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6
7 **IN THE UNITED STATES DISTRICT COURT**
8 **NORTHERN DISTRICT OF CALIFORNIA**
9 **SAN FRANCISCO DIVISION**

11 DANIELLE PATTERSON, an individual,

12 Plaintiff,

13 v.

14 BAYER HEALTHCARE LLC, a Delaware
corporation; BAYER HEALTHCARE
15 PHARMACEUTICALS, INC., a Delaware
corporation; BAYER ESSURE, INC., a Delaware
16 corporation; and DOES 1-10, inclusive

17 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

1
2 COMES NOW Plaintiff DANIELLE PATTERSON, and files this Complaint seeking
3 judgment against Defendants BAYER HEALTHCARE LLC; BAYER HEALTHCARE
4 PHARMACEUTICALS, INC.; BAYER ESSURE, INC.; and DOES 1 through 10 inclusive,
5 (hereinafter collectively referred to as “Defendants” or “Bayer”) for personal injuries suffered as a
6 result of Plaintiff DANIELLE PATTERSON (hereinafter “Plaintiff”) being prescribed and using the
7 defective and unreasonably dangerous product Essure®. At all times relevant hereto, Essure® was
8 manufactured, designed, formulated tested, packaged, labeled, produced, created, made, constructed,
9 assembled, marketed, advertised, distributed and sold by Defendants or by Conceptus, Inc. which
10 merged with Bayer on or about April 28, 2013.

11 **I. PARTIES, JURISDICTION AND VENUE**

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

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

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

26 4. At all times relevant hereto, Plaintiff is and was a resident of Mesa, Arizona.
27
28

1 5. Defendant BAYER HEALTHCARE LLC is a for-profit corporation incorporated in
2 the state of Delaware. Defendant is authorized to and does business throughout the states of
3 California and Arizona.

4 6. Defendant BAYER ESSURE INC. is a for-profit corporation incorporated in the state
5 of Delaware. Defendant is authorized to and does business throughout the states of California and
6 Arizona.

7 7. Defendant BAYER PHARMEUCITALS, INC., is a for-profit corporation
8 incorporated in the state of Delaware. Defendant is authorized to and does business throughout the
9 states of California and Arizona.

10 **II. FACTS AND ALLEGATIONS COMMON TO ALL CLAIMS**

11 8. This Complaint is brought by Plaintiff who relied on express warranties of Defendants
12 before being implanted with a female birth control device, known as “Essure.” As a result of (1)
13 Defendants negligence described *infra* and (2) her reliance on Defendants’ warranties, Defendants’
14 Essure® device was placed in both of her fallopian tubes. After the device was implanted, Plaintiff
15 has suffered from migraines, severe abdominal, ovarian and pelvic pain, sharp, stabbing pain, pain
16 during intercourse, heavy bleeding, emotional pain and mental anguish.

17 9. Essure® had Conditional Premarket Approval (“CPMA”) by the Food and Drug
18 Administration (“FDA”). As discussed herein, this CPMA became “invalid” and the product
19 “adulterated” pursuant to the FDA due to Defendants’ failure to comply with the CPMA order. As a
20 result, Defendants’ CPMA is “invalid” and its “adulterated” product, Essure®, should never have
21 been marketed or sold to Plaintiff.

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

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

28 12. 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.

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

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

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

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

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

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

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

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

24 **A. Description Of Essure® And How It Works**

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

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

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

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

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

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

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

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

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

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

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

28 **B. Evolution Of Essure®**

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

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

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

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

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

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

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

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

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

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

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

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

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

1 43. In the CPMA Order issued by the FDA, the FDA expressly stated, “Failure to comply
2 with the conditions of approval **invalidated this approval order**.” The following were the
3 conditions of approval:

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

6 (b) “Successful bilateral placement of Essure is documented for newly trained
7 physicians.”

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

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

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

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

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

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

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

21 (c) Defendants failed to notice the FDA of several adverse reactions and actively
22 concealed the same. Most egregiously, Defendants **failed to report eight (8) perforations** which
23 occurred as a result of Essure® and **was cited for the same by the FDA** via Form 483¹.

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

28 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.”

1 (e) As outlined in “Facts and Warranties” *infra*, Defendants’ warranties were not
2 truthful, accurate, and not misleading.

3 (f) Defendants’ warranties were not consistent with applicable Federal and State
4 law.

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

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

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

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

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

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

26 **C. Defendant’s Training, Entrustment And Distribution Plan**

27 51. Defendants (1) failed to adequately train the implanting physician on how to use its
28 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

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

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

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

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

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

18 56. Defendants provided no training to the implanting physician on how to *remove*
19 Essure® should it migrate or cause serious medical conditions necessitating its removal.

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

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

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

1 60. According to Defendants, these agreements allowed Defendants to “gain market
2 presence [...] and expend [...] market opportunity by driving adoption among a group of physicians.”

3 61. In regard to the entrustment of such specialized equipment, Defendants admitted: “**We**
4 **cannot be certain how successful these programs will be, if at all.**”

5 62. Defendants “handed out” this equipment to unqualified physicians, including
6 Plaintiff’s implanting physician, in an effort to sell its product.

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

10 64. In return for providing the hysteroscopic equipment, **Defendants required that the**
11 **implanting physician purchase two Essure® “kits” per month.** This was part of Defendants’
12 unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with
13 reckless disregard for the safety of the public and Plaintiff.

14 65. Defendants’ distribution plan included requiring the implanting physician to purchase
15 two (2) Essure® “kits” per month, **regardless of whether he or she used them or not.** This
16 distribution plan created an environment which induced the implanting physician to “push” Essure®
17 and implant the same into Plaintiff.

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

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

25 68. Defendants’ distribution plan also included (1) negligently distributing Essure®
26 against FDA order and sections 501(f), 502(q) and (r) of the FD&C Act by marketing and selling an
27 adulterated product; (2) the promotion of Essure® through representatives of the hysteroscopic
28 equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding
Essure®; (3) failing to report and actively concealing eight perforations which occurred as a result of

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

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

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

10 **D. Plaintiff's History**

11 71. Prior to the operation, Plaintiff went to the implanting physician to discuss options for
12 permanent sterilization. The implanting physician recommended that Plaintiff have Essure®
13 implanted in her fallopian tubes instead of a standard tubal ligation procedure.

14 72. In or around May 7, 2009, Plaintiff returned to the implanting physician for the
15 Essure® procedure. The implanting physician implanted the Essure® coils into both her left and
16 right fallopian tubes.

17 73. After procedure to implant the device, Plaintiff started experiencing severe constant
18 daily pain, and severe bleeding. Since the device was implanted, Plaintiff has also suffered from
19 heavy bleeding, menorrhagia, constant pain, and mental and emotional anguish.

20 74. Plaintiff had a uterine ablation on or about September 4, 2013 to control the heavy
21 bleeding.

22 75. Plaintiff did not become aware that Essure® was the cause of her above-described
23 physical, emotional, and medical problems until 2015 when she learned, through internet research, of
24 other women having similar issues.

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

28 77. In fact, plaintiff was advised by her physicians that Essure® was not the cause of any
of her above-described symptoms.

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

6 **E. Facts And Warranties**

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

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

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

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

21 83. A key study found that a learning curve for this hysteroscopic procedure was seen for
22 procedure time, but not for successful placement, pain, and complication rates, evidencing that
23 Defendants' training methods were failing².

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

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

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

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

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

14 **a. Website Warranties**

15 88. Defendants marketed on its website the following:

16 (a) *“Only FDA approved female sterilization procedure to have **zero pregnancies***
17 *in the clinical trials.”* However, there were actually **four pregnancies** during the clinical trials and
18 five pregnancies during the first year of commercial experience. Defendants concealed this
19 information from Plaintiff.

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

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

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

1 (e) *“Worry free: Once your doctor confirms that your tubes are blocked, you*
2 *never have to worry about unplanned pregnancy.”* However, several pregnancies have been reported
3 subsequent to confirmation. Defendants concealed this information from Plaintiff. However, from
4 1997 to 2005, 64 pregnancies were reported to Defendants. Defendants concealed this information
5 from Plaintiff. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy
6 after the three month Confirmation Test was confirmed. Defendants concealed this information from
7 Plaintiff. However, there have been over 30 pregnancies after “doctors confirmed the tubes were
8 blocked.” However, women who have Essure® have **10 times greater risk** of pregnancy after one
9 year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four
10 (4) times greater³.

11 (f) *“Essure is the most effective permanent birth control available-even more*
12 *effective than tying your tubes or a vasectomy.”* Yet, Defendants’ SEC filings, Form 10-K show
13 that Defendants never did a comparison to a vasectomy or tubal ligation. Defendants stated, **“We**
14 **did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation.”**
15 Defendants concealed this information from Plaintiff. In fact, women who have Essure® have 10
16 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten
17 years, the risk of pregnancy is almost 4 times greater⁴.

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

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

26
27 ³ *Probability of Pregnancy After Sterilization: A Comparison Of Hysteroscopic Versus Laparoscopic Sterilization*, Garipey, Aileen.
Medical Publication "Contraception." Elsevier 2014.

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

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

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

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

14 **b. Advertisement Warranties**

15 89. Defendants advertised:

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

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

22 **c. Fact Sheet Warranties**

23 90. Defendants represented in its Fact Sheet:

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

28 **d. Warranties By Agents**

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

5 92. Defendants' CEO stated: "*Essure® allows you to push away the constant worry*
6 *about an unplanned pregnancy that's our message and that's our theme.*" However, there were
7 actually **four pregnancies** during the clinical trials and five pregnancies during the first year of
8 commercial experience. Defendants concealed this information from Plaintiff. However, between
9 1997—2005, 64 pregnancies were reported to Defendants. Defendants concealed this information
10 from Plaintiff. However, there have been over 30 pregnancies after "doctors confirmed the tubes
11 were blocked."

12 **e. Marketing Warranties**

13 93. Defendants marketed with commercial stating:

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

16 (b) "The non-surgical" permanent birth control for woman." However, the
17 procedure is most commonly done with surgery. Defendants concealed this information from
18 Plaintiff. However, Essure® is not permanent as the coils migrate, perforate organs and are expelled
19 by the body. However, all Essure® procedures are done under hysteroscopy, which is a surgical
20 procedure.

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

26 95. Defendants warranted that Essure® "allows for visual confirmation of each insert's
27 proper placement both during the procedure and during the Essure Confirmation Test." However,
28 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.

1 **f. Brochure Warranties**

2 96. Defendants' Essure® brochure warrants:

3 (a) *"Worry free."* However, Defendants **actively concealed** and **failed to report**
 4 **8 perforations which occurred as a result of Essure® to the FDA evidence** in a Form 483 issued
 5 by the FDA to Defendants. Defendants actively concealed this from Plaintiff. *See* Most egregiously,
 6 Defendants were issued another Form 483 when it **"erroneously used non-conforming material."**
 7 Defendants actively concealed this and were issued an additional Form 483 for "failing to adequately
 8 document the situation." Defendants actively concealed this from Plaintiff. However, Defendants'
 9 facility was also issued a notice of violation as it **"no longer uses pre-sterile and post-sterile**
 10 **cages."** Defendants actively concealed this from Plaintiff. However, Defendants were also issued a
 11 notice of violation when **"it failed to obtain a valid license...prior to manufacturing medical**
 12 **devices."** Defendants were manufacturing devices for three years without a license. Defendants
 13 actively concealed this from Plaintiff. However, Defendants were also issued a notice of violation as
 14 it was manufacturing medical devices from 2005 at an unlicensed facility. Defendants actively
 15 concealed this from Plaintiff.

16 (b) *"The Essure inserts stay secure, forming a long protective barrier against*
 17 *pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're*
 18 *properly in place."* However, the micro-inserts do not remain secure but migrate and expelled by the
 19 body. Defendants actively concealed this information from Plaintiff. However, Defendants actively
 20 concealed and **failed to report 8 perforations which occurred as a result of Essure® to the FDA**
 21 **as evidenced in** Form 483 issued to Defendants by the FDA.

22 (c) *"The Essure® inserts are made from the same trusted, silicone free material*
 23 *used in heart stents."* However, the micro-inserts are not made from the same material as heart stents.
 24 Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue
 25 growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiff.
 26 PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants
 27 also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known."
 28 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 were issued another Form 483

1 when they “**erroneously used non-conforming material.**” Defendants actively concealed this and
 2 were issued another Form 483 for “failing to adequately document the situation.”

3 (d) “*Surgery-free.*” However, all Essure® procedures are done under
 4 hysteroscopy, which is a surgical procedure.

5 (e) “*Anesthesia-free.*” However, Essure® is not “anesthesia-free”, rather
 6 anesthesia is not required.

7 (f) Step Two: “*pregnancy cannot occur*”; Step Three: *The Confirmation.*
 8 However, Defendants also state that it is only **after** “The Confirmation” that pregnancy cannot occur,
 9 *i.e.* the complete opposite of what is warranted in the brochure. However, Adverse Event Report
 10 ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was
 11 confirmed. However, between 1997—2005, 64 pregnancies were reported to Defendants.
 12 Defendants concealed this information from Plaintiff. However, there have been over 30 pregnancies
 13 after “doctors confirmed the tubes were blocked.” However, there have been incidents where the
 14 micro-inserts were expelled from the body even after the Confirmation Test⁶.

15 (g) “*Essure® eliminates the risks, discomfort, and recovery time associated with*
 16 *surgical procedures.*” However, Essure® is not “surgery-free”. Rather laparoscopic surgery is not
 17 required.

18 97. *The PET fibers are what cause the tissue growth.* However, during the PMA meeting
 19 with the FDA, Defendants represented that the **trauma** caused by the expanding coil striking the
 20 fallopian tubes is **what caused the inflammatory response** of the tissue. Defendants concealed this
 21 information from Plaintiff.

22 **g. Essure® Booklet Warranties**

23 98. Defendants’ Essure® booklet warrants:

24 (a) “*This viewable portion of the micro-insert serves to verify placement and does*
 25 *not irritate the lining of the uterus.*” However, the device does irritate the uterus. Defendants
 26 concealed this information from Plaintiff. However, Defendants actively concealed and **failed to**
 27 **report 8 perforations** which occurred as a result of Essure® to the FDA as evidence in Form
 28 483.

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

3 **h. Data Warranties**

4 99. Summary of Safety and Effectiveness Data states:

5 (a) *“The Essure® System provides permanent birth control without invasive*
 6 *surgery or general anesthesia, and their associated risks.”* However, Essure® is not “surgery-free”
 7 or “anesthesia-free,” rather laparoscopic surgery and anesthesia are not required.

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

11 (c) *“Namely, the Essure® system is delivered hysteroscopically without general*
 12 *anesthesia.”* However, Essure® is not “surgery-free” or “anesthesia-free,” rather laparoscopic
 13 surgery and anesthesia are not required.

14 **i. PMA Supplement**

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

20 **j. SEC Filings**

21 101. Defendants warranted that the Essure® system has “**no risks**” for patients because...
 22 the Essure® system does not involve the use of radiofrequency energy. At the same time,
 23 Defendants also states that there are limited risks with Essure®.

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

1 (a) However, Defendants' site has been inspected 7 times since 06/25—
2 07/09/2002. The most recent FDA audit occurred on 05/30—6/26/2013. The FDA has issued 4 Form
3 483 inspectional observations.

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

6 (c) Most egregiously, Defendants were issued another Form 483 when they
7 **“erroneously used non-conforming material.”** Defendants actively concealed this and were issued
8 another Form 483 for “failing to adequately document the situation.”

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

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

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

20 **FIRST CAUSE OF ACTION**

21 **MANUFACTURING DEFECT**

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

24 105. At all relevant times, Defendants were engaged in the business of selling Essure® in
25 the states of California and Arizona.

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

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

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

8 109. As a direct and proximate result of Plaintiff's use of Essure®, she was forced to
9 undergo a surgical procedure to control the heavy bleeding caused by the Essure® coils.

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

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

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

21 113. There are contraceptives and surgical procedures on the market with safer alternative
22 designs in that they provide equal or greater efficacy and far less risk.

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

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

SECOND CAUSE OF ACTION

DESIGN DEFECT

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

116. Defendants were and are engaged in the business of selling Essure® in the States of California and Arizona.

117. 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.

118. 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.

119. 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.

120. As a direct and proximate cause of Plaintiff's use of Essure®, she was forced to undergo medical procedures to manage her symptoms, developed severe pain, suffers from migraines and has undergone numerous procedures.

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

122. 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.

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

124. 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.

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

4 **THIRD CAUSE OF ACTION**

5 **NEGLIGENCE**

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

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

- 10 a. failed to properly and thoroughly test Essure® before releasing the system to
11 market;
12 b. failed to properly and thoroughly analyze the data resulting from the
13 premarketing tests of Essure®;
14 c. failed to conduct sufficient post-market testing and surveillance of Essure®;
15 d. designed, manufactured, marketed, advertised, distributed, and sold Essure® to
16 consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of
17 Essure® and without proper instructions to avoid the harm which could foreseeably occur as a result
18 of using the system;
19 e. failed to exercise due care when advertising and promoting Essure®; and,
20 f. negligently continued to manufacture, market, advertise and distribute
21 Essure® after Defendants knew or should have known of its adverse effects.

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

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

28 **FOURTH CAUSE OF ACTION**

FAILURE TO WARN

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

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

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

14 132. Essure® was under the exclusive control of Defendants and was unaccompanied by
15 appropriate warnings regarding all of the risks associated with its use. The warnings given did not
16 accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or
17 physicians. The promotional activities of Defendants further diluted or minimized the warnings given
18 with the product.

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

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

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

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

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

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

8 139. Defendants had a continuing duty to warn consumers, including Plaintiff and her
9 physicians, and the medical community of the dangers associated with its use, Defendants breached
10 their duty. Under Ninth Circuit federal law, Plaintiff's claims for breach of failure to warn after FDA
11 approval are not preempted by the Medical Device Act ("MDA"). Stengel v. Medtronic Incorporated,
12 704 F.3d 1224 (9th Cir. 2013).

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

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

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

25 **FIFTH CAUSE OF ACTION**

26 **STRICT LIABILITY**

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

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

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

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

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

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

17 148. Defendants failed to provide adequate initial warnings and post-marketing warnings or
18 instructions after the manufacturer and/or supplier knew or should have known of the extreme risks
19 associated with Essure® and continues to promote Essure® in the absence of those adequate
20 warnings.

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

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

27 **SIXTH CAUSE OF ACTION**

28 **BREACH OF IMPLIED WARRANTY**

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

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

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

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

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

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

19 **SEVENTH CAUSE OF ACTION**

20 **BREACH OF EXPRESS WARRANTY**

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

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

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

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

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

7 **EIGHT CAUSE OF ACTION**

8 **NEGLIGENT MISREPRESENTATION**

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

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

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

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

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

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

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

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

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

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

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

9 **NINTH CAUSE OF ACTION**

10 **FRAUDULENT MISREPRESENTATION**

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

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

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

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

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

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

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

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

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

4 **TENTH CAUSE OF ACTION**
5 **FRAUD BY CONCEALMENT**

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

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

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

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

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

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

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

22 **REQUEST FOR PUNITIVE DAMAGES**

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

25 184. At all times relevant herein, Defendants:

- 26 a. knew that Essure® was dangerous and ineffective;
- 27 b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists,
28 other medical providers, the FDA, and the public at large;

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

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

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

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

15 187. Defendants are liable jointly and/or severally for all general, special and compensatory
16 damages and equitable relief to which Plaintiff is entitled by law. Plaintiff seeks actual and punitive
17 damages from Defendants and alleges that the conduct of Defendants was committed with knowing,
18 conscious, reckless, deliberate and grossly negligent disregard for the rights and safety of consumers,
19 including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to
20 punish Defendants and deter them from similar conduct in the future.

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

24 **RELIEF REQUESTED**

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

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

- 1 3. Loss of earnings and impaired earning capacity according to proof at trial;
- 2 4. Medical expenses, past and future, according to proof at the time of trial;
- 3 5. Past and future pain and suffering damages, including mental and, emotional stress
- 4 arising from Plaintiff's physical injuries, according to proof at the time of trial;
- 5 6. Equitable relief as requested and/or as the Court deems just and proper;
- 6 7. Declaratory judgment that Defendants are liable to Plaintiff for all future evaluative,
- 7 monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs
- 8 and losses caused by Defendants' wrongdoing;
- 9 8. Medical monitoring, whether denominated as damages or in the form of equitable
- 10 relief according to proof at the time of trial;
- 11 9. Punitive or exemplary damages according to proof at the time of trial;
- 12 10. Costs of suit incurred herein;
- 13 11. Pre-judgment interest as provided by law; and
- 14 12. Such other and further relief as the Court may deem just and proper.

15 **DEMAND FOR JURY TRIAL**

16 Plaintiff hereby demands a trial by Jury.

17

18 Dated: November 5, 2015

19

20 s/Martin Schmidt

21 By: Martin Schmidt

22 Attorney for Plaintiff

23

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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

Danielle Patterson

(b) County of Residence of First Listed Plaintiff Maricopa (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 (800)214-1010

DEFENDANTS

Bayer Healthcare LLC; Bayer Pharmaceuticals, Inc.; Bayer Essure, Inc.

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, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Motor Vehicle, Personal Injury, etc.

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, 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 manufacture and sale 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 Hon. William Alsup DOCKET NUMBER 3:15-cv-03995-WHA

DATE 11/05/2015 SIGNATURE OF ATTORNEY OF RECORD s/Martin Schmidt

00F0K0UQPCN'CUH PO GPV'EklrIN0/05/4+

(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.

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

UNITED STATES DISTRICT COURT

for the

Northern District of California

DANIELLE PATTERSON, an individual

Plaintiff(s)

v.

BAYER HEALTHCARE, LLC, a Delaware limited liability company; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware Corp.; BAYER ESSURE, INC.; a Delaware Corp.; and DOES 1-10

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) BAYER HEALTHCARE, LLC, 100 Bayer Blvd., Whippany, N.J. 07981 (Serve: CSC Lawyers Incorporating Service, 2710 Gateway Oaks Dr., Suite 150 N. Sacramento, CA 95833); BAYER HEALTHCARE PHARMACEUTICALS, INC., 100 Bayer Blvd., Whippany, N.J. 07981 (Serve: CSC Lawyers Incorporating Service, 2710 Gateway Oaks Dr., Suite 150 N. Sacramento, CA 95833); BAYER ESSURE, INC., 100 Bayer Blvd., Whippany, N.J., 07981 (Serve: CSC Lawyers Incorporating Service, 2710 Gateway Oaks Dr., Suite 150 N. Sacramento, CA 95833; and DOES 1-10 inclusive

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:

Martin Schmidt, Esq. (SBN 171673)
SCHMIDT NATIONAL LAW GROUP
4241 Jutland Dr., Suite 200
San Diego, CA 92117

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: