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future.

67. The aforesaid conduct of Defendant was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

Dated: February 8, 2013

Respectfully submitted,

Cantor , Dolce & Panepinto

By: /s/Sean E. Cooney_____
Sean E. Cooney, Esq.
1600 Main Place Tower
350 Main Street
Buffalo, New York 14202
(716) 852-1888 Office
(716) 852-3588 Fax
scooney@cldplaw.com

Carmen S. Scott*
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000 Office
(843) 216-9450 Fax
cscott@motleyrice.com
**Pro Hac Vice Motion pending*

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: February 8, 2013

Respectfully submitted,

Cantor , Dolce & Panepinto

By: /s/Sean E. Cooney
Sean E. Cooney, Esq.
1600 Main Place Tower
350 Main Street
Buffalo, New York 14202
(716) 852-1888 Office
(716) 852-3588 Fax
scooney@cldplaw.com

Attorneys for Plaintiff
KRISTIE B. DONOVAN

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Kristie B. Donovan

(b) County of Residence of First Listed Plaintiff Erie County, NY
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Sean E. Cooney, Cantor, Dolce & Panepinto, 1600 Main Place Tower
350 Main Street, Buffalo, NY 14202; (716) 852-1888

DEFENDANTS
Bayer Healthcare Pharmaceuticals, Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC Sections 1391 and 1392
Brief description of cause:
Product Liability, Diversity

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 12/12)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of New York

Kristie B. Donovan

Plaintiff(s)

v.

Bayer Healthcare Pharmaceuticals, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Bayer Healthcare Pharmaceuticals, Inc.
SOP Department
Corporation Service Center
Suit 400
2711 Centerville Road
Wilmington, DE 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Sean E. Cooney, Esq.
1600 Main Place Tower
350 Main Street
Buffalo, New York 14202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc: