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IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

TANYA DE LA PAZ, an individual,

Plaintiff,

v.

BAYER, CORP., an Indiana corporation; BAYER HEALTHCARE LLC, a Delaware corporation ; BAYER ESSURE, INC., a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation; BAYER A.G., a German corporation; and DOES 1-10, inclusive

Defendants

Case No.:

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

(1) Manufacturing
(2) Design Defect
(3) Negligence
(4) Failure to warn
(5) Strict Liability
(6) Breach of Implied Warranty
(7) Breach of Express Warranty
(8) Negligent Misrepresentation
(9) Fraudulent Misrepresentation
(10) Fraud by Concealment

COMES NOW Plaintiff Tanya De La Paz, and files this Complaint seeking judgment against Defendants BAYER, CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE, INC.; BAYER HEALTHCARE PHARMACEUTICALS, INC; BAYER A.G and DOES 1 through 10 inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Plaintiff TANYA DE LA PAZ (hereinafter "Plaintiff") being prescribed and using the defective and unreasonably dangerous product Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated tested, packaged, labeled, produced, created, made constructed, assembled, marketed, advertised, distributed and sold by Defendants or by Conceptus, Inc. which

merged with Bayer on or about April 28, 2013.

PARTIES, JURISDICTION AND VENUE

1. This Court has diversity subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a): The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between (1) citizens of different states. Damages to Plaintiff are estimated in good faith to exceed the sum or value of $75,000.00, exclusive of interest and costs. The Court also has personal jurisdiction over the parties because Plaintiff submits to the jurisdiction of the Court and Defendants systematically and continually conducts business here and Conceptus, Inc. ("Conceptus"), a wholly owned subsidiary of Bayer A.G. and/or Bayer Healthcare LLC, is headquartered in Mountain View, California. Conceptus, which is now part of Bayer, designed, developed, conducted clinical trials and manufactured Essure® at its Mountain View, California facilities.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. §1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Northern District of California, including the design, clinical testing, marketing and manufacturing of the Essure® system.

4. At all times relevant hereto, Plaintiff is and was a resident of Greenville, South Carolina.

5. Defendant BAYER CORP is a for-profit corporation incorporated in the state of Indiana. Defendant is authorized to and does business throughout the states of California and South Carolina.

6. Defendant BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the state of Delaware. Defendant is authorized to and does business throughout the states of California and South Carolina.

7. Defendant BAYER ESSURE INC. is a for-profit corporation incorporated in the state of Delaware. Defendant is authorized to and does business throughout the states of California and South Carolina.

8. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware. Defendant is authorized to and does business throughout the states of California and South Carolina.

9. Defendant BAYER A.G. is a German for-profit corporation. Defendant is authorized to and does business throughout the states of California and South Carolina.

10. This Complaint is brought by Plaintiff who relied on express warranties of Defendants before being implanted with a female birth control device, known as "Essure". As a result of (1) Defendants negligence described *infra* and (2) her reliance on Defendants' warranties, Defendants' Essure® device fractured inside her right fallopian tube during one procedure. Plaintiff now has daily pain, headaches, abdominal pain, heavy bleeding, intense pelvic pain, emotional pain and mental anguish. Plaintiff has been advised by several medical doctors that she is need of total hysterectomy as a result.

11. Essure® had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed herein, this CPMA became "invalid" and the product "adulterated" pursuant to the FDA due to Defendants' failure to comply with the CPMA order. As a result, Defendants' CPMA is "invalid" and its "adulterated" product, Essure®, should never have been marketed or sold to Plaintiff.

12. Plaintiff's first cause of action is based in Defendants' negligence in (1) failing to adequately train Plaintiff's implanting physician ("the implanting physician"); and (2) entrusting the implanting physician with specialized hysteroscopic equipment he was not qualified to use, and (3) distributing the product in an unreasonably dangerous manner, as fully discussed below.

13. The training, entrustment, of specialized hysteroscopic equipment to the implanting physician and method of distribution did not have CPMA by the FDA.

14. Plaintiff's second cause of action is based entirely on the express warranties made by Defendants to Plaintiff, which were relied upon by Plaintiff prior to having the device implanted. Under California law, Plaintiff's claims for breach of express warranties are not preempted by the Medical Device Act ("MDA"). Stengel v. Medtronic Incorporated, 704 F.3d 1224 (9th Cir. 2013).

15. Notwithstanding, the fact that Plaintiff's two causes of action **fall outside the purview of the MDA**, Defendants' CPMA is "invalid" and Essure® is an "adulterated" product per the FDA.

16. In short, according to the FDA, the CPMA order became invalid because Defendants failed to comply with any of the following express conditions:

(a) "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(b) "Report to the FDA whenever it receives information from any sources that reasonably suggests that the device may have caused or contributed to a serious injury."

17. The fact that Defendants failed to comply with these conditions is not a mere allegation made by Plaintiff. It is an **FDA finding**.

18. As discussed in detail *infra*, Defendants were **cited by the FDA** and the **Department of Health** for (1) **failing to report and actively concealing 8 perforations which occurred as a result of Essure®**; (2) erroneously using non-conforming material in the manufacturing of Essure®; (3) failing to use pre-sterile and post-sterile cages; (4) manufacturing Essure® at an unlicensed facility and (5) manufacturing Essure® for three years without a license to do so.

19. These violations invalidated the CPMA, rendering the product "adulterated"-precluding Defendants from marketing or selling Essure® per the FDA, and, more importantly, endangered the life of Plaintiff and the safety of the public.

20. Defendants actively concealed these violations and never advised Plaintiff of the same. Had Plaintiff known that **Defendants were concealing adverse reactions, not using conforming material approved by the FDA, not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license to do the same**, she never would have had Essure® implanted.

DESCRIPTION OF ESSURE® AND HOW IT WORKS

21. Essure® is a permanent form of female birth control (female sterilization). In short, the device is intended to cause bilateral occlusions (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage.

22. Essure® consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use.

23. The micro-inserts are comprised of two metal coils which are placed in a woman's fallopian tubes via Defendants' disposable delivery system and under hysteroscopic guidance (camera).

24. The hysteroscopic equipment needed to place Essure® was manufactured by a third party, is not part of Defendants' CPMA, and is not a part of Essure®. However, because Plaintiff's implanting physician did not have such equipment, Defendants provided it to that they could sell Essure®.

25. The coils are comprised on nickel, steel, nitinol, and PET fibers.

26. Defendants' disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery and release. Physicians are allowed to visualize this complicated process through the hysteroscopic equipment provided by Defendants.

27. After placement of the coils in the fallopian tubes by Defendants' disposable delivery system, the micro-inserts expand upon release and anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

28. The coils are alleged to remain securely in place in the fallopian tubes for the life of the consumer and do not migrate.

29. After three months following the device being implanted, patients are to receive a "Confirmation" test to determine that the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hystersalpinogram ("HSG Test" or "Confirmation test").

30. Regardless of the Confirmation Test, Defendants also warrant that Essure® allows for visual confirmation of each insert's proper placement **during the procedure**.

31. Essure® was designed, manufactured, and marketed to be used by gynecologists throughout the world, as a "**quick and easy**" outpatient procedure and without general anesthesia.

EVOLUTION OF ESSURE®

32. Essure® was first designed and manufactured by Conceptus, Inc. ("Conceptus").

33. Conceptus and Bayer merged on or about April 28, 2013.

34. For purpose of this lawsuit, Conceptus and Bayer are one and the same.

35. Essure®, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendants.

36. Defendants also trained physicians on how to use its device and other hysteroscopic equipment, including Plaintiff's implanting physician.

37. Prior to the sale of Conceptus to Bayer, Conceptus obtained CPMA for Essure®.

38. By way of background, Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

39. PMA is a stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA.

40. An approved PMA is, in effect, a private license granting the application (or owner) permission to market the device.

41. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission.

42. According to the FDA, a class III device that **fails to meet the CPMA** requirements is considered to be **adulterated under section 501(f)** of the Federal Food, Drug and Cosmetic Act ("FD&C Act") **and cannot be marketed**.

43. Regarding the Premarket Approval Process, devices can either be "approved," "conditionally approved," or "not approved."

44. Essure® was "**conditionally approved**" or in other words, had only CPMA not outright PMA, the "gold standard."

45. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval **invalidated this approval order**." The following were the conditions of approval:

(a) "Effectiveness of Essure is established by annually reporting on the 745 women who took part in clinical tests."

(b) "Successful bilateral placement of Essure is documented for newly trained physicians."

(c) "Within 10 days after [Defendant] received knowledge of any adverse reaction to report the matter to the FDA."

(d) "Report to the FDA whenever it received information from any source that reasonably suggested that the device may have caused or contributed to a serious injury,"

(e) Warranties are truthful, accurate and not misleading.

(f) Warranties are consistent with applicable Federal and State law.

46. Although failure to comply with just *one* of the conditions invalidated the CPMA Order, Defendants failed to comply with *several* conditions; thereby invalidating the CPMA pursuant to the very language of the CPMA order. Specifically:

(a) Defendants failed to timely provide the FDA with reports after 12 months, 18 months and then a final report. All reports failed to meet the respective deadlines.

(b) Defendants failed to document successful placement of Essure® concealing the failure rates.

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Most egregiously, Defendants **failed to report eight (8) perforations** which occurred as a result of Essure® and **was cited for the same by the FDA** via Form 483[1].

(d) Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury thereby concealing the injuries. Again, Defendants **failed to report eight (8) perforations** which occurred as a result of Essure® **to the FDA as evidenced in** Form 483.

[1] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

(e) As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

(f) Defendants' warranties were not consistent with applicable Federal and State law.

47. By failing to comply with several CPMA conditions, Essure® is also considered to be an "adulterated" device under section 501(f) of the FD&C Act **and cannot be marketed per the FDA**. However, Defendants continued to market the product to Plaintiff.

48. The CPMA also required Defendants to comply with Sections 502(q) and (r) of the FD&C Act which **prohibits Defendants from offering Essure® "for sale** in any State, if its advertising is false or misleading."

49. Defendants violated Sections 502(q) and (r) by falsely and misleadingly advertising the product as described below under "Facts and Warranties." However, Defendants continued to sell its product against the CPMA with misleading and false advertising.

50. Lastly, per the FDA, "a PMA may be sold to another company" however "the sponsor **must submit a PMA amendment** to notify the FDA of the new owner… The… supplement should include: the effective date of the ownership transfer; a statement of the new owner's commitment to comply with all the conditions of approval applicable to the PMA; and either a statement that the new owner has a complete copy of the PMA including all amendment, supplements, and reports or a request for a copy from the FDA files."

51. There were 36 PMA supplements filed with the FDA in regard to Essure® (P020014). **None of the PMA supplements included notification of the new owner** (Bayer).

52. In short, notwithstanding the fact that Plaintiff's claims fall outside the purview of the MDA, (1) the CPMA is invalid **per the FDA**; (2) Essure® is considered an "adulterated" product that cannot be marketed or sold **per the FDA**; and (3) the invalid CPMA was not properly transferred to Bayer and, therefore, Defendants does not have any form of PMA for Essure®.

DEFEDNANT'S TRAINING, ENTRUSTMENT AND DISTRIBUTION PLAN

53. Defendants (1) failed to adequately train the implanting physician on how to use its delivery system and the hysteroscopic equipment manufactured by a third party; (2) provided specialized hysteroscopic equipment manufactured by a third party; and (3) created an unreasonably

dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiff's safety and well-being.

54. Because Essure® was the first device of its kind, the implanting physician was **trained by Defendants** on how to properly insert the micro-inserts using the disposable delivery system and was given hysteroscopic equipment by Defendants.

55. In order to capture the market, Defendants independently undertook a duty of training physicians, including the implanting physician, on how to properly use (1) its own mechanism of delivery and (2) the specialized hysteroscopic equipment manufactured by a third party.

56. Regarding Essure®, Defendants' Senior Director of Global Professional Education stated "**training is the key factor** when clinicians choose a new procedure" and "For the Essure® procedure, the patient is **not under anesthesia**, therefore a **skilled approach is crucial.**"

57. In fact, because gynecologists and Plaintiff's implanting physician were unfamiliar with the device and how to deliver it, Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses- where Defendants observed physicians until Defendants believed they were competent; (4) created Essure® Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures."

58. Defendants provided no training to the implanting physician on how to *remove* Essure® should it migrate.

59. Defendants also kept training records on all physicians "signed-off to perform Essure procedures."

60. In order to sell its product and because the implanting physician did not have access to the expensive hysteroscopic equipment, Defendants **provided the implanting physician with hysteroscopic equipment** which, although is not a part of Essure®, is needed to implant Essure®. The entrustment of this equipment is not part of any CPMA.

61. Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc., (1) to obtain specialized hysteroscopic equipment to then give to physicians and (2) to increase its sales force to promote Essure®.

62. According to Defendants, these agreements allowed Defendants to "gain market presence […] and expend […] market opportunity by driving adoption among a group of physicians."

63. In regard to the entrustment of such specialized equipment, Defendants admitted: "**We cannot be certain how successful these programs will be, if at all.**"

64. Defendants "handed out" this equipment to unqualified physicians, including Plaintiff's implanting physician, in an effort to sell its product.

65. Defendants knew or failed to recognize that the implanting physician was not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physician in order to capture the market.

66. In return for providing the hysteroscopic equipment, **Defendants required that the implanting physician purchase two Essure® "kits" per month.** This was part of Defendants' unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff.

67. Defendants' distribution plan included requiring the implanting physician to purchase two (2) Essure® "kits" per month, **regardless of whether he or she used them or not**. This distribution plan created an environment which induced the implanting physician to "push" Essure® and implant the same into Plaintiff.

68. In short, Defendants used the expensive hysteroscopic equipment to induce the implanting physician into an agreement as "bait." Once the implanting physician "took the bait," he was required to purchase 2 Essure® "kits" per month, regardless of whether he sold any Essure® "kits."

69. This was an unreasonably dangerous distribution scheme as it compelled the implanting physician to sell two (2) devices per month at the expense of Plaintiff's safety and well-being.

70. Defendants' distribution plan also included (1) negligently distributing Essure® against FDA order and sections 5019f), 502(q) and (r) of the FD&C Act by marketing and selling an adulterated product; (2) the promotion of Essure® through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure®; (3) failing to report and actively concealing eight (8) perforations which occurred as a

result of Essure®; (4) erroneously using non-conforming material in the manufacturing of Essure®; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure® at an unlicensed facility and (7) manufacturing Essure® for three years without a license to do so.

71. In short, Defendants (1) failed to adequately train the physicians on how to use its delivery system and the hysteroscopic equipment manufactured by a third party; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing and monopolizing on the birth control market.

72. Unfortunately, this was done at the expense of Plaintiff's safety.

PLAINTIFF'S HISTORY

73. In or around July 2012, Plaintiff went to the implanting physician to have Essure® implanted in her fallopian tubes.

74. The implanting physician attempted to implant the device, but the procedure was abandoned after the implanting physician perforated her fallopian tube causing bleeding. Plaintiff was admitted to Greenville Memorial Hospital of 24 hour observation due to the bleeding.

75. Plaintiff returned to the implanting physician in September 2012 for a second attempt to insert the device. At this time, the implanting physician inserted the Essure® device into Plaintiff's fallopian tubes.

76. After the device was implanted, Plaintiff started experiencing severe bleeding, and constant, daily pain. She contacted the implanting doctor many times to complain about her symptoms.

77. In or around December 2012, Plaintiff returned to the implanting doctor for the HSG test to confirm placement of the device. The HSG test disclosed that the left micro-insert was properly located in the fallopian tube. The right micro-insert, however, was stretched or possibly broken. The implanting physician contacted Defendant regarding the broken coil, and was instructed to remove it from Plaintiff's body.

78. In or around February 2013, due to the broken Essure® device, Plaintiff underwent surgery to remove the right fallopian tube and the broken pieces of the right micro-insert.

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79. Plaintiff is now experiencing the same constant daily pain and heavy bleeding due to the left coil. Since the device was implanted, Plaintiff has also suffered from heavy bleeding, weight gain, stomach issues with pelvic pain and mental and emotional anguish, and continues to suffer at this time.

80. Plaintiff is seeking a doctor to remove the left Essure® micro-insert and surgery has been scheduled for on or about September 19, 2015.

81. Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortuous conduct. Under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

82. Additionally, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, defendant was not only actively and fraudulently concealing adverse reports of migrations and perforations from Plaintiff, but also from the FDA. This active concealment is not mere allegation, but evidenced by FDA findings and its citations to Defendant for failing to report eight (8) perforations.

FACTS AND WARRANTIES

83. First, Defendants negligently trained physicians, including the implanting physician, on how to use its device and in hysteroscopic procedures.

84. The skills needed to place the micro-inserts as recognized by the FDA panel "are way beyond the usual gynecologist."

85. Accordingly, Defendants went out and attempted to train the implanting physician on (1) how to use its device and (2) in hysteroscopy. Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created Essure® Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedure." Defendants had no experience in training others in hysteroscopy.

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86. Defendants failed to adequately train Plaintiff's implanting physicians and provided hysteroscopic equipment to the implanting physician who was not qualified to use such complicated equipment.

87. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendants' training methods were failing[2].

88. Second, Defendants provided hysteroscopic equipment to the implanting physician who was not competent to use such device. Defendants knew the implanting physician was not competent to use such sophisticated equipment, yet provided the equipment anyway in order to sell its product.

89. Third, Defendants' distribution plan of requiring the implanting physician to purchase two (2) Essure® kits a month, was an unreasonably dangerous plan as it compelled the implanting physician to insist that Essure® be used in Plaintiff.

90. Defendants' distribution plan also included (1) negligently distributing Essure® against FDA order and sections 501(f), 502(q) and (r) of the FD&C Act by marketing and selling an adulterated product; (2) the promotion of Essure® through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure®; (3) failing to report and actively concealing (8) perforations which occurred as a result of Essure®; (4) erroneously using non-conforming material in the manufacturing of Essure®; (5) failing to use pre-sterile and post sterile cages; (6) manufacturing Essure® at an unlicensed facility and (7) manufacturing Essure® for three years without a license to do so.

91. Lastly, Plaintiff relied on the following warranties by Defendants and/or its agents, outlined in the subsequent Paragraphs:

WEBSITE WARRANTIES

92. Defendants marketed on its website the following:

(a) "*Only FDA approved female sterilization procedure to have **zero** pregnancies in the clinical trials."* However, there were actually **four pregnancies** during the clinical trials and

[2] *Learning Curve of Hysteroscopic Placement of Tubal Sterilization Micro-Inserts*, US National Library of Medicine, Janse, JA.

five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(b) "*There were Zero pregnancies in the clinical trials.*" However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(c) *"Physicians must be signed-off to perform Essure procedure."* However, Defendants failed to adequately train the implanting physician and "signed-off" on the implanting physician who did not have the requisite training. Defendants concealed this information from Plaintiff.

(d) "*Surgery-free*." However, Essure® is not "surgery-free", rather surgery is not required. All Essure® procedures are done under hysteroscopy, which is a surgical procedure.

(e) "*Worry free: Once your doctor confirms that your tubes are blocked, you* ***never*** *have to worry about unplanned pregnancy."* However, several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiff. However, between1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. Defendants concealed this information from Plaintiff. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked." However, women who have Essure® have **10 times greater risk** of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater[3].

(f) *"Essure is the most effective permanent birth control available-even* ***more effective than tying your tubes or a vasectomy.***" Yet, Defendants' SEC filings, Form 10-K show that Defendants never did a comparison to a vasectomy or tubal ligation. Defendants stated, "**We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation.**" Defendants concealed this information from Plaintiff. In fact, women who have Essure® have 10

[3] *Probability of Pregnancy After Sterilization: A Comparison Of Hysteroscopic Versus Laparoscopic Sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[4].

(g) "*Correct placement...is* ***performed easily*** *because of the design of the micro-insert."* However, Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their **own experts in hysteroscopy** (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiff.

(h) "*an Essure trained doctor inserts spring-like coils, called micro-inserts...*" However, the implanting physician who implanted the device was not adequately trained. Defendants concealed this information from Plaintiff.

(i) "*the Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."* However, Defendants failed to adequately train the implanting physician. Defendants concealed this information from Plaintiff.

(j) "*In order to be trained in Essure you* ***must be a skilled operative hysteroscopist****. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."* However, Defendants "signed off" on the implanting physician who was not a skilled operative hysteroscopist, in order to monopolize and capture the market, including the implanting physician. Defendants concealed this information from Plaintiff.

(k) "*Essure is a surgery-free* ***permanent birth control****."* However, Essure® is not permanent as the coils migrate, perforate organs and are expelled by the body.

ADVERTISEMENT WARRANTIES

93. Defendants advertised:

(a) "*Zero pregnancies*" in its clinical and pivotal trials. However, there were at least four pregnancies. Defendants concealed this information from Plaintiff.

[4] *Probability of Pregnancy After Sterilization: A Comparison Of Hysteroscopic Versus Laparoscopic Sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

(b) *In order to be identified as a qualified Essure® physician, a minimum of one Essure® procedure must be performed every 6-8 weeks*. However, Defendants "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physician. Defendants concealed this information from Plaintiff.

FACT SHEET WARRANTIES

94. Defendants represented in its Fact Sheet:

(a) *Data from two clinical studies show that 99 percent of the women who had the Essure® procedure rated their long-term comfort with the micro-inserts as 'good', 'very good' or 'excellent'*." However, the actual choices given to the clinical participants were 'poor', 'very good' or 'excellent'. Defendants concealed this information from Plaintiff.

WARRANTIES BY AGENTS

95. Defendants' Senior Director of Global Professional Education represented to the public that "*For the Essure procedure, the patient is not under anesthesia, therefore a* ***skilled approach*** *is crucial*." Yet, Defendants also claims that "Correct placement…is **performed easily** because of the design of the micro-insert"

96. Defendants' CEO stated: "*Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme."* However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff. However, between 1997—2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

MARKETING WARRANTIES

97. Defendants marketed with commercial stating:

(a) *Essure® has been in use for over 5 years*. However, Essure® was only in use for 4 years at the time of the warranties. Defendants concealed this information from Plaintiff.

(b) "The non-surgical" permanent birth control for woman." However, the procedure is most commonly done with surgery. Defendants concealed this information from Plaintiff. However, Essure® is not permanent as the coils migrate, perforate organs and are expelled

by the body. However, all Essure® procedures are done under hysteroscopy, which is a surgical procedure.

98. Defendants created a fake blog entitled "Diary of a Decision" in order to induce Plaintiff to use Essure®. Defendants created a fictitious person, names "Judy" who pretended to have had the procedure and answered questions from Plaintiff. However, "Judy" never had the procedure as represented and was actually Debbie Donovan. Defendants concealed this information from Plaintiff.

99. Defendants warranted that Essure® "allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure Confirmation Test." However, Essure® does not allow for visual confirmation of proper placement during the procedure evidenced by the fact that three micro-inserts were placed into Plaintiff.

BROCHURE WARRANTIES

100. Defendants' Essure® brochure warrants:

(a) "*Worry free.*" However, Defendants **actively concealed** and **failed to report 8 perforations which occurred as a result of Essure® to the FDA evidence** in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiff. *See* Most egregiously, Defendants was issued another Form 483 when it **"erroneously used non-conforming material."** Defendants actively concealed this and were issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiff. However, Defendants' facility was also issued a notice of violation as it **"no longer uses pre-sterile and post-sterile cages."** Defendants actively concealed this from Plaintiff. However, Defendants also was issued a notice of violation when **"it failed to obtain a valid license…prior to manufacturing medical devices."** Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiff. However, Defendants was also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. Defendants actively concealed this from Plaintiff.

(b) "*The Essure **inserts stay secure**, forming a long protective barrier against pregnancy. They also **remain visible outside your tubes**, so your doctor can confirm that they're properly in place*." However, the micro-inserts do not remain secure but migrate and expelled by the

body. Defendants actively concealed this information from Plaintiff." However, Defendants actively concealed and **failed to report 8 perforations which occurred as a result of Essure® to the FDA as evidenced in** Form 483 issued to Defendants by the FDA.

(c) "*The Essure inserts are made from the same trusted, silicone free material used in heart stents."* However, the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiff. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." However, the PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants was issued another Form 483 when it "**erroneously used non-conforming material."** Defendants actively concealed this and were issued another Form 483 for "failing to adequately document the situation."

(d) "*Surgery free.*" However, all Essure® procedures are done under hysteroscopy, which is a surgical procedure.

(e) "*Anesthesia-free*." However, Essure® is not "anesthesia-free", rather anesthesia is not required.

(f) Step Two: "*pregnancy **cannot** occur*"; Step Three: *The Confirmation*. However, Defendants also states that it is only **after** "The Confirmation" pregnancy cannot occur. *i.e.* the complete opposite of what is warranted in the brochure. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed. However, between 1997—2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked." However, there have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[6].

(g) "*Essure **eliminates** the risks, discomfort, and recovery time associated with surgical procedures*." However, Essure® is not "surgery-free". Rather surgery is not required.

101. *The **PET fibers are what cause** the tissue growth*. However, during the PMA meeting with the FDA, Defendants represented that the **trauma** caused by the expanding coil striking the

fallopian tubes is **what caused the inflammatory response** of the tissue. Defendants concealed this information from Plaintiff.

ESSURE® BOOKLET WARRANTIES

102. Defendants' Essure® booklet warrants:

(a) "*This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus.*" However, the device does irritate the uterus. Defendants concealed this information from Plaintiff. However, Defendants actively concealed and **failed to report 8 perforations which occurred as a result of Essure® to the FDA as evidence in** Form 483.

(b) "*There was no cutting, **no pain**, no scars…*" However, Plaintiff has experienced pain as a result of Essure®. Defendants concealed this information from Plaintiff.

DATA WARRANTIES

103. Summary of Safety and Effectiveness Data states:

(a) "*The Essure System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks*." However, Essure® is not "surgery-free" or "anesthesia-free," rather surgery and anesthesia is not required.

(b) "*In addition to the above benefits, none of the women in the Essure clinical trials. Defendants concealed this information from Plaintiff*." However, there were at least four pregnancies during the clinical trials. Defendants concealed this information from Plaintiff.

(c) "Namely, the Essure system is delivered hysteroscopically without general anesthesia." However, Essure® is not "surgery-free" or "anesthesia-free", rather surgery and anesthesia is not required.

PMA SUPPLEMENT

104. Defendants represented to Plaintiff that it was the expanding coil and tissue growth which caused the coil to be attached to the tube, not any type of coating. Yet, in Supplement 18, Defendants represented that "A doctor placed the coil at the uterine-fallopian tube junction, where its **coating caused it be attached** to the tube." The coating is a hydrophilic polymer coating produced by AST Products, Inc. Defendants actively concealed this from Plaintiff.

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SEC FILINGS

105. Defendants warranted that the Essure® system has **"no risks"** for patients because… the Essure® system does not involve the use of radiofrequency energy. At the same time, Defendants also states that there are limited risks with Essure®.

106. "*Our Mountain View, California facility underwent an International Organization for Standardization ("ISO") inspection in September 2011 which resulted in continuing approval and ISO certification through May 2013. In December 2010/January 2011, we underwent an FDA audit; all findings from the audit were satisfactorily addressed*." However, Defendants actively concealed the following:

(a) However, Defendants' site has been inspected 7 times since 06/25—07/09/2002. The most recent FDA audit occurred on 05/30—6/26/2013. The FDA has issued 4 Form 483 inspectional observations.

(b) However, Defendants actively concealed and **failed to report 8 perforations which occurred as a result of Essure® to the FDA** as evidence in Form 483.

(c) Most egregiously, Defendants was issued another Form 483 when it **"erroneously used non-conforming material."** Defendants actively concealed this and were issued another Form 483 for "failing to adequately document the situation."

(d) However, Defendants' facility was also issued a violation as it **"no longer uses pre-sterile and post-sterile cages."**

(e) However, Defendants also was issued a violation when it **"failed to obtain a valid license…prior to manufacturing medical devices."** Defendants were manufacturing devices for three years without a license.

107. The subsequent negligence claims are not products liability causes of action. **The claims have nothing to do with the Essure® product or its invalid CPMA**, but rather (1) the failure of Defendants to adequately train and instruct the implanting physician and/or (2) the fact that Defendants provided the implanting physician, who was not a hysteroscopist, with hysteroscopic equipment in order to sell their product and/or (3) Defendants' unreasonably dangerous distribution of Essure®.

FIRST CAUSE OF ACTION

MANUFACTURING DEFECT

108. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and alleges as follows:

109. At all relevant times, Defendants were engaged in the business of selling Essure® in the states of California and South Carolina.

110. The Essure® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Defendants was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

111. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Essure® outweighs any benefit derived there from. The unreasonably dangerous nature of Essure® caused serious harm to Plaintiff.

112. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injured sustained by the Plaintiff and Defendants placed Essure® into the stream of commerce with wanton and reckless disregard for the public safety.

113. As a direct and proximate result of Plaintiff's use of Essure®, she was forced to undergo surgical removal of the Essure® micro-insert.

114. Defendants knew and, in fact, advertised and promoted the use of Essure® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the Defendants' advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

115. Despite the fact that evidence that existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Essure® and in fact acted to deceive the medical community and public at large, including all potential users of Essure® by promoting it as safe and effective.

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116. Defendants knew or should known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

117. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

118. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION

DESIGN DEFECT

119. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

120. Defendants were and are engaged in the business of selling Essure® in the States of California and South Carolina.

121. The Essure® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

122. The foreseeable risks associated with the design or formulation of the Essure® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

123. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

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124. As a direct and proximate cause of Plaintiff's use of Essure®, she was forced to undergo surgical removal of the Essure®, developed severe pain, suffered from infection, and underwent numerous procedures.

125. Defendants placed Essure® into the stream of commerce with wanton and reckless disregard for the public safety.

126. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

127. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

128. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, cost of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION

NEGLIGENCE

129. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

130. Upon information and belief, Defendants failed to use reasonable care in designing Essure® in that they:

a. failed to properly and thoroughly test Essure® before releasing the system to market;

b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Essure®;

c. failed to conduct sufficient post-market testing and surveillance of Essure®;

d. designed, manufactured, marketed, advertised, distributed, and sold Essure® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of

Essure® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the system;

e. failed to exercise due care when advertising and promoting Essure®; and,

f. negligently continued to manufacture, market, advertise and distribute Essure® after Defendants knew or should have known of its adverse effects.

131. A reasonable manufacturer would or should have known that the risks created by Essure® are unreasonably greater than that of other contraceptives and that Essure® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

132. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

FOURTH CAUSE OF ACTION

FAILURE TO WARN

133. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

134. Essure® is a defective and therefore an unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, uterine perforation post insertion, or the possibility that device complications such as migration and perforation may cause abscesses, infections, require surgery for removal and/or may necessitate hysterectomy, oophorectomy, salpingectomy, and other complications.

135. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold and otherwise released into the stream of commerce Essure®, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Essure®.

136. Essure® was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or

physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

137. Defendants downplayed the serious and dangerous side effects of Essure® to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

138. Essure® was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks associated with Essure®, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

139. Plaintiff used Essure® as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

140. Plaintiff could not have discovered any defect in Essure® through the exercise of reasonable care.

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

142. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

143. Defendants had a continuing duty to warn consumers, including Plaintiff and her physicians, and the medical community of the dangers associated with its use, Defendants breached their duty.

144. Although Defendants knew, or were reckless in not knowing, of the defective nature of Essure®, they continued to manufacture, design, formulate, test, package, label, produce, create, made, construct, assemble, market, advertise, distribute and sell Essure® without providing adequate warnings and instructions concerning the use of Essure® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Essure®.

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145. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries as alleged herein, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION

STRICT LIABILITY

146. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

147. Defendants are manufacturers and/or suppliers of Essure® and are strictly liable to Plaintiff for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Essure® into the stream of commerce.

148. Essure®, manufactured and/or supplied by Defendants, was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

149. Essure® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

150. Essure® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Essure® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendants failed to adequately warn of these risks.

151. Essure® was defective due to inadequate pre-marketing testing.

152. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the extreme risks

associated with Essure® and continues to promote Essure® in the absence of those adequate warnings.

153. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

154. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

155. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Essure® as safe for use by the public at large, including Plaintiff, who purchased Essure®. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

156. Plaintiff reasonably relied on the skill and judgment of the Defendants, and as such their implied warranty, in using Essure®.

157. Contrary to same, Essure® was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

158. As a direct and proximate result of one or more of these wrongful acts r omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

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SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

159. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

160. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Essure® were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendants warranted Essure® to be in all respects safe, effective and proper for such purposes.

161. Essure® does not conform to these express warranties and representations because Essure® is not safe or effective and may produce serious side effects.

162. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

EIGHT CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

163. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

164. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Essure®, owed a duty to provide accurate and complete information regarding Essure®.

165. Defendants falsely represented to Plaintiff that Essure® was an effective contraceptive option. The representations by Defendants were in fact false, as Essure® is not safe and is dangerous to the health of its users.

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166. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and her health care providers, information about the propensity of Essure® to cause great harm.

167. Defendants negligently misrepresented claims regarding the safety and efficacy of Essure® despite the lack of information regarding same.

168. These misrepresentations were made by Defendants with the intent to induce Plaintiff to use Essure®, which caused her injury.

169. At the time of Defendants' misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

170. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product.

171. Plaintiff reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Essure®.

172. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

NINTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

173. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

174. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Essure® described herein, owed a duty to provide accurate and complete information regarding Essure®.

175. Defendants fraudulently misrepresented material facts and information regarding Essure® including, but not limited to, its propensity to cause serious physical harm.

176. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

177. Defendants knew this information to be false, incomplete and misleading.

178. Defendants intended to deceive and mislead Plaintiff so that she might rely on these fraudulent misrepresentations.

179. Plaintiff had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

180. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

TENTH CAUSE OF ACTION

FRAUD BY CONCEALMENT

181. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

182. Defendants had a duty and obligation to disclose to Plaintiff that Essure® was dangerous and likely to cause serious health consequences to users when used as prescribed.

183. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff with the intent to defraud her as herein alleged.

184. Neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

185. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

186. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

187. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

188. At all times relevant herein, Defendants:

a. knew that Essure® was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Essure®; and,

d. with full knowledge of the health risks associated with Essure® and without adequate warnings of the same, manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Essure® for routine use.

189. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the general public.

190. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

191. Defendants are liable jointly and/or severally for all general, special and compensatory damages and equitable relief to which Plaintiff is entitled by law. Plaintiff seeks actual and punitive damages from Defendants and alleges that conduct of Defendants was committed with knowing, conscious, reckless, deliberate and grossly negligent disregard for the rights and safety of consumers,

including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

RELIEF REQUESTED

WHEREFORE Plaintiff prays for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiff, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;

2. Past and future economic and special damages according to proof at trial;

3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Past and future pain and suffering damages, including mental and, emotional stress arising from Plaintiff's physical injuries, according to proof at the time of trial;

6. Equitable relief as requested and/or as the Court deems just and proper;

7. Declaratory judgment that Defendants are liable to Plaintiff for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants wrongdoing;

8. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

9. Punitive or exemplary damages according to proof at the time of trial;

10. Costs of suit incurred herein;

11. Pre-judgment interest as provided by law; and

12. Such other and further relief as the Court may deem just and proper.

Dated: September 1, 2015

s/Martin Schmidt
By: Martin Schmidt
Attorney for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by Jury.

JS 44 (Rev. 12/12) cand rev (1/15/13)

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

Tanya De La Paz

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Martin Schmidt, Esq.
Schmidt National Law Group
4241 Jutland Dr., Suite 200, San Diego, CA 92117 ph.(800)214-1010

DEFENDANTS

Bayer, Corp.; Bayer Healthcare LLC; Bayer Essure, Inc.; Bayer Healthcare Pharmaceuticals; Bayer A.G.

County of Residence of First Listed Defendant Allegheny, PA
(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)***:
USC Section 1332(a)

Brief description of cause:
Negligence; Failure to warn, etc. for sale and manufaturer of Essure contraceptive device

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
09/01/2015

SIGNATURE OF ATTORNEY OF RECORD
s/Martin Schmidt

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only) ☑ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA

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.