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Attorney for Plaintiff: ALBA SANCHEZ

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SANTA CLARA
DTS DIVISION

ALBA SANCHEZ, an individual,

Plaintiff,

vs.

BAYER HEALTHCARE LLC, a Delaware limited liability company; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.), a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation; ; and DOES 1-10, inclusive,

Defendants.

CASE NO. 16CV292783

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

(1) Breach of Express Warranty
(2) Negligent Misrepresentation
(3) Fraudulent Concealment
(4) Fraudulent/Intentional Deceit
(5) Strict Products Liability – Inadequate Warnings
(6) Strict Products Liability – Manufacturing Defect
(7) Negligent Failure to Warn
(8) Breach of Implied Warranty
(9) Negligence / Negligence *Per Se*
(10) Violations of Business & Professions Code §§ 17200, Et Seq.
(11) Violations of Business & Professions Code §§ 17500, Et Seq.
(12) Violations of Cal. Civil Code §1750

By Fax

COMES NOW Plaintiff ALBA SANCHEZ (f/k/a ALBA MARTINEZ), and files this Complaint seeking judgment against Defendants BAYER HEALTHCARE LLC; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 10, inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Plaintiff ALBA SANCHEZ (hereinafter "Plaintiff") being 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.

I. INTRODUCTION

1. A woman's decision to have a medical device implanted into her body to serve as permanent birth control is a monumental one. This decision is made only after careful consideration of the risks and benefits associated with the device. For this decision to be adequately informed, the patient—and her doctor--must have access to complete, accurate, and current safety and efficacy information about the device. The primary responsibility for timely communicating this essential risk and benefit information rests with the manufacturer of the device because the manufacturer has superior, and in many cases, exclusive access to the relevant safety and efficacy information, including post market complaints.

2. To fulfill this essential responsibility, a manufacturer must vigilantly monitor at least two sources of information. First, the manufacturer must closely evaluate the post-market clinical experience with the device and its components and rapidly provide updated safety and efficacy information to the healthcare community and to consumers. Such post-market vigilance is never more important than in the case of a new medical device, which has not withstood the test of time. Many risks emerge only after the device has been widely used. Second, the manufacturer must carefully monitor its own manufacturing operations and quality controls to ensure that the device uniformly conforms to the manufacturer's representations and warranties regarding its safety and efficacy and complies with specifications of approval.

3. This action arises from Defendants' post-market failures and misrepresentations about the safety and efficacy of their novel permanent birth control device, Essure®, and their failures to timely communicate accurate, complete, and current information about the risks of the device as learned from post-market experiences. For example, Defendants failed to report many of the roughly 16,000 complaints of serious and life altering injuries associated with Essure® to the FDA and the public, and failed to update Essure®'s labeling or report to the FDA and the medical community, their post-market Essure® complaint information. Not only did Defendants fail to perform the required post-market reporting of adverse events which they were aware of, they also failed to monitor the complaints made to the FDA and other sources that were publically available. Defendants also failed to perform required

post-market surveillance of the medical literature related to the necessary component parts and materials utilized in Essure®, rendering it unsafe and ineffective and with inadequate warnings.

4. It is clear that patient adverse experiences and medical literature call into question the safety and efficacy of Essure®. Defendants wrongfully concealed mounting reports of personal injuries and unintended pregnancies resulting from the post-market experience with Essure®. Defendants also hid widespread problems with their manufacturing process and quality controls that rendered Essure® unreasonably unsafe and ineffective. Notably, Defendants also utterly failed to warn of the dangers of the use of the hysteroscope required for implantation of the device. The hysteroscope does not maintain pre-market approval protection.

5. Defendants wrongfully misrepresented and concealed adverse event information at a time when Defendants knew, or should have known, that Essure® dangerously failed to conform to Defendants' representations to consumers and healthcare practitioners about the safety and efficacy of the device. Defendants also falsely advertised, warranted and represented that Essure® was safer and more effective than other methods of permanent birth control. Because of this wrongful conduct, Plaintiff has suffered severe and life-altering personal injuries for which she seeks compensation.

II. PARTIES, JURISDICTION AND VENUE

6. The Court has personal jurisdiction over Defendants because Plaintiff and Defendant Bayer Essure Inc. (f/k/a Conceptus, Inc.) and Bayer HealthCare LLC are citizens of and/or do business in the State of California and a substantial part of the events giving rise to Plaintiff's claims occurred in California, including the design, formulation, testing, packaging, labeling, production, creation, construction, making, assembly, advertising, clinical testing, marketing, promotion, distribution, and manufacturing of the Essure® system.

7. Venue is proper in this county in accordance with § 395(a) of the California Code of Civil Procedure because Defendant BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.) resides in this county and the injuries alleged herein arose from conduct that occurred in this county.

8. Plaintiff is a citizen and resident of San Antonio, Bexar County, Texas.

9. Defendant BAYER HEALTHCARE LLC is a for-profit limited liability company organized under the laws of 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 California and has manufacturing operations located in Berkeley, Alameda County, California and research and development operations in San Francisco, San Francisco County, California.

10. 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 in 1992 by Julian Nikolchev, a self-described "medical technology developer and serial entrepreneur." On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. 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 was renamed "Bayer Essure Inc." For purposes of this Complaint, Conceptus, Inc. and Bayer Essure Inc. are one and the same. Bayer Essure Inc.'s headquarters were located at 1021 Howard Avenue, San Carlos, California 94070 until 2005 when they relocated to 331 East Evelyn Avenue, Mountain View, California 94041. In July of 2013, Bayer Essure Inc. moved its headquarters to 1011 McCarthy Boulevard, Milpitas, Santa Clara County, California 95035. Defendant Bayer Essure Inc. is authorized to and does business throughout the state of California.

11. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. 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 California.

12. The true names and capacities of those defendants designated as DOES 1-10, whether individual, corporate, association or otherwise, are unknown to Plaintiff at the time of filing this Complaint and Plaintiff, therefore, sues said defendants by such fictitious names and will ask leave of Court to amend this Complaint to show their true names or capacities when the same have been ascertained. Plaintiff is informed and believes, and thereon alleges, that each of the DOE defendants is, in some manner, responsible for the events and happenings herein set forth and proximately and/or directly caused injury and damages to Plaintiff as herein alleged.

III. DESCRIPTION OF ESSURE®

13. Essure® is a medical device manufactured, designed, formulated, tested, packaged, labeled,

produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

14. 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.

15. Essure® is touted as a form of permanent female birth control (female sterilization) with a 99.74% effectiveness rate of preventing pregnancy. The device was developed to prevent pregnancy through the insertion of micro-inserts into the fallopian tubes that then expand and anchor, causing fibrous tissue growth and, in turn, bilateral occlusion (blockage) of the fallopian tubes. Defendants intended the device to be implanted "permanently," *i.e.*, for the duration of each patient's lifetime.

16. 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 a single use.

17. The micro-inserts are composed of two metal coils: one coil made of nitinol (nickel and titanium) and the other made of steel with polyethylene terephthalate ("PET") fibers wound in and around the coil. The micro-inserts are placed in a woman's fallopian tubes via Defendants' disposable delivery system.

18. Defendants' disposable delivery system consists of a single handle that contains a nitinol core 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 monitor this complicated process through hysteroscopic equipment including a hysteroscope, a lightbox, and a monitor, collectively known as a "tower." Upon information and belief, the towers were valued at approximately $20,000 and were provided by Defendants to physicians for free if the physician purchased twenty five Essure® units. . The hysteroscopic equipment is not part of the Essure® device or subject to pre-market approval, but necessary to visualize placement of it.

19. After placement of the coils in the fallopian tubes, the micro-inserts expand upon release and anchor into the fallopian tubes. Defendants claim in their physician training manual and patient information booklets that the expanded coils and chronic inflammatory and fibrotic response to the PET

fibers elicit tissue growth that blocks the fallopian tubes and prevents pregnancy. According to Defendants, "the tissue in-growth into the insert caused by the PET fibers results in both insert retention and pregnancy prevention."

20. Defendants further claim in advertising materials that the coils will remain securely in place in the fallopian tubes for the life of the patient, claiming, for example, Essure is "proven permanent birth control procedure that works with your body to create a natural barrier against pregnancy" and that its "not reversible."

21. 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 ("HSG").

22. Defendants have stated in a publicly available Form 10-K filed with the U.S. Securities and Exchange Commission that 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." Defendants do not, however, share this information with patients.

23. Even without the Confirmation Test, Defendants also claim on their website and advertising materials that "correct placement" of Essure® "is performed easily because of the design of the microinsert," and the physician training manuals lead one to believe the system and hysteroscope allows for visual confirmation of each insert's proper placement during the procedure.

24. Essure® was designed, manufactured, marketed, and promoted by Defendants to be used by gynecologists throughout the world. In advertisements and patient information booklets, Defendants touted their product as a "quick and easy," "surgery-free" outpatient "simple" procedure that did not require general anesthesia and "requires no downtime for recovery." Defendants claimed in a publicly available Form 10-K filed with the U.S. Securities and Exchange Commission 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."

25. Defendants provided inadequate training to physicians, including physician, as to how to use the Essure® system and hysteroscopic equipment. Indeed, the Defendants' "training" was not provided by physicians, but instead the Defendants' unqualified sales representatives.

IV. PRE-MARKET APPROVAL

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

27. 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. § 360(e); 21 C.F.R. § 814.3(e).

28. A PMA application must contain certain information that is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. Under 21 C.F.R. § 814.20, 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 non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e. each of the functional components or ingredients of the device;

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

g. any other data or 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, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

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

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

51. In the CPMA Order issued by the FDA, the FDA stated that "[f]ailure to comply with the conditions of approval invalidated this approval order." Conditions of the CPMA for Essure® specifically included the following requirements:

a. conduct a post approval study in the U.S. to "document the bilateral placement rate [of Essure®] for newly trained physicians";

b. establish the effectiveness of Essure® by annually reporting on the patients who took part in the Pivotal and Phase II clinical investigations;

c. include results from the annual reporting on the patients who took part in the Pivotal and Phase II clinical investigations in the labeling as these data become available;

d. submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures, necessitate a labeling, manufacturing, or device modification;

e. submit a PMA supplement whenever there is use of a different facility or establishment to manufacture, process, or package the device;

f. submit a PMA supplement whenever there are changes to the performance of the device;

g. submit a report to the FDA within 10 days after Defendants receive or have knowledge or information of any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that has not been addressed by the device's labeling and must also submit a report to the FDA within 10 days after receiving or gaining knowledge or information of any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that has been addressed by the device's labeling but is occurring with unexpected severity or frequency;

h. submit a report to the FDA within 10 days after Defendants receive or have knowledge or information of any failure of the device to meet specifications established in the approved PMA that are not correctable by adjustments or procedures described in the approved labeling;

i. include in the Annual Report any failures of the device to meet the specifications established in the approved PMA that were correctable by procedures described in the approved labeling;

j. "[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";

k. Defendants' warranties and representations concerning the product must be truthful, accurate and not misleading; and

l. Defendants' warranties and representations concerning the product must be consistent with applicable Federal and State law.

32. The CPMA for Essure® further outlined reporting requirements that Defendants were required to follow under the Medical Device Reporting regulations ("MDR"). Under these requirements, Defendants must:

a. report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury; and

b. report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

33. Defendants were at all times responsible for maintaining the labeling of Essure®. Accordingly, Defendants had the ability to file a "Special PMA Supplement- Changes Being Effected" ("CBE") which allows Defendants to unilaterally update the labeling of Essure® to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or

reliability of the device.

54. In addition to the delineated requirements set forth in the CPMA, the CPMA also reminded Defendants to consult the PMA regulations for further guidance on complying with requirements that were not summarized in the CPMA. Defendants were required to comply with all FDA requirements for Class III medical devices. Their obligations include, but are not limited to, their duties 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, and conduct an investigation of each event and evaluate the cause of the event, 21 C.F.R. §§ 803.50, et seq.;

b. monitor the product after pre-market 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 C.F.R. §§ 814, et seq.;

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

d. establish and maintain quality system requirements to ensure that quality requirements are met, 21 C.F.R. § 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 C.F.R. §§ 820.30, et seq.;

f. document all Corrective Action and Preventative Actions taken by the Manufacturer to address non-conformance and other internal quality control issues, 21 C.F.R. §§ 820.100, et seq.;

g. establish internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198 and §§ 820.100, et seq.;

h. establish Quality Management System ("QMS") procedures to assess potential causes of non-conforming products and other quality problems, 21 C.F.R. §§ 820.70, et seq. and

21 C.F.R. §§ 820.90, et seq.;

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

j. advertise the device accurately and truthfully, 21 C.F.R. §§ 801, et seq.

35. Defendants thus had the ability under federal law and the duty under state and federal law to maintain labeling that provides adequate warnings about risks and instructions for use, ensure that the product was manufactured utilizing Good Manufacturing Practices and can be used safely in accordance with the instructions, and that any labeling, warranties, or representations Defendants made were not false or misleading in any respect. They failed to do so.

36. Defendants breached their duties under state law to take reasonable steps to prevent foreseeable and intended risks, including to the Plaintiff, in multiple ways, as discussed below.

V. DEFENDANTS ENGAGED IN FALSE AND MISLEADING SALES AND MARKETING TACTICS

37. Defendants violated the Essure® CPMA and §§ 502(q) and (r) of the FDCA and parallel state laws by engaging in false and misleading advertising of Essure®.

38. Defendants continue to sell their product with misleading and false advertising in violation of the conditions of the Essure® CPMA and state laws.

39. The marketing campaign for Essure® was described by Defendants as follows: "Through the use of public relations and targeted advertising, we intend to 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*."

40. 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." In reality, the training and medical comprehensiveness of the Essure® Accredited Practice program is a falsehood.

41. Defendants advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets stating the following about Essure®, while failing to report the actual material facts:

a. The Essure® patient brochure stated Essure® was the "[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 related to the ESS 205 device dated October 3, 2006 evidences an ectopic pregnancy, which can be life-threatening to the mother, 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.

b. The Essure® website, print advertising, and patient brochure described Essure® as "[s]urgery-free" or words to that effect. However, Essure® is not "surgery-free." All Essure® procedures are done under hysteroscopy, which is a surgical procedure. Defendants also failed to disclose post-market adverse events arising from the implant, and that many of those events required surgery to remove the device. In reality, a recent controlled study of device found that women who were implanted with the Essure were 10 times more likely to need reoperations over women who had tubal ligations.

c. The Essure® website, print advertising and patient brochure described Essure® as "[w]orry free," and 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 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 failed in their post-market obligations to monitor and report these serious adverse events.

d. The Essure® website, print advertising and patient brochure stated "[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 that were inadequately monitored and reported by the Defendants.

e. The Essure® website, print advertising and patient brochure stated the "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. Specifically, the micro-inserts are made of PET fibers that trigger inflammation and scar tissue growth. The PET fibers also degrade and leach carcinogens when in temperatures over 65 degrees, and the human body is at an average of 98 degrees, 33 degrees hotter than when degradation begins. Studies related to PET fiber degradation and leaching became increasingly available post-market, yet the Defendants never warned about it or reconsidered safer alternative materials. Importantly, the PET fibers are not designed or manufactured for use in human implantation. Moreover, 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. Like the PET fibers, studies became available post-market

that put the Defendants on notice of the dangers of nickel to implanted women, yet the Defendants failed to adequately warn about it until it was too late for many women and failed to implement safeguards given this danger.

f. The Essure® website, print advertising, and patient brochure stated "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 admitted, "We did not conduct a clinical trial to compare the Essure® procedure to laparoscopic tubal ligation."

g. The Essure® website claims "[c]orrect placement...is performed easily because of the design of the microinsert" or words to that effect. However, Defendants 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. Moreover, Defendants fail to warn of the dangers associated with the hysteroscopic procedure, a necessary part of implantation of the device.

h. The Essure® physician training manual states "[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, indicating the dangerous PET fibers are entirely unnecessary.

42. Doctors and patients, including Plaintiff and her implanting physicians, relied on these misrepresentations by Defendants.

43. Defendants advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets the following statements about physicians performing the Essure® procedure, while failing to report the actual material facts:

a. "An Essure® trained doctor inserts spring-like coils, called micro-inserts" and "[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 implanting physicians who did not have the requisite training.

b. 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; "[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, and often utilized sales representatives to "train" physicians.

c. "In 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.

44. Doctors and patients, including Plaintiff and her implanting physicians, also relied on these omissions and/or misrepresentations by Defendants.

45. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

46. On September 24 and 25, 2015, the FDA convened a public hearing concerning the safety and efficacy of the Essure® device. At that public hearing, Defendants continued to misrepresent the safety and efficacy of Essure®:

a. Defendants testified that 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.

b. Defendants testified that 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.

c. Defendants testified that Essure® was an alternative to laparoscopic tubal ligation and that Essure® 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.

d. Defendants testified that most of the reports of adverse events to the FDA have come from consumers and not Defendants, which is unusual. In reality, Defendants failed to report thousands of the complaints of adverse events that it had received.

47. Defendants' conduct violated the Essure® CPMA, parallel state laws regarding post-marketing conduct, and the FDA post-marketing regulations, which ultimately prevented Plaintiff, physicians, and the public from understanding the true nature of Essure®'s adverse events, risks and ineffectiveness.

VI. DEFENDANTS WERE AWARE OF DEFECTS AND SERIOUS ADVERSE EVENTS ASSOCIATED WITH ESSURE® AND FAILED TO COMPLY WITH THE FDA AND OTHER REGULATIONS VIOLATING CALIFORNIA STATE LAW

48. Defendants have a duty under California law to exercise reasonable care in warning Plaintiff and/or Plaintiff's physicians about the dangers of Essure® that were known or knowable to Defendants at the time of distribution. Defendants also have a post-market duty to monitor and report adverse events and risks associated with its device.

49. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of California

law and FDA regulations.

50. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all field activities, including inspections and enforcement. During an inspection, ORA investigators may observe conditions they deem to be objectionable. These observations are required to be listed on an FDA Form 483 when the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA requirements.

51. FDA Form 483s typically are discussed with a company's management team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of every possible deviation from law and regulation. There may be other objectionable conditions that exist that are not cited on the FDA Form 483. Companies must take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that exist.

52. In July 2002, FDA inspectors issued a Form 483 to Defendants, reporting that certain adverse events were not captured in the data submitted for Essure®'s PMA.

53. In June and July 2003, the FDA conducted a six-day inspection of Conceptus' San Carlos headquarters.

54. During the six-day inspection, the FDA documented two conditions which it found objectionable and/or constituted violations of the FDCA and related Acts.

55. 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- such as rejection of raw materials and subassemblies- 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. These failures contribute to manufacturing defects in the product.

56. Defendants' conduct violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA regulations including, but not limited to, 21 C.F.R. §§ 820.90, et seq.; 21 C.F.R. §§ 814, et seq.; 21 C.F.R. § 820.198 and §§ 820.100, et seq.; 21 C.F.R. §§ 820.70, et seq.; 21 C.F.R. §§ 820.184, et seq.; and 21 C.F.R. § 820.30.

57. After obtaining its CPMA, Conceptus became aware of potential quality and failure modes

associated with the Essure® device. For example, Conceptus became aware that the following failures can occur with the device and lead to adverse consequences for patients:

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

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

c. the "no lead" solder can 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, can 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. PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues; and

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

58. Upon obtaining knowledge of these potential device failure modes, Defendants were required under the Essure® CPMA, 21 C.F.R. §§ 820.30, et seq., 21 C.F.R. §§ 820.100, et seq., and the FDA Recognized Consensus Standard ISO 14971, to use this information to routinely update the risk analyses for the Essure® device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendants were required to establish QMS procedures to assess potential causes of non-conforming products and other quality problems with the product, such as latent manufacturing defects. 21 C.F.R. §§ 820.70, et seq.; 21 C.F.R. §§ 820.30, et seq. Lastly, Defendants were required to take necessary

such as filing PMA Supplements, unilaterally updating their labeling through the CBE Process, and/or timely submitting MDRs- to advise users of Essure® of the defects and risks described above. Defendants failed to comply with each and every one of these FDA regulations and its duties under California state law, thereby jeopardizing the health of patients.

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

60. 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.

61. 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.

62. This conduct by Defendants violated the conditions of the Essure® CPMA.

63. This conduct violated parallel California state laws governing the post-marketing conduct by Conceptus.

64. This conduct violated FDA regulations including, but not limited to, 21 C.F.R. § 814.39 and 21 C.F.R. §§ 820.70, et seq.

65. 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 the FDA's attention.

66. During the fifteen-day "For Cause" inspection, the FDA noted conditions that it found objectionable and/or constituted violations of the FDCA and related Acts. The objectionable conditions were communicated to Conceptus by the FDA via a Form 483 dated January 6, 2011, and included:

a. Conceptus' failure to submit MDR determinations to the FDA within 30 days for reports of a serious injury involving the Essure® device, including but not limited to two reports of bowel perforation, and one report of pain and the Essure® device breaking into pieces immediately following implant, and 41 complaints that involved perforation of the uterus

or fallopian tubes;

b. Conceptus' failure to submit MDR's to the FDA within 30 days for reports of a serious injury involving the Essure® device, including but not limited to five reports of the Essure® coils perforating the fallopian tubes and penetrating the peritoneal cavity;

c. Conceptus' failure to submit MDR's to the FDA reports of perforation with a post-procedural radiograph (HSG or CT) showing a coil in the abdominal or peritoneal cavity;

d. Conceptus' 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;

e. Conceptus' failure to submit MDR's to the FDA for reports of the device failing to function as specified in the PMA and would be likely to cause or contribute to serious injury; and

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

67. The FDA inspector specifically advised Defendants that any instances of the device migrating to, perforating, or penetrating areas in the body outside of the fallopian tubes (its intended permanent placement) constituted a malfunction and should be reported.

68. Defendants' actions set forth above violated the conditions of the Essure® CPMA.

69. Defendants' actions violated parallel state laws governing the post-marketing conduct of Conceptus.

70. Defendants' actions violated FDA Regulations, including, but not limited to, 21 C.F.R. §§ 803.50, et seq.; 21 C.F.R. §§ 814, et seq.; 21 C.F.R. §§ 820.30, et seq.; and 21 C.F.R. § 820.198 and §§ 820.100, et seq.

71. In May and June 2013, the FDA conducted another inspection that included an evaluation of Conceptus'/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®

essee between January 2011 and the date of the inspection, only 183 of which were reported by Defendants to the FDA as MDRs.

72. The inspector reviewed 29 random complaint forms received by Defendants. All of the randomly reviewed complaints in which one or more coils were imaged outside of the fallopian tubes, none were reported to the FDA as MDRs.

73. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus and FDA Regulations.

74. Defendants failed to take necessary action- such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs- to advise users of Essure® of the defects and risks described above, violating California state law.

75. Conceptus also failed to timely submit Post-Approval Studies under the Essure® CPMA. For example, the six month report was due on August 24, 2012 but was not received by the FDA until December 14, 2012. Other reports were likewise untimely.

76. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus and FDA Regulations, including, but not limited to, 21 C.F.R. §§ 814.80, et seq.

77. 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 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."

78. However, no PMA Supplement to notify the FDA of Conceptus' (and the Essure® CPMA's) change of ownership was submitted after Conceptus was acquired by Defendants.

79. These actions violated the conditions of the Essure® CPMA.

80. As presented above, Defendants failed to comply with several of the aforementioned conditions of the CPMA and FDA regulations, thereby invalidating the CPMA.

81. By failing to update their labeling as new post-marketing information became available to ensure

as its labeling remained both accurate and adequate, Defendants also rendered Essure® a "misbranded" device under the FDCA and thus not allowed to be marketed. These actions also violated parallel state laws governing Defendants' marketing representations and warnings.

82. By failing to comply with several CPMA conditions and FDA post-marketing regulations prior to implant into Plaintiff, Essure® was also considered to be an "adulterated" device under § 501(f) of the FDCA and not allowed to be marketed. 21 U.S.C. § 351(h); 21 C.F.R. §§ 814.80, et seq. However, Defendants continued to market Essure®.

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

84. Prescribing and implanting physicians, healthcare providers and patients, including Plaintiff and their healthcare providers, neither knew, nor had reason to know at the time of their use of Essure® of the existence of the aforementioned adverse events and defects. Ordinary consumers would not have recognized the potential risks or side effects which Defendants concealed and misrepresented through their promotion of Essure® as safe and effective for pregnancy prevention.

VII. PLAINTIFF'S HISTORY

85. On or about August 9, 2013, Ms. Sanchez underwent an Hysteroscopic Essure® procedure.

86. On or about July 24, 2019 prior to the date of being implanted with the Essure® coils Ms. Sanchez was given a copy of the Manufacturer's brochure which listed the many benefits of the Essure® procedure over alternative forms of birth control. Also prior to the date of the Essure procedure® Ms. Sanchez went online to the manufacturer's website named Essure.com and read the many benefits of Essure®, and testimonials, including "real stories from women with Essure". After reviewing and relying on the manufacturer's brochure and website, Ms Sanchez decided to undergo the Essure® procedure.

87. On or about August 16, 2013 Ms. Sanchez returned to the implanting doctor for an ultrasound to confirm placement. The ultrasound showed that the bilateral coils were properly placed. This was also confirmed by an HSG test approximately 3 months after implantation. The HSG test also showed bilateral occlusion of the fallopian tubes.

88. After being implanted with Essure® Ms. Sanchez could feel the coils in her body, and began

[redacted] pelvic pain. At first time she thought it was normal as scar tissue was forming around the [redacted]. Thereafter Ms. Sanchez began experiencing worsening symptoms including more severe pelvic pain, dizziness, fatigue, brain fog, discomfort during sexual intercourse, bleeding after sexual intercourse, lack of periods, bloating, chronic cervical inflammation, vitamin D deficiency and other symptoms.

89. On or about April 16, 2014 Ms. Sanchez underwent a second transvaginal ultrasound due to her worsening symptoms. The ultrasound showed an ovarian cyst on right side.

90. On or about May 21, 2014 Ms. Sanchez underwent a third ultrasound which showed the ovarian cyst seen on the previous ultrasound had disappeared. However her symptoms remained.

91. On or about June 16, 2014 Ms. Sanchez underwent a diagnostic pelvic laparoscopy due to ongoing pelvic pain.

92. On September 3, 2014 Ms. Sanchez underwent a total hysterectomy to remove the Essure® coils.

93. On April 7, 2014 Ms. Sanchez began to do internet research on Essure® to see if this could be the cause of her physical and emotional deterioration. It was then Ms. Sanchez learned of other women discussing their symptoms on online forums and websites.

94. Prior to seeing the online forums in April 2014, 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 statutory limitations period.

95. Plaintiff exercised reasonable diligence in investigating potential causes of her injury by discussing her injuries with healthcare providers. None of Plaintiff's conversations with her healthcare providers gave Plaintiff a reason to suspect, or reasonably should have given Plaintiff a reason to suspect, that the Essure® products implanted in Plaintiff were defective.

96. 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 relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person

discovered the actual facts. 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 statutory limitations period.

97. Defendants are and were under a continuing duty to monitor and 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 defense.

FIRST CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

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

99. Defendants expressly warranted Essure® to be safe for use by the general public, including Plaintiff and/or her healthcare providers.

100. Defendants also expressly warranted that Essure® was safer and more effective than other permanent methods of birth control, such as tubal ligation.

101. Defendants' express warranties as described in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics," were specifically negotiated and expressly communicated to Plaintiff in such a manner that Plaintiff understood and accepted them.

102. Defendants' affirmations of fact or promise and descriptions of Essure® as described in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics," regarding Essure® created a basis of the bargain for Plaintiff and/or her physicians.

103. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which Essure® was to be used and warranted the same to be in all respects fit, safe, effective, and proper for such purpose. Essure® was unaccompanied by adequate warnings of its dangerous propensities and lack of effectiveness that were either known or knowable to Defendants at the time of distribution and sale.

104. Defendants' breaches of their express warranties under state law parallel their violations of

105. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

106. Plaintiff and/or her healthcare providers reasonably relied upon the skill and judgment of Defendants, and upon said express warranties, in using Essure®. The warranties and representations were untrue in that Essure® was unsafe and unsuited for the use for which it was intended.

107. As soon as the true nature of Essure® and the fact that the warranties and representations were false was ascertained, Defendants were on notice of the breach of said warranties.

108. As a proximate result of Defendants' warranties and Plaintiff's reliance on same, Plaintiff has suffered and continues to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

SECOND CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

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

111. 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 they did not, in those undertakings, create unreasonable risks of personal injury to others.

112. 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 Essure® for their patients.

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®.

114. Defendants disseminated false information, as described in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics," to physicians, the medical community, and the public with knowledge that the information was, in fact, false and misleading.

115. Defendants made misrepresentations which are specifically outlined in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics."

116. 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 healthcare industry generally.

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

118. Defendants' breach of their duties under state law parallel their violation of federal law; the Essure® CPMA specifically mandates, and state law independently requires, that any representations regarding the device must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

119. 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®.

120. In willfully supplying the false and misleading information, Defendants negligently failed to exercise reasonable care to ensure that the information disseminated to physicians and patients concerning the properties and effects of Essure® was accurate and not misleading.

121. By failing to ensure representations regarding Essure® were truthful, accurate, and not misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

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

misrepresentations, as Defendants intended.

124. Specifically, Plaintiff would have never had Essure® implanted had she been aware that there had been 16,047 complaints regarding Essure®, or the falsity of the representations specifically delineated in the preceding paragraphs.

125. 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 loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

THIRD CAUSE OF ACTION

FRAUDULENT CONCEALMENT

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

128. 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®.

129. Defendants concealed material facts concerning Essure® from Plaintiff, her physicians, and other healthcare providers, including but not limited to 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."

b. Defendants fraudulently concealed eight perforations which were caused by Essure® and which Defendants failed to disclose to Plaintiff, Plaintiff's healthcare providers, and the FDA. The FDA memorialized this concealment in its Investigative Report and Form 483 dated January 25, 2011, stating: "the firm had not properly evaluated eight complaints of

peritoneal perforation for reporting to the FDA as an adverse event. Also, the firm's risk analysis did not include an evaluation of the risk associated with perforation of the peritoneal cavity."

c. On January 6, 2011, the FDA issued a violation to Defendants for not submitting timely MDR reports when it received information that reasonably suggested that Essure® "may have caused or contributed to a death or serious injury if the malfunction were to recur." This information included incidents regarding perforation of bowels, Essure® coils breaking into pieces, and Essure® coils migrating out of fallopian tubes. Defendants had notice of 168 perforations but only disclosed twenty-two to the FDA.

d. On January 6, 2011, the FDA cited Defendants for failing to document Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' design. In addition, Defendants' CAPA did not mention the non-conformity of materials used in Essure® or certain detachment failures, despite Defendants' knowledge of same.

130. 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.

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

132. Neither Plaintiff nor her healthcare providers were aware of the concealed and/or suppressed facts set forth herein. Had Plaintiff and/or her healthcare providers been aware of those facts, she would not have purchased and used Essure®, and Plaintiff would not have been injured as a result.

133. 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® device implanted had she been aware that there were eight reports of perforations of human cavities or that there had been 16,047 complaints regarding Essure®.

134. Plaintiff, her physicians, and the healthcare industry, justifiably relied on Defendants'

representations 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 and effective because as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

135. Defendants had a duty to warn Plaintiff, her physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. Defendants also had a post-market duty to monitor, report and update its labeling to show the true safety and risk parameters of the device.

136. As a proximate result of the concealment and/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 herein. Defendants' concealment was a substantial contributing factor in causing Plaintiff's injuries.

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

138. 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 loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

FOURTH CAUSE OF ACTION

FRAUDULENT/INTENTIONAL DECEIT

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

141. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk, is liable for any damages which she thereby suffers.

142. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the suggestion, as a fact, of that which is not true, by one who does not believe it to be true; the assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true; or the

suppression of fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact.

143. Defendants willfully deceived Plaintiff, her healthcare providers, the medical community, and the public in general, by suggesting untrue facts about their product that they knew to be false or had no reasonable ground for believing to be true, and by concealing material information concerning Essure®, which Defendants had a duty to disclose.

144. At the time Essure® was manufactured, distributed, and sold to Plaintiff, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiff and her physicians.

145. Through their unique knowledge and expertise regarding the defective nature of Essure®, and through their marketing statements to physicians and patients in advertisements, promotional materials, labels, and other communications as herein alleged, Defendants professed to physicians and Plaintiff that they were in possession of facts demonstrating that Essure® was safe and effective for its intended use and was not defective, when in fact Defendants concealed material information that they had a duty to disclose to ensure such physicians and patients were not misled.

146. Defendants intentionally and/or recklessly made false representations to Plaintiff and/or her physicians. Defendants made such representations to intentionally defraud Plaintiff and her physicians and to induce the purchase of Essure®.

147. Plaintiff and/or her healthcare providers reasonably relied on these false and misleading representations. Specifically, Plaintiff would have never had Essure® implanted had she been aware that there were eight reports of perforations of human cavities, that there had been 16,047 complaints regarding Essure®, or the falsity of the representations specifically delineated in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics."

148. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Essure®.

149. Defendants intentionally concealed and suppressed the true facts concerning Essure® with the intent to defraud Plaintiff, her physicians, the medical, scientific, and healthcare community, and the general public, and to induce Plaintiff and/or her physician to use Essure®. Plaintiff would not have

Essure® if she had known the true facts concerning the dangers of Essure®.

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

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

FIFTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY- INADEQUATE WARNINGS

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

153. In accordance with the California state law, Defendants owed the public, including Plaintiff, a duty to use reasonable care to provide adequate warnings reasonably necessary to advise users like Plaintiff and Plaintiff's doctors of any dangers inherent in the use of Essure® through timely reporting to the FDA and public. Defendants also had a post-market duty to monitor complaints and perform surveillance on its products, including, but not limited to, scientific literature related to the necessary component parts and materials utilized in Essure®.

154. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

155. Specifically, Defendants failed to: (a) report many of the roughly 16,000 complaints about Essure® to the FDA or the public; (b) report Essure®'s nonconformity with its performance specifications; and (c) update Essure®'s labeling or report to the FDA and the medical community their post-market information regarding complaints about Essure®. Defendants also failed to revise their labeling to warn of the accurate rate of occurrence of adverse events based upon the post-market adverse event information available to them.

156. Plaintiff's Essure® was defective at the time of its sale and distribution, and at the time it left the possession of Defendants, in that Defendants failed to adequately warn of the risks for migration, perforation, penetration, device breakage, removal, chronic abnormal bleeding and pain, autoimmune response, and other injuries involved in the use of Essure®. The accurate rate of occurrence for these

other injuries associated with the use of Essure® were not [illegible]

consumer, including Plaintiff and/or Plaintiff's physicians.

157. The Essure® was defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the product created a serious risk of migration, perforation, penetration, autoimmune response, and other harm to consumers, and Defendants failed to adequately warn consumers of said risks- including Plaintiff and/or her healthcare physicians- in accordance with California state law.

158. The Essure® manufactured and sold by Defendants was defective and unreasonably dangerous due to inadequate warnings and instructions because Defendants knew or should have known that Essure® created, among other things, a higher than expected risk for adverse events, and Defendants failed to adequately warn of those risks, to monitor those risks, report them and update its labeling regarding such risks when the information became available.

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

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

161. Despite the fact that evidence existed that the use of Essure® was unreasonably dangerous and likely to place users at serious risk to their health, Defendants failed to monitor and warn of the defects, health hazards and risks associated with Essure®.

162. 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 and implant Essure® for their patients.

163. Defendants knew that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive device despite its potential for serious severe and permanent side effects.

164. Defendants were required to provide adequate warnings to consumers and the medical community under federal and California state law, but failed to do so in a timely and responsibly

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

166. 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®.

167. 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 loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

168. By reason of the foregoing, Plaintiffs have been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

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

SIXTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY- MANUFACTURING DEFECT

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

171. Defendants owed the public, including Plaintiff, a duty to use reasonable care in testing and inspecting their product, in monitoring and assessing the manufacture of the Essure® devices placed into Plaintiff and accompanying implantation equipment, and in manufacturing and marketing Essure® according to the terms of its design specifications.

172. The Essure® system was defective at the time of its sale and distribution, and at the time it left the possession of Defendants, in that the system differed from Defendants' intended result and design specifications.

173. Defendants violated California law by placing the Essure® system into the stream of commerce in a defective and unreasonably dangerous condition.

174. For example, Defendants were cited by the FDA for, *inter alia*:

a. manufacturing Essure® with material that failed to conform to the approved design specifications;

b. failing to use pre-sterile and post-sterile cages;

c. manufacturing Essure® at an unlicensed facility;

d. failing to analyze or identify existing potential causes of non-conforming product and other quality problems;

e. failing to track non-conforming product;

f. failing to follow procedures used to control products which did not conform to specifications;

g. failing to have a complete Design Failure Analysis; and

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

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

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

177. Defendants knew that the Essure® system would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

178. Despite the fact that evidence existed that the use of Essure® was unreasonably dangerous and likely to place users at serious risk to their health, Defendants failed to report and warn of the defects, health hazards and risks associated with Essure®.

179. At all times relevant to this action, the dangerous propensities of Essure® were known to Defendants or were reasonably 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.

180. Defendants knew that physicians and other healthcare providers began commonly prescribing and implanting this product as a safe and effective contraceptive device despite its potential for serious severe and permanent injury.

Defendants failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of Essure®.

182. Defendants failed to adequately inspect, test, and validate Essure® after completion of assembly and immediately before delivery to Plaintiff.

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

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

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

186. As a proximate result of the Essure®'s defective condition at the time it was sold, the Essure® coils implanted into Plaintiff caused her to suffer excessive bleeding during her menstrual cycle, a constant burning sensation, pain, bloating, hives, severe abdominal cramping and extreme tenderness in her pelvic area associated with the sensation of the presence of a foreign object, leading to Plaintiff to undergo a laparoscopic salpingectomy and hysterectomy. Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

SEVENTH CAUSE OF ACTION

NEGLIGENT FAILURE TO WARN

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

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

190. Defendants had a duty under California state law to exercise reasonable care to provide adequate

warning about the risks and dangers of Essure® that were known or knowable to Defendants at the time of distribution.

191. Defendants breached their duty in that they failed to warn Plaintiff and her physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Essure® prior to the time of Plaintiff's implant, including failure to communicate adverse events similar to the injuries suffered by Plaintiff.

192. Specifically, Defendants breached these duties and violated federal and state law by, *inter alia*: receiving and failing to warn of or report many of the approximately 16,000 complaints about Essure® to the FDA or the public; failing to warn of or report Essure®'s failure to meet its performance specifications or perform as intended under the CPMA and FDA requirements; and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Essure®, including but not limited to:

a. instances of perforation and/or penetration of the fallopian tubes;

b. instances of perforation and/or penetration of the uterus;

c. instances of perforation and/or penetration of the bowel;

d. instances of perforation and/or penetration of the abdominal cavity;

e. instances of perforation and/or penetration of the peritoneal cavity;

f. instances of chronic/persistent abdominal and pelvic pain/cramping;

g. instances of chronic/persistent irregular vaginal bleeding;

h. instances of the device internally separating or breaking into pieces; and

i. instances of adverse events/reactions requiring device removal.

193. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to warn or otherwise ensure the safety of its users in violation of California state law, the Essure® CPMA and FDA regulations.

194. In addition, the Essure® CPMA set forth specific reporting requirements -as described above- that obligated Defendants to report:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;

b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;

c. any knowledge or information of Essure®'s failure to meet device specifications established in the approved CPMA;

d. any changes to the performance of the device;

e. changes to the facility or establishment to manufacture, process, or package the device;

f. whenever there is use of a different facility or establishment to manufacture, process, or package the device;

g. any information from any source that reasonably suggests a device may have caused or contributed to serious injury; and

h. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

195. Defendants negligently failed to comply with the above requirements and failed to take necessary actions- such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs- to advise users of Essure® of the defects and risks described above.

196. Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded.

197. If Defendants complied with their duty to warn, Plaintiff and her physician would have become aware of the information regarding adverse events and the ineffectiveness of the device in time to prevent her injuries. Defendants could have included this information in its labeling, physician use materials and patient pamphlets, which Plaintiff and her physician reviewed and relied upon, but Defendants chose not to include it. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, physicians began to study them further and published articles in well-respected medical journals. This information would have been available for review by Plaintiff and Plaintiff's physician.

198. Indeed, if Plaintiff had been adequately warned of these serious risks and adverse events, she

not have agreed to the Essure® implant. As a proximate and legal result of Defendants' failure to comply with its CPMA and FDA post-marketing regulations, Defendants breached their duty of care to Plaintiff under state law and caused Plaintiff past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

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

201. Plaintiff was prescribed, purchased, implanted, and used Essure®, as directed, for its intended purpose.

202. At all times mentioned herein, Defendant manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold Essure®, and- prior to the time that it was prescribed to Plaintiff, and after Plaintiff's implantation and continued use of Essure®- Defendants impliedly warranted to Plaintiff that Essure® was of merchantable quality and safe and fit for the use for which it was intended.

203. Defendants intended their warranties to reach members of the consuming public, including consumers such as Plaintiff.

204. This implied warranty extended to Plaintiff as the ultimate consumer and user of Essure®.

205. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge, judgment, and implied warranty of Defendants that Essure® was of merchantable quality and safe and fit for the use for which it was intended.

206. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the true nature of the risks associated with Essure® and was subsequently injured by its use.

207. Defendants sold Plaintiff a device unfit for its ordinary purpose because Defendants violated FDA regulations and the Essure® CPMA in the manufacture, design, testing, labeling, marketing, and promotion of Essure®.

208. Contrary to Defendants' implied warranty for Essure®, the device was not of merchantable quality, and it was neither safe nor fit for its intended use and purpose, as alleged herein.

209. Plaintiff and her physicians relied, to their detriment, on Defendants' implied warranties.

210. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered and will continue to severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

NINTH CAUSE OF ACTION

NEGLIGENCE / NEGLIGENCE *PER SE*

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

213. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their CPMA and with the FDCA in the manufacture, development, design, promotion, marketing, labeling, distribution, and sale of Essure®. *See* Essure® CPMA; 21 U.S.C. ch. 9 §§ 301, et seq.

214. Violations of the following federal regulations also constitute violations of Defendants' state law duties and give rise to negligence *per se*: 21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; and 21 § C.F.R. 820.70.

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

216. Defendant's violations of these statutes and regulations proximately caused Plaintiff's injuries alleged herein.

217. The conditions of the Essure® CPMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the CPMA. *See* 21 C.F.R. § 814.82(c).

218. Defendants had a parallel duty under California 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 Essure®, in manufacturing Essure®, and in marketing Essure® to the public. Defendants also undertook a duty to certify and train physicians on the proper implantation of the device.

219. Defendants were negligent under California state law in their development, promotion, 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 components into the design, manufacture, and assembly of Essure® that could not stand up to normal usage;

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

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

f. failing to exercise reasonable care to appropriately certify and train physicians on prescribing and implantation of the device.

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

221. Defendants also had a duty under California state law to exercise ordinary care in the manufacture of Essure® consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval.

222. Defendants negligently failed to manufacture Essure® consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval.

223. Defendants were cited by the FDA for, *inter alia*:

a. erroneously using non-conforming material in the manufacturing of Essure®;

b. failing to use pre-sterile and post-sterile cages;

c. manufacturing Essure® at an unlicensed facility;

d. manufacturing Essure® for three years without a license to do so;

e. failing to analyze or identify existing potential causes of non-conforming product and other quality problems;

f. failing to track non-conforming product;

g. failing to follow procedures used to control products which did not conform to specifications;

h. failing to have a complete Design Failure Analysis; and

i. failing to document CAPA activities for a supplier correction action.

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

225. Defendants further had a duty to ensure the physicians using the Essure® system were adequately trained, including on the use of the hysteroscopic equipment necessary for implantation of the device.

226. Defendants advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets that Essure® placement procedures were to be performed by doctors who were specifically trained, tested, certified, and authorized by Defendants to do so.

227. Only doctors authorized by Defendants were permitted to perform Essure® placement procedures.

228. As described above, Defendants negligently failed to adequately train implanting physicians in the implantation procedure, negligently certified/authorized implanting physicians who did not have the requisite training, failed to adequately train implanting physicians in hysteroscopy, and failed to ensure that certified/ authorized implanting physicians performed the procedure as frequently as required to maintain their certification/authorization by Defendants.

229. Upon information and belief, Physicians were incentivized to purchase Essure® by Defendants' distribution of free hysteroscopic equipment valued at approximately $20,000 to physicians that purchased twenty five Essure® kits. And while the hysteroscopic equipment was required to implant the device, the Defendants never provided a training manual or appropriate training for use of the

[redacted]scope.

230. Lastly, Defendants negligently failed to adequately train Defendants' employees who provided recommendations and advice to physicians who implanted the device.

231. 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.

232. Had Defendants exercised ordinary care, and complied with the then existing standards of care, Plaintiff would not have been injured.

233. 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 loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

TENTH CAUSE OF ACTION

VIOLATIONS OF CALIFORNIA BUSINESS & PROFESSIONS CODE §§17200, ET SEQ.

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

236. California Business & Professions Code § 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

237. Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of their products.

238. The acts and practices described above were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of California Business & Professions Code § 17200. The acts of untrue and misleading advertising set forth in preceding paragraphs are incorporated by reference and are, by definition, violations of California Business & Professions Code § 17200. This conduct is set forth fully herein, and includes, but is not limited to:

a. representing that Essure® was safe, fit, and effective for human use, knowing that said representations were false, and concealing that Essure® products had a serious propensity

to cause injuries to users;

b. engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Essure® was safer than other forms of permanent contraception, even though Defendants knew this to be false, and even though Defendants had no reasonable grounds to believe them to be true;

c. purposely downplaying and understating the health hazards and risks associated with Essure®;

d. issuing promotional literature and commercials deceiving potential users of Essure® by relaying positive information, while downplaying adverse and serious health effects known to Defendants, and concealing material relevant information regarding the safety and efficacy of Essure®;

e. failing to provide physicians with appropriate information to protect patients, including Plaintiff, by failing to disclose complaints regarding Essure®, failing to conduct proper pre-market testing and post-market surveillance, signal detection and follow up, and failing to disclose safety issues and safe prescribing practices for Essure® to physicians and healthcare providers; and

f. falsely representing that all doctors using Essure had special experience and training in the proper use of the device.

239. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code § 17200.

240. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Essure® and would not have incurred related medical costs and injury.

241. Defendants engaged in wrongful conduct, while at the same time obtaining under false pretenses, substantial sums of money from Plaintiff for the defective Essure® that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

242. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians, and consumers was to create demand for the sale of Essure®. Each aspect of Defendants' conduct combined to artificially create

sales of Essure®.

243. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in deciding whether to use Essure®.

244. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars from the prescription and sale of Essure® in California, sold in large part as a result of the acts and omissions described here.

245. Defendants are liable to Plaintiff for all damages which Plaintiff has suffered as a result of Defendant's unlawful, unfair, deceptive and fraudulent business practices. Under statutes enacted in California to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Plaintiff is a consumer who purchased Essure® pursuant to a consumer transaction for personal use and is, therefore, subject to protection under such legislation.

246. Under statutes enacted in California to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, Defendants are the supplier, manufacturer, advertiser, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

247. Defendants violated the statutes enacted in California to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising, by knowingly and falsely representing that Essure® was fit to be used for the purpose for which it was intended, when in fact Essure® was defective and dangerous as described above. These representations were made to Plaintiff, her physician, and the medical community at large.

248. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in California to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, and false advertising.

249. Defendants had actual knowledge of the defective and dangerous condition of Essure®, and failed to take any action to cure such defective and dangerous conditions.

250. As a direct and proximate result of Defendant's violations of Business and Professions Code § 17200, Plaintiff has sustained economic loss and other damages and is entitled to compensatory relief in

an amount to be proven at trial.

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

ELEVENTH CAUSE OF ACTION

VIOLATIONS OF BUSINESS & PROFESSIONS CODE §§ 17500, ET SEQ.

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

253. Plaintiff brings this cause of action pursuant to California Business & Professions Code § 17500.

254. California Business & Professions Code § 17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

255. At all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements as defined by California Business & Professions Code § 17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Essure®:

a. representing that Essure® was safe, fit, and effective for human use, knowing that said representations were false, and concealing that Essure® products had a serious propensity to cause injuries to users;

b. engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Essure® was safer than other forms of permanent contraception, even though Defendants knew this to be false, and even though Defendants had no reasonable grounds to believe them to be true;

c. purposely downplaying and understating the health hazards and risks associated with Essure®;

d. issuing promotional literature and commercials deceiving potential users of Essure® by relaying positive information, while downplaying adverse and serious health effects known to Defendants, and concealing material relevant information regarding the safety and efficacy of Essure®;

e. failing to provide physicians with appropriate information to protect patients, including Plaintiff, by failing to disclose complaints regarding Essure®, failing to conduct proper

pre-market testing and post-market surveillance, signal detection and follow up, and failing to disclose safety issues and safe prescribing practices for Essure® to physicians and other healthcare providers; and

f. falsely representing that all doctors using Essure had special experience and training in the proper use of the device.

256. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code § 17500.

257. The acts of untrue and misleading statements by Defendants described herein present a continuing threat to members of the public in that the acts alleged herein are continuous and ongoing, and the public will continue to suffer the harm alleged herein.

258. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars from the prescription and sale of Essure® in California, sold in large part as a result of the acts and omissions described herein.

259. As a direct and proximate result of Defendant's violations of Business and Professions Code § 17500, Plaintiff has sustained economic loss and other damages and is entitled to compensatory relief in an amount to be proven at trial.

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

TWELFTH CAUSE OF ACTION

VIOLATIONS OF CAL. CIVIL CODE §§ 1750, ET SEQ.

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

262. Plaintiff is informed and believes and thereon alleges that Defendants, by the acts and misconduct alleged herein, violated the Consumers Legal Remedies Act, California Civil Code §§ 1750, et seq. ("CLRA").

263. The CLRA applies to Defendants' actions and conduct described herein because it extends to transactions which are intended to result, or which have resulted, in the sale of goods to consumers.

264. Plaintiff is a "consumer" within the meaning of California Civil Code § 1761(d).

265. Defendants have violated, and continue to violate, the CLRA in representing that Essure® has characteristics and benefits which it does not have, in violation of California Civil Code § 1770(a)(5).

266. Defendants have committed acts of disseminating untrue and misleading statements as defined by California Civil Code § 1770, by engaging in the following acts and practices with the intent to induce members of the public to purchase and use Essure®:

a. representing that Essure® was safe, fit, and effective for human use, knowing that said representations were false, and concealing that Essure® products had a serious propensity to cause injuries to users;

b. engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Essure® was safer than other forms of permanent contraception, even though Defendants knew this to be false, and even though Defendants had no reasonable grounds to believe them to be true;

c. purposely downplaying and understating the health hazards and risks associated with Essure®;

d. issuing promotional literature and commercials deceiving potential users of Essure® by relaying positive information, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety and efficacy of Essure®; and/or

e. failing to provide physicians with appropriate information to protect patients, including Plaintiff, by failing to disclose complaints regarding Essure®, failing to conduct proper pre-market testing and post-market surveillance, signal detection and follow up, and failing to disclose safety issues and safe prescribing practices for Essure® to physicians and other healthcare providers.

267. The foregoing practices constitute false and misleading advertising and representations within the meaning of California Civil Code § 1770.

268. As a direct and proximate result of Defendant's violations of the California Consumer Legal Remedies Act, Plaintiff has sustained economic loss and other damages and is entitled to compensatory relief in an amount to be proven at trial.

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

REQUEST FOR PUNITIVE DAMAGES

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

270. 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, 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, promoted, marketed, advertised, distributed, and sold Essure® for use.

271. 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.

272. Defendants' misrepresentations include 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.

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

274. 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®.

275. 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.

276. 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.

277. 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.

278. 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; and
8. 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: March 15 2016

By: _____
MARTIN SCHMIDT, ESQ (SBN 171673)
Schmidt National Law Group
Attorney for Plaintiff