IN THE UNITED STATES DISTRICT COURT

DISTRICT OF CONNECTICUT

April Norman, an individual, Plaintiff, vs. BAYER, CORP., an Indiana corporation; BAYER HEALTHCARE LLC, a Delaware corporation; BAYER ESSURE®, INC., (F/K/A CONCEPTUS, INC.) a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation; BAYER A.G., a German corporation, Defendants.	**CASE NO. _____** **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL** (1) Strict Products Liability – Failure to Warn and Manufacturing Defect (2) Negligent Failure to Warn (3) Negligence in Training (4) Negligence / Negligence Per Se (5) Negligent Misrepresentation (6) Fraudulent Concealment (7) Violations of Connecticut Products Liability Act

COMES NOW Plaintiff April Norman, and files this Complaint seeking judgment against Defendants BAYER, CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE®, INC. (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC; and BAYER A.G (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Plaintiff April Norman (hereinafter "Plaintiff") being prescribed and implanted with 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, promoted, distributed, and sold by Defendants or by Conceptus, Inc. which merged with Bayer on or about April 28, 2013.

I. PARTIES, JURISDICTION AND VENUE

1. Plaintiff is Ms. April Norman. At all times relevant hereto, Plaintiff is and was a citizen and resident of Hartford County, Connecticut.

2. Defendant BAYER CORP. is a for-profit corporation incorporated in the state of Indiana and is a

wholly owned subsidiary of Bayer A.G. Defendant is authorized to and does business throughout the state of Connecticut.

3. Defendant BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. Defendant is authorized to and does business throughout the state of Connecticut.

4. Defendant BAYER ESSURE® INC. (F/K/A CONCEPTUS, INC.) is a for-profit corporation incorporated in the state of Delaware, and is a wholly owned subsidiary of Bayer A.G and/or Bayer HealthCare LLC. Conceptus, Inc. (Conceptus) was founded by Julian Nikolchev, a self-described "medical technology developer and serial entrepreneur," in 1992.[1] On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC.[2] On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly owned subsidiary of Bayer HealthCare LLC and/or Bayer A.G., and thereafter renamed "Bayer Essure® Inc."[3] For purposes of this Complaint, Conceptus, Inc. and Bayer Essure® Inc. are one and the same. Bayer Essure® Inc.'s headquarters are located at 331 East Evelyn Avenue, Mountain View, California 94041. Defendant is authorized to and does business throughout the state of Connecticut.

5. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer AG. Defendant is authorized to and does business throughout the state of Connecticut.

6. Defendant BAYER A.G. is a German for-profit corporation. Defendant is authorized to and does business throughout the state of Connecticut through its wholly owned subsidiaries.

7. 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)

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[1] *See* Julian Nikolchev, LINKEDIN, *available at* https://www.linkedin.com/in/julian-nikolchev-392bb2a.

[2] *See* EX-99.(A)(5)(D), Subject: Bayer and Conceptus—Off to a Great Start, *available at* http://www.sec.gov/Archives/edgar/data/896778/000119312513211471/d537063dex99a5d.htm.

[3] The Bayer Group, *Tender offer successful: Bayer acquires majority interest in Conceptus*, PR NEWSWIRE (Jun. 5, 2013, 2:30 PM), http://www.prnewswire.com/news-releases/tender-offer-successful-bayer-acquires-majority-interest-in-conceptus-210199021.html.

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..

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

9. Defendants have significant contacts with the federal judicial district of Connecticut such that they are subject to the personal jurisdiction of the United States District Court for the District of Connecticut.

10. A substantial part of the actions and omissions giving rise to Plaintiff's causes of action occurred in the federal judicial district for the District of Connecticut. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

II. DESCRIPTION OF ESSURE®

11. Essure® is a Class III medical device manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

12. Essure® was first manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Conceptus, Inc. and initially developed under the name Selective Tubal Occlusion Procedure or "S/TOP™" Permanent Contraception device.

13. Essure® is a form of permanent female birth control (female sterilization). The device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which are supposed to anchor and then elicit tissue growth creating the blockage of the fallopian tubes.

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

15. The micro-inserts are comprised of two metal coils, made of nitinol (nickel and titanium), steel, and PET fibers, which are placed in a woman's fallopian tubes via Defendants' disposable delivery system and under hysteroscopic guidance (camera).

16. 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.

17. 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. Defendants claim that the coils allegedly elicit tissue growth, blocking off the fallopian tubes.

18. The coils are alleged to remain securely in place in the fallopian tubes for the life of the patient.

19. Three months post implant, patients are to receive a "Confirmation Test" to determine that the coil micro-inserts have created a complete occlusion in each fallopian tube. The Confirmation Test used is a hysterosalpingogram (" Confirmation Test" or "HSG").

20. Defendants have stated that the HSG is "often painful" and "is also known to be highly inaccurate, with false-positive results in as many as 40% of HSG-diagnosed cases of proximal tubal occlusion ("PTO"). Various factors are believed to be responsible for these false indications of tubal occlusion, including tubal spasm (a natural function of the tubes) and a build-up in the tube of natural cellular debris and mucous."[4]

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

22. Essure® was designed, manufactured, and marketed to be used by gynecologists throughout the world, as a "quick and easy" outpatient procedure that did not require general anesthesia and had a quick recovery time. Defendants claimed that Essure® "will allow many tubal therapies for . . . permanent contraception which are currently performed surgically to be performed transcervically, thereby reducing the cost, trauma and recovery time associated with those therapies."[5]

23. Defendants provided training to physicians on how to use the Essure® system and other hysteroscopic equipment, including Plaintiff's implanting physician.

24. In April 2002, Conceptus submitted its Premarket Approval Application to the United States Food and Drug Administration (FDA) for the Essure® device.

[4] Conceptus, Inc., Annual Report (Form 10-k) (Dec. 31, 1996).

[5] *Id.*

25. Premarket Approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. *See* 21 U.S.C. § 515(b); 21 CFR § 814.3(e). 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.

26. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a. proposed indications for use;

b. device description including the manufacturing process;

c. any marketing history;

d. summary of studies (including nonclinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e. methods used in manufacturing the device, including compliance with current good manufacturing practices; and

f. information relevant to an evaluation of the safety and effectiveness of the device known or that should reasonably be known to the manufacturer from any source, including commercial marketing experience.

27. On November 4, 2002, the FDA conditionally approved Conceptus's Essure® PMA application.

28. According to the FDA, a Class III device that fails to meet the Conditional Premarket Approval (CPMA) requirements after marketing is considered to be adulterated under § 501(f) of the Federal Food, Drug and Cosmetic Act (FDCA) and cannot continue to be marketed.

29. In the CPMA Order issued by the FDA, the FDA expressly stated that "[f]ailure to comply with the conditions of approval invalidated this approval order."[6] The following were the conditions of the CPMA for Essure®:

[6] FOOD & DRUG ADMIN., PREMARKET APPROVAL, (Nov. 4, 2002), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014A.pdf.

a. "[e]ffectiveness of Essure® is established by annually reporting on the 745 women who took part in clinical tests."

b. "[s]uccessful bilateral placement of Essure® is documented for newly trained physicians."

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

d. "[r]eport 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 and representations concerning the products are truthful, accurate and not misleading; and

f. warranties and representations concerning the product are consistent with applicable Federal and State law.

30. In addition to the requirements set forth in the CPMA, Defendants are required to comply with all FDA requirements for Class III medical devices, including, but not limited to:

a. report to the FDA information suggesting that one of the Manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;

b. monitor the product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

c. submit a PMA Supplement for any change in Manufacturing Site, 21 CFR §§ 814.39 et seq.;

d. establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;

e. establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 CFR §§ 820.30 et seq.;

f. document all Corrective Action and Preventative Actions taken by the Manufacturer to address nonconformance and other internal quality control issues, 21 CFR §§ 820.100 et seq.;

g. establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.;

h. establish Quality Management System (QMS) procedures to assess potential causes of nonconforming products and other quality problems, 21 CFR §§820.70 et seq. and 21 CFR §§ 820.90 et seq.;

i. report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80 et seq.; and

j. advertise product accurately and truthfully, 21 CFR §§ 801 et seq.

31. As presented below, Defendants failed to comply with several of the aforementioned conditions of the CPMA and federal regulations and requirements, thereby invalidating the CPMA under the FDCA.

32. By failing to comply with several CPMA conditions and federal regulations and requirements prior to implant into Plaintiff, Essure® was also considered to be an "adulterated" device under § 501(f) of the FDCA and cannot be marketed per the FDA. 21 U.S.C. §§ 351(h); 21 CFR §§ 814.80 et seq. However, Defendants have continued to market the product to the present.

33. In June and July of 2003, the FDA conducted a six day inspection of Conceptus' San Carlos headquarters.[7]

34. During the six day inspection, the FDA documented two (2) conditions which it found objectionable and/or constituted violations of the FDCA and federal regulations and requirements.

35. The two objectionable conditions were communicated to Conceptus by the FDA via a Form 483 dated July 7, 2003, and included: (1) Conceptus' failure to analyze all data from quality sources to identify existing and potential causes of nonconforming product and other quality problems related to the Essure® device; and (2) Conceptus' failure to follow procedures to control products that do not conform to specifications.[8]

[7] 2003 483 Form

[8] *Id.*

36. These objectionable conditions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 820.90 et seq.; 21 CFR §§ 814 et seq; 21 CFR §§ 820.198 et seq.; §§ 820. 100 et seq.; 21 CFR §§ 820.20 et seq.; 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.184 et seq.; and 21 CFR §§ 820.30.

37. Subsequent to obtaining its CPMA, Conceptus became aware of potential quality and failure modes associated with the Essure® devices. For example, Conceptus became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

a. the stainless steel used in Essure® can become un-passivated, which allows it to rust;

b. the nitinol could have a nickel rich oxide, which the body attacks;

c. the no lead solder could in fact have trace lead in it;

d. the Galvanic action between the metals used to manufacture Essure®, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;

e. the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;

f. latent manufacturing defects, such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may exist in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

g. degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;

h. the mucosal immune response to nickel is different than the immune response in nonmucosal areas of the body.

38. Upon obtaining knowledge of these potential device failure modes, the Defendants were required under 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq. and the FDA Recognized Consensus Standard ISO 14971[9] to use this information to routinely update the risk analyses for the Essure® device

[9] http://www.fda.gov/OHRMS/DOCKETS/98fr/050701b.htm.

and take any and all Corrective Action and Preventative Actions (CAPA) necessary to address nonconformance and other internal quality control issues. Furthermore, Defendants were required to establish Quality Management Systems (QMS) procedures to assess potential causes of nonconforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq. Defendants failed to comply with these and other federal regulations and requirements, thereby jeopardizing the health of patients, including Plaintiff.

39. In November or December 2005, Conceptus moved its manufacturing facility from San Carlos, California to Mountain View, California. It did not file a PMA Supplement with the FDA to advise it of the change in manufacturing site in violation of its post-marketing duties under 21 CFR § 814.39.

40. On June 10 and 11, 2008, the California Department of Public Health, Medical Device Safety Section (CDPH), conducted an inspection of Conceptus' 331 East Evelyn Avenue location in Mountain View, California.[10]

41. During this inspection the CDPH issued a Notice of Violation to Conceptus for: (1) failing to obtain a valid license to manufacture medical devices after Conceptus moved from its previous location in 2005; and (2) failing to maintain its procedure for inventory transfer.

42. These conditions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 814.39; and 21 CFR §§ 820.70 et seq.

43. On or about December 2010, the FDA conducted a fifteen day "For Cause" inspection. The purpose of the inspection was to investigate a specific problem that had come to FDA's attention.[11]

44. During the fifteen day For Cause Inspection, the FDA noted four conditions which it found objectionable and/or constituted violations of the FDCA and federal regulations and requirements. The four objectionable conditions were communicated to Conceptus by the FDA via a Form 483 dated January 6, 2011, and included:

a. Conceptus's failure to submit Medical Device Reporting (MDR) determinations to the FDA within 30 days for reports of a serious injury involving the Essure® device including

[10] Conceptus, Inc., Annual Report (Form 10-k) (Mar. 13, 2009).

[11] 2011 Form 483

two reports of bowel perforation, and one report of pain and the Essure® device breaking into pieces immediately following implant;

b. Conceptus's failure to submit MDR's to the FDA within 30 days for reports of a serious injury involving the Essure® device including five reports of the Essure® coils perforating the fallopian tubes and penetrating the peritoneal cavity;

c. Conceptus's failure to include perforation of the Essure® micro-coil insert into the peritoneal cavity in its Design Failure Mode Effects Analysis (DFMEA) for Essure®, despite having documented at least 508 complaints of perforation involving the Essure® device; and

d. Conceptus's failure to adequately document in a CAPA an incident involving the erroneous use of uncertified material by Conceptus's contract manufacturer in a validation protocol.

45. These actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 803.50 et seq; 21 CFR §§ 814 et seq; 21 CFR §§ 820.30 et seq; and 21 CFR §§ 820.198; 21 CFR §§ 820.100 et seq; and 21 CFR §§ 820.20.

46. In May and June 2013, the FDA conducted another inspection that included an evaluation of Conceptus's/Bayer's complaint handling and adverse event reporting practices. As part of the inspection process, part of the FDA's review focused on 16,047 complaints Conceptus received on the Essure® device between January 2011 and the date of the inspection, only 183 of which were reported by Defendants to the FDA as MDRs.[12]

47. These actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 803.50 et seq; and 21 CFR §§ 820.198; 21 CFR §§ 820.100 et seq.; and 21 CFR §§ 820.20 et seq.

48. Conceptus also failed to timely submit Post-Approval Studies under the Essure® CPMA. The six

[12] *See* FDA Review Document, *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463486.pdf.

month report was due on August 24, 2012 but was not received by the FDA until December 14, 2012;[13] the one year report was due February 23, 2013 but was not received by the FDA until March 8, 2013;[14] and the eighteen month report due August 24, 2013 but was not received by the FDA until September 12, 2013.[15]

49. These actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 814.80 et seq.

50. The FDA also requires that upon purchase of a company holding a CPMA, the CPMA sponsor "must submit a PMA amendment to notify the FDA of the new owner. . . . The . . . supplement should also 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."[16]

51. However, no PMA supplement notifying the FDA of Conceptus's (and the Essure® CPMA's) change of ownership after Conceptus was acquired by Defendants was submitted. These actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 814.39 et seq.

52. Defendants also violated §§ 502(q) and (r) of the FDCA by engaging in false and misleading advertising of Essure®.

53. Defendants continued to sell its product with misleading and false advertising in violation of the conditions of the CPMA and federal regulations and requirements. The marketing campaign for Essure® was described as follows: "Through the use of public relations and targeted advertising, we intend to

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[13]http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/UCM413807.pdf.

[14]http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/UCM413808.pdf.

[15]http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/UCM413831.pdf.

[16] Food & Drug Admin., *PMA Frequently Asked Questions*, *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm051387.htm.

increase awareness of Essure® among consumers, general practitioners and the broader medical community. In April 2003, we presented Essure® at the annual conference of the American College of Obstetricians and Gynecologists. At this meeting, we had two presentations and there was a Continuing Medical Education, or CME, accredited symposium with Essure® as the main topic. In early June 2003, we commenced a direct mail campaign to 500,000 women in the Atlanta and Chicago areas, with the goal of encouraging these women to contact our call center for additional information. In turn, our call center has the ability to offer a referral to a practicing Essure® physician in a consumer's area. We had also conducted regional advertisement in a variety of magazines, such as *Parents* and *Self*."[17]

54. In addition, Defendants operated websites for "physicians and patients" and "established a call center for patients that are seeking additional information about Essure® and who wish to be referred to physicians that are trained to perform the Essure® procedure. Physicians that we refer our patients to are those that have chosen to participate in our Essure® Accredited Practice program aimed at providing an optimal patient experience."[18]

55. Defendants advertised, promoted and marketed on its website, in its print and/or video advertisements, brochures and fact sheets the following representations about Essure®:

a. "[o]nly FDA approved female sterilization procedure to have zero pregnancies in the clinical trials" or words to that effect. However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Additionally, several pregnancies have been reported subsequent to Essure implantation. Between 1997–2005, 64 pregnancies were reported to Defendants. Adverse Event Report ESS 205 dated October 3, 2006 evidences a pregnancy after the three-month Confirmation Test was confirmed. Furthermore, a recent study indicates that women implanted with Essure have a ten times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater. Defendants concealed this information from patients, including Plaintiff;

[17] Conceptus, Inc., Annual Report (Form 10-k) (Mar. 15, 2004).

[18] Conceptus, Inc., Annual Report (Form 10-k) (Mar. 31, 2005).

b. that Essure was a "non-surgical"[19] permanent birth control option or words to that effect. However, Essure is not "non-surgical." All Essure procedures are done under hysteroscopy, which is a surgical procedure. Defendants concealed this information from patients, including Plaintiff;

c. "[w]orry free," is a "simple procedure performed in your doctor's office" that takes "less than 10 minutes" and "requires no downtime for recovery" and "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures" or words to that effect. However, Defendants actively concealed and failed to report complaints of perforations and pain which occurred as a result of Essure® as noted above. Essure® can cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications. Defendants concealed this information from patients, including Plaintiff;

d. "[t]he 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" or words to that effect. However, the micro-inserts do not necessarily remain secure and can migrate and be expelled by the body, as evidenced by the multiple complaints concerning perforation. Defendants concealed this information from patients, including Plaintiff;

e. "[t]he Essure® inserts are made from the same trusted, silicone free material used in heart stents" or words to that effect. However, the micro-inserts are not made from the same material as heart stents and do not elicit tissue growth. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. 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

[19] Essure.com

known."[20] However, the PET fibers are made of the same materials as the PVT material in some vaginal meshes which have a high rate of expulsion. The Essure® inserts also contain nickel, which can cause severe reactions in patients. Defendants concealed this information from patients, including Plaintiff;

f. "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure® is not "surgery-free" and can cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications. Defendants concealed this information from patients, including Plaintiff;

g. "Essure® is the most effective permanent birth control available—even more effective than tying your tubes or a vasectomy" or words to that effect. Yet, Defendants' SEC Form 10-K filing shows 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."[21] Defendants concealed this information from patients, including Plaintiff; and

h. "[c]orrect placement . . . is performed easily because of the design of the microinsert" or words to that effect. 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 one out of seven clinical participants. Defendants concealed this information from patients, including Plaintiff.

56. Defendants advertised, promoted and marketed on its websites, in its print and/or video advertisements, brochures, and fact sheets the following about physicians performing the Essure® procedure:

[20] http://www.accessdata.fda.gov/cdrh_docs/pdf2/p020014b.pdf.

[21] Conceptus, Inc., Annual Report (Form 10-k) (Mar. 15, 2004).

a. "[p]hysicians must be signed-off to perform Essure® procedure" or words to that effect. 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 patients, including Plaintiff.

b. "an Essure® trained doctor inserts spring-like coils, called micro-inserts" or words to that effect. However, the implanting physician who implanted the device was not adequately trained. Defendants concealed this information from patients, including Plaintiff.

c. "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" or words to that effect. However, Defendants failed to adequately train the implanting physician. Defendants concealed this information from patients, including Plaintiff;

d. "[i]n 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®" or words to that effect. However, Defendants "signed off" on physicians who were not skilled operative hysteroscopists, in order to monopolize and capture the market, including the implanting physician. Defendants concealed this information from patients, including Plaintiff;

e. "[i]n order to be identified as a qualified Essure® physician, a minimum of one Essure® procedure must be performed every 6–8 weeks" or words to that effect. However, Defendants "signed off" on "Essure® physicians" who did not perform the procedure every 6–8 weeks. Defendants concealed this information from patients, including Plaintiff; and

f. "[t]he PET fibers are what caused the tissue growth," and Essure® "works with your body to create a natural barrier against pregnancy" or words to that effect. However, during the PMA meeting with the FDA in 2002, Defendants represented that the trauma caused

by the expanding coil striking the fallopian tubes is what causes the inflammatory response of the tissue.[22] Defendants concealed this information from patients and the public, including Plaintiff.

57. On September 24 and 25, 2015, the FDA convened a public hearing concerning the safety and efficacy of the Essure® device.[23] At that public hearing, Defendants testified as follows:

a. the efficacy rates for Essure® are 99.6%; in reality, studies show that the chances of becoming pregnant with Essure® are higher than with tubal ligations and higher than the rates reported by Bayer to the FDA at the public hearing;[24]

b. skin patch testing is not a reliable predictor of clinically significant reactions to nickel-containing implantable devices, including Essure®; despite this, Bayer told physicians and patients that a nickel sensitivity test was sufficient to determine whether a patient was a suitable candidate for an Essure® device;[25]

c. as an alternative to Essure®, laparoscopic tubal ligation is a safe and effective method of permanent birth control; in reality, studies show that the chances of becoming pregnant with Essure® are higher than with tubal ligations, and Essure® patients are much more likely to require additional surgeries to correct complications associated with the sterilization procedure; and[26]

d. most of the reports of adverse events to the FDA have come from consumers and not Defendants, which is unusual; in reality, Bayer's failure to file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling or complaints that were occurring with an unexpected increase in severity and frequency from the more than 16,000 complaints that it has received violated the CPMA and the FDA post-marketing regulations, which prevented Plaintiff, physicians and the public from

[22] Pg. 98-99 of transcript.

[23] Adcom transcript.

[24] *Id.*

[25] *Id.*

[26] *Id.*

understanding the true nature of Essure®'s adverse events.[27]

58. At all relevant times, Defendants' Essure® product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

III. PLAINTIFF'S HISTORY (APRIL NORMAN)

59. On or about March 2012, Ms. Norman presented to Dr. Stacy Spiro requesting a means of permanent contraception. Dr. Spiro recommended the Essure® device to Ms. Norman, Ms. Norman relied on the benefits and risks as relayed by Dr. Spiro in reaching her decision to have the Essure® procedure.

60. On March 11, 2012, Ms. Norman underwent the Essure® procedure, which was performed by Dr. Stacy Sprio at St. Francis Hospital in Hartford, Connecticut.

61. On February 13, 2013, Ms. Norman underwent a hysterectomy for removal of the Essure® implants bilaterally at St. Francis Hospital in Hartford, Connecticut performed by Dr. Peggy Ku. Ms. Norman underwent the removal procedure to treat pelvic pain, weight gain, heavy bleeding, blood clots, painful intercourse, hair loss, and depression due to the Essure® device.

62. Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to inquire or discover Defendants' tortious conduct. Under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable three-year statutory limitations period.

63. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiff and her physicians of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Defendants' misconduct and fraudulent concealment of the relevant facts, as described *infra*, tolls any relevant statute of limitations. Under appropriate application of the discovery rule, Plaintiff's suit is filed well within the applicable three-year statutory limitations period.

64. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of Essure®. Because of Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendants are estopped from relying on any statute of limitations

[27] *Id.*

defense.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

65. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

66. After obtaining their CPMA, Defendants owed the public, including Plaintiff, a duty to comply with the CPMA, federal regulations and requirements, and to use reasonable care in, *inter alia*, testing and inspecting their product, in monitoring and assessing the design of the Essure® devices placed into Plaintiff and accompanying implantation equipment, and in manufacturing and marketing Essure® according to the terms of the CPMA, its Supplements, the Conditions of Approval, and the federal regulations and requirements.

67. Because Defendants did not comply with specifications and protocols set forth in the requirements, federal regulations, PMA, Supplements, and/or the Conditions of Approval, Defendants manufactured a defective product. This failure results in a manufacturing defect that renders the device unreasonably dangerous for its intended use and Plaintiff could not have anticipated the danger the defect in this product created.

68. This defect was present in the device when it left the hands of the manufacturer and the device was ultimately used for the purpose in the manner for which it was normally intended. The manufacturing flaws in the Essure® were a primary and substantial cause of Plaintiff's injuries. Neither Plaintiff nor any of her treating medical professionals could have discovered the defects in time to avert her injury or prevent her damages.

69. The Essure® product was defective at the time of its sale and distribution, and at the time it left the possession of the Defendants, in that the product differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

70. Defendants violated federal law in the manufacture of Essure® and were cited by the FDA for violations of federal requirements, including, *inter alia*:

a. failing to report and actively concealing 8 perforations which occurred as a result of Essure®;

b. failing to report complaints in which Essure® migrated;

c. failing to report to the FDA incidents of bowel perforation, Essure® coils breaking into pieces and migrating out of the fallopian tubes;

d. failing to report these complaints in their risk analysis for the design of Essure®;

e. failing to have a complete risk analysis for Essure®;

f. failing to have complete Design Failure Analysis;

g. failing to document CAPA activities for a supplier correction action;

h. failing to disclose 16,047 complaints to the FDA as Medical Device Reports; and

i. failing to provide the FDA with timely post-approval reports for its six months, one year, eighteen month, and two-year report schedules.

71. Defendants violated parallel Connecticut law by failing to comply with applicable federal regulations and placing the Essure® product into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the manufacture, design and/or formulation.

72. Upon information and belief, the Essure® manufactured and sold by Defendants and implanted into Plaintiff was defective in manufacture because it did not comply with Defendants' own design specifications, used non-conforming material, and deviated from seemingly identical products from the same product line.

73. At all relevant times, Defendants' Essure® product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

74. At all times relevant to this action, the dangerous propensities of Essure® were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to prescribe Essure® for their patients.

75. The Essure® manufactured, designed, marketed, and sold by Defendants was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

76. Defendants knew that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive device despite its lack of efficacy and potential for

serious severe and permanent side effects.

77. Defendants failed to adequately visually inspect Essure® after completion of assembly and immediately before delivery to Plaintiff.

78. Upon information and belief, when Essure® was manufactured, Defendants had the technological capability to design and manufacture Essure® in a reasonably safe manner and is held to the level of knowledge of an expert in the field.

79. Defendants were entitled to withdraw Essure® from the market at any time or provide adequate warnings to consumers and the medical community, but failed to do so in a timely and responsibly manner.

80. Essure®, which was manufactured, distributed, tested, sold, marketed, advertised, and represented defectively by Defendants was a substantial contributing factor in bringing about Plaintiff's injuries and would not have occurred but for the use of Essure®.

81. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of Essure®.

82. The only way Plaintiff's implanting physician would have been aware of the adverse events or additional warnings would have been for Defendants to report the adverse events or warnings to the FDA.

83. Had Defendants properly warned or reported the adverse events to the FDA as required under federal law, the warnings would have reached Plaintiff's implanting physician in time to prevent Plaintiff's injuries.

84. As a proximate result of the Essure®'s defective condition at the time it was sold, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

85. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

NEGLIGENT FAILURE TO WARN

86. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

87. Defendants designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure®, including the Essure® devices that were implanted into Plaintiff.

88. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a).

89. Defendants have a continuing duty to monitor their product post-approval and to discover and report to the FDA any complaints about product performance and any health consequences of which they are aware that may be attributable to the product. Defendants also have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with the Essure® device.

90. The Defendants breached their duty in that they failed to warn Plaintiff and her physician by failing to communicate to the FDA via federally mandated Adverse Event Reports prior to the time of Plaintiff's implant, including failure to communicate adverse events similar to the injuries suffered by the Plaintiff. The FDA publishes the adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm. Had Defendants complied with the federal requirements and timely and adequately reported the adverse events as required by federal law, additional information would have been available to Plaintiff and/or Plaintiff's physician regarding the dangers of Essure that were known or knowable to Defendants at the time of distribution.

91. Defendants also had a parallel duty under Connecticut law to exercise reasonable care in warning the public, including Plaintiff and/or Plaintiff's physicians, about the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

92. Defendants' failure to adequately and timely report adverse events is a violation of the federal

requirements and state law.

93. Specifically, Defendants breached these duties and violated federal law by, *inter alia*:

a. receiving and failing to properly report 16,047 complaints about Essure® to the FDA;

b. receiving information and complaints about Essure®, including complaints relating to the Essure® devices migrating outside the fallopian tube and causing perforations, and failing to report this information to the FDA or the public;

94. Had Defendants properly and timely reported the adverse events to the FDA as required under federal law, it would have effectively warned physicians, including Plaintiff's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. It would also have provided more complete information to the public at large through the FDA's MAUDE database.

95. If Plaintiff had been aware of these adverse events, she would not have agreed to the Essure® implant and, upon information and belief, her physician would not have recommended the implant for her.

96. As a proximate and legal result of Defendants' failure to comply with its CPMA and federal regulations and requirements, Defendants breached their duty of care to Plaintiff under Connecticut law and caused Plaintiff past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

97. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION

NEGLIGENCE IN TRAINING

98. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

99. 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.

100. Defendants were negligent in choosing not to take reasonable steps in developing a training program for the Essure procedure, educating employees to properly train physician users on the safe and proper methods of the Essure procedure, and supervising employees while training physician users on the safe and proper methods of the Essure procedure.

101. Defendants were negligent in not safely and properly training Plaintiff's implanting physician, Dr. Stacy Sprio, on how to safely and properly perform the Essure procedure.

102. Defendants (1) undertook a duty to train physicians on the safe and proper use of the Essure procedure; (2) failed to adequately train the physicians on how to use its delivery system and the hysteroscopic equipment manufactured by a third party; (3) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (4) it was foreseeable that Defendants' negligent training program would cause harm to Plaintiff.

FOURTH CAUSE OF ACTION

NEGLIGENCE / NEGLIGENCE PER SE

103. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

104. Defendants were and are under a continuing duty to comply with the federal requirements, including the CPMA, its Supplements, the Conditions of Approval, and with the Federal Food, Drug, and Cosmetic Act in the manufacture, development, design, marketing, labeling, distributing, and sale of Essure® and its implementing. *See* Essure® CPMA; 21 U.S.C. ch. 9 § 301 et seq.

105. Plaintiff alleges the federal regulations and requirements define the standard of care, and thus, Defendants duties are contained in, but not limited to, the following: 21 CFR 803.10; 21 CFR 803.50; 21 CFR 803.52; 21 CFR 803.53; 21 CFR 803.56; 21, CFR 806; 21 CFR 814.1; 21 CFR 814.3; 21 CFR 814.9; 21 CFR 814.20; 21 CFR 814.37; 21 CFR 814.39; 21 CFR 814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70.

106. Plaintiff is within the class of persons the statutes and regulations protect and Plaintiff's injuries are the type of harm these statutes and regulations are to prevent.

107. The conditions for CPMA for the Essure® devices incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the approval order. *See* 21 CFR 814.82(c). Defendants failed to comply with the conditions of the CMPA and Federal Regulations.

108. Specifically, Defendants violated federal law and/or were cited by the FDA for, inter alia:

a. failing to report and actively concealing 8 perforations which occurred as a result of Essure®;

b. failing to establish Quality Control Procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects

c. not reporting complaints, including complaints in which Essure® migrated;

d. not reporting to the FDA incidents of pain, bowel perforation, Essure® coils breaking into pieces and migrating out of the fallopian tubes;

e. not considering these complaints in their risk analysis for the design of Essure®;

f. failing to have a complete risk analysis for Essure®;

g. failing to have complete Design Failure Analysis;

h. failing to document CAPA activities for a supplier correction action;

i. failing to disclose 16,047 complaints to the FDA as Medical Device Reports; and

j. failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two-year report schedules.

109. Defendants had a parallel duty under Connecticut law to exercise reasonable care in testing and inspecting their product, in monitoring the design of the Essure® placed into Plaintiff, in performing continuing risk-analysis and risk assessments of the Essure® device, and in manufacturing and marketing Essure® to the public.

110. Defendants were negligent under this parallel Connecticut law in its development, design, marketing, manufacture, distribution, and/or sale of Essure® in one or more of the following particulars:

a. in failing to properly meet the applicable standard of care by not complying with applicable federal regulations;

b. carelessly and negligently selling and distributing Essure® in violation of the CPMA and

federal law;

c. negligently incorporating into the design and assembly of the Essure® parts that could not stand up to normal usage;

d. failing to exercise reasonable care in its inspecting and testing of the product; and

e. failing to exercise reasonable care in its manufacturing and quality control processes.

111. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Essure®.

112. Despite the fact that Defendants knew or should have known that Essure® caused unreasonable, dangerous side effects, Defendants continued to market Essure® to consumers, including Plaintiff and her healthcare providers.

113. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

114. Had Defendants exercised ordinary care, and complied with federal regulations and parallel state law, Plaintiff would not have been injured.

115. As a proximate and legal result of Defendants' failure to exercise reasonable care and the resulting defective condition of Essure®, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

116. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

117. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

118. Defendants owed a duty in all of its several undertakings, including the communication of information concerning Essure®, and to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

119. Defendants, in the course of its business profession, knowingly and negligently disseminated

information to physicians concerning the properties and effects of Essure®, with the intent and expectation that physicians would rely on that information in their decisions in recommending and prescribing the Essure® device for their patients.

120. When Defendants disseminated information to physicians and/or patients concerning the properties and effects of Essure®, they knew or should have known that physicians and/or patients would reasonably rely on that information in their decisions concerning the use of Essure®.

121. Defendants disseminated false information, as described above, to physicians and the medical community and to their patients with knowledge that the information was false or in conscious its truth or falsity.

122. Defendants made misrepresentations which are specifically outlined in Paragraphs 52–56.

123. Defendants made these misrepresentations and concealed adverse information at a time when Defendants knew, or should have known, that Essure had defects, dangers, and characteristics that were other than what Defendants had represented to consumers and the health care industry generally.

124. Defendants had no reasonable grounds for believing these representations were true when they were made; in fact, Defendants knew the representations to be false.

125. Defendants disseminated the false information, as referenced above, to physicians, the medical community, and the public with the intention to deceive physicians and their patients and to induce the physicians to prescribe Essure®.

126. Defendants failed to exercise reasonable care to ensure that the information disseminated to physicians concerning the properties and effects of Essure® was accurate and not misleading.

127. Defendants expected or should have expected that patients implanted with Essure® in reliance on false information would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to the device.

128. Plaintiff and/or Plaintiff's physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended. Specifically, Plaintiff would have never had the Essure® implanted had she been aware that there were 8 perforations of human cavities, that there had been 16,047 complaints regarding Essure®, or the falsity of the representations specifically delineated in the preceding paragraphs.

129. As a proximate and foreseeable result of the foregoing misrepresentations by Defendants, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

130. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

131. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

132. At all times mentioned in this Complaint, Defendants had the duty and obligation to disclose to Plaintiff and/or her healthcare providers, the true facts concerning Essure®.

133. Defendants concealed material facts concerning Essure® from Plaintiff and/or her physicians and healthcare providers, including the following:

a. Defendants received and fraudulently concealed 16,047 complaints regarding Essure® where pain was experienced by consumers. The FDA's Establishment Inspection Report on June 26, 2013 states: "the inspection found that the firm was not reporting as MDRs complaints in which their product migrated from the fallopian tube into the peritoneal cavity, the firm did not consider these complaints in their risk analysis for the design of their product, and the firm failed to document CAPA activities."

134. Defendants made affirmative representations to Plaintiff and/or her physicians before Essure® was implanted in Plaintiff that Essure® was safe and effective while concealing the material facts set forth herein with the intent or purpose that Plaintiff, her physicians, and the healthcare industry would rely on them, leading to the use of Essure® by Plaintiff.

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

136. Neither Plaintiff nor her healthcare providers were aware of the concealed facts set forth herein. Had they been aware of those facts, they would not have used Essure®, and Plaintiff would not have been injured as a result.

137. Plaintiff and her physicians justifiably relied on and/or were induced by Defendants' misrepresentations and/or concealment. Specifically, Plaintiff would never have had the Essure® implanted had she been aware that there had been 16,047 complaints regarding Essure®.

138. Plaintiff, her physicians, and the healthcare industry, justifiably relied on Defendants' misrepresentations that Essure® was safe and effective as it is reasonable that Plaintiff, her physicians, and the healthcare industry would rely on the statements of Defendants regarding whether Essure® was safe because as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

139. Defendants had a post-sale duty to warn Plaintiff, her physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner.

140. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff and her healthcare providers reasonably relied on Defendants' deception and, Plaintiff was implanted with Essure® and subsequently sustained injuries and damages as described here. Defendants' concealment was a substantial contributing factor in causing Plaintiff's injuries.

141. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff seeks punitive damages according to proof.

142. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

143. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION

PRODUCT LIABILITY CLAIM PURSUANT TO THE CONNECTICUT PRODUCT LIABILITY ACTIONS C.G.S.A. §§ 52-527m *et seq.*

144. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

145. Connecticut General Statute section 52-572m *et seq.* governs "all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula,

preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, or labeling of any product." Claims under this section "shall include, but [are] not limited to, all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent."

146. Defendants designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure®, including the Essure® devices that were implanted into Plaintiff.

147. Defendants have a continuing duty to monitor their product post-approval and to discover and report to the FDA any complaints about product performance and any health consequences of which they are aware that may be attributable to the product. Defendants also have a continuing duty to provide ongoing warnings and instructions regarding safety hazards associated with the Essure® device.

148. Defendants had a parallel duty under Connecticut General Statute section 52-572m *et seq.* to exercise reasonable care in warning the public, including Plaintiff and/or Plaintiff's physicians, about the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

149. Defendants' failure to adequately and timely report adverse events is a violation of the federal requirements and state law.

150. Specifically, Defendants breached these duties and violated federal law by, *inter alia*:

a. receiving and failing to properly report 16,047 complaints about Essure® to the FDA;

b. receiving information and complaints about Essure®, including complaints relating to the Essure® devices migrating outside the fallopian tube and causing perforations, and failing to report this information to the FDA or the public;

151. If Plaintiff had been aware of these adverse events, she would not have agreed to the Essure® implant and, upon information and belief, her physician would not have recommended the implant for her.

152. In addition, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of Essure®, and in the recruitment and training of physicians to implant Essure®.

153. As a proximate and legal result of Defendants' failure to comply with its CPMA and federal regulations and requirements, Defendants breached their duty of care to Plaintiff under Connecticut law and caused Plaintiff past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

154. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

REQUEST FOR PUNITIVE DAMAGES

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

156. At all times relevant herein, Defendants:

a. knew or should have known that Essure® was dangerous and ineffective;

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

c. attempted to misrepresent and did knowingly make misrepresentations to Plaintiff, her physicians, hospitals, and other 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 use.

157. Defendants, by and through its 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, wanton, conscious, and/or reckless disregard for the safety of Plaintiff and the general public.

158. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of Essure®. Defendants' conduct was willful, wanton, and undertaken with a disregard for Plaintiff's rights.

159. Notwithstanding the foregoing, Defendants continued to market Essure® to consumers, including Plaintiff herein, without disclosing the risks.

160. Defendants knew of Essure®'s lack of warnings, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell Essure® without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Essure®.

161. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using Essure® against its benefits.

162. 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.

163. 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 the conduct of Defendants was committed with knowing, conscious, careless, reckless, willful, wanton, deliberate, and grossly negligent disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

164. 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 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. Economic and non-economic damages in an amount as provided by law and to be supported by

evidence at trial;

2. For compensatory damages according to proof;

3. For declaratory judgment that Defendants are liable to Plaintiff for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Defendants' wrongdoing;

4. For disgorgement of profits;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest and the costs of suit;

7. Punitive or exemplary damages according to proof;

8. Injunctive relief; and

9. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: February 16, 2016

THE PLAINTIFF
APRIL NORMAN, an INDIVIDUAL

BY _____

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