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**IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA**
**COUNTY OF ALAMEDA - UNLIMITED JURISDICTION**

MYRNA MIGLIACCIO, an individual,

Plaintiff,

v.

BAYER CORP., BAYER HEALTHCARE LLC, BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER AG, and DOES 1-10, INCLUSIVE,

Defendants.

Case No. RG16809292

COMPLAINT

**DEMAND FOR JURY TRIAL**

**(1) Negligent Failure to Warn**

**(2) Negligence**

**(3) Strict Products Liability**

**(4) Fraud**



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Plaintiff Myrna Migliaccio seeks judgment against Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Essure Inc. (f/k/a Conceptus, Inc.), Bayer Healthcare Pharmaceuticals Inc., Bayer AG, and Does 1 through 10 inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries resulting from Plaintiff being prescribed and implanted with Defendants' Essure® device. At all relevant times, Essure® was manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants or by Conceptus, Inc. which merged with Bayer on or about April 28, 2013.

## I. INTRODUCTION

1. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer; the manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

2. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the healthcare community and to consumers. The manufacturer also must carefully monitor its own manufacturing operations and quality controls to ensure that the device uniformly conforms to the manufacturer's approved design, as well as its representations and warranties and with specifications of approval.

3. When monitoring and reporting adverse events, as required by both federal regulations and California law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could mean that researchers, regulatory bodies, and the medical community are years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report post-market experiences, but it must also report the data as soon as it is received.



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4. This action arises from Defendants' post-market failures and misrepresentations about the safety and efficacy of their 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. The conduct of Bayer, as set forth below, violated its obligations under relevant federal and state regulations governing the post-market conduct of Class III medical device manufacturers. The same conduct also violated Bayer's duties under California law, thereby causing injury to the Plaintiff for which she seeks damages.

## II. PARTIES, JURISDICTION AND VENUE

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

6. Venue is proper in this county in accordance with Section 395(a) of the California Code of Civil Procedure because Defendant BAYER HEALTHCARE LLC resides in this county and the injuries alleged herein arose from conduct that occurred in this county.

7. At all times relevant hereto, Plaintiff is and was a citizen and resident of San Diego County, California.

8. Defendant BAYER CORP. is a for-profit corporation incorporated in the state of Indiana and is a wholly-owned subsidiary of Bayer AG. Defendant is authorized to and does business throughout the state of California.

9. Defendant BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the state of Delaware and is a wholly-owned subsidiary of Bayer AG. Defendant is authorized to and does business throughout the state of 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 AG and/or Bayer HealthCare LLC. Conceptus, Inc. ("Conceptus") was founded by Julian Nikolchev, a self-described "medical technology developer and serial entrepreneur," in 1992. 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 AG, and thereafter 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 are located at 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 AG. Defendant is authorized to and does business throughout the state of California.

12. Defendant BAYER AG is a German for-profit corporation. Defendant is authorized to and does business throughout the state of California through its wholly owned subsidiaries.

13. The true names and capacities of those defendants designated as DOES 1-10, whether individual, corporate, associate 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®

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

15. Essure® was first manufactured, 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 "STOP™" Permanent Contraception device.

16. Essure® is touted as a form of permanent female birth control (female sterilization). The device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes. The inserts are supposed to anchor and then elicit tissue growth creating the blockage of the fallopian tubes. Defendants intended the device to be implanted "permanently," *i.e.*, for the duration of each patient's lifetime.

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

18. The micro-inserts are comprised of two metal coils: one coil allegedly made of nitinol (nickel and titanium) and the other allegedly 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 and under hysteroscopic guidance (camera).

19. Defendants' disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians monitor this complicated process through hysteroscopic equipment including a hysteroscope, a lightbox, and a monitor, collectively known as a "tower."

20. Upon information and belief, the towers are valued at approximately $20,000 and were provided by Defendants to physicians for free if the physician purchased a certain number of Essure® units. The hysteroscopic equipment is a Class II medical that is not subject to pre-market approval; instead it was cleared for use through the 510(k) regulatory pathway.

21. After placement of the coils in the fallopian tubes, the micro-inserts expand upon release and allegedly anchor into the fallopian tubes. Defendants claim in their physician training manual and patient information booklets that the expanded coils and 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."

22. Defendants further claim in advertising materials that the coils will remain securely in place in the fallopian tubes for the life of the patient.

23. Defendants 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 implant procedure.

24. The Instructions for Use accompanying the Essure® device provide that patients should be counseled to receive a confirmation test three months post-implant to determine that the coil micro-inserts have created a complete occlusion in each fallopian tube. The Confirmation Test used is a hysterosalpingogram ("HSG") and is part of the design and formulation of the Essure® product.

25. Defendants have stated in a publicly available Form 10-K filed with the U.S. Securities and Exchange Commission that the HSG is "often painful" and "is also known to be highly inaccurate, with false-positive results in as many as 40% of HSG-diagnosed cases of proximal tubal occlusion. 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 and physicians.

26. Essure® was manufactured, and marketed to be used by gynecologists throughout the world, as a "quick and easy," "surgery-free" outpatient "simple" procedure that did not require general anesthesia and "requires no downtime for recovery." Defendants claimed that Essure® "will allow many tubal therapies for . . . permanent contraception which are currently performed surgically to be performed transcervically, thereby reducing the cost, trauma and recovery time associated with those therapies."

## IV. PRE-MARKET APPROVAL

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

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

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

a. proposed indications for use;

b. device description including the manufacturing process;

c. any marketing history;

d. summary of studies (including 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, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

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

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

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

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.

33. 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.

34. In addition to the requirements set forth in the CPMA, Defendants are required to comply with all FDA post –marketing requirements for Class III medical devices. Approval of a device through the PMA process signals the beginning, not the end, of a device manufacturer's duties to patients under both federal regulations and established California law. The requirements under federal regulations include, but are not limited to:

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

b. monitor the product after 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 CFR §§ 814 et seq.;

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

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

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

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

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

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

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

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

35. 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 contains 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.

36. 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.

37. 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.

38. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury, or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

39. The FDA publishes the adverse events and MDRs in a public, searchable Internet database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.



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## V. DEFENDANTS' ACTIONS VIOLATED FEDERAL AND STATE REGULATIONS GOVERNING THE DEVICE AND ALSO VIOLATED CALIFORNIA STATE LAW

40. 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 here failed to do so.

41. Defendants also have a duty under California law to exercise reasonable care in the manufacture, development, design, marketing, labeling, distributing, and sale of Essure® after it was approved for sale by the FDA in 2002. Defendants here failed to do so.

42. Defendants also had the obligations and the ability under federal regulations to maintain labeling that provides adequate warnings about risks and instructions for use; to ensure that the product was manufactured utilizing Good Manufacturing Practices; to conduct prompt, accurate and thorough post-market surveillance; to take action to ensure that the device can be used safely in accordance with the instructions; to maintain quality controls to adequately address, investigate, and assess the product's performance post-market; and to ensure that any labeling, warranties, or representations that Defendants made were not false or misleading in any respect. Defendants' conduct here failed to meet these federal obligations and also violated California law.

43. 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.

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

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

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



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47. Defendants' conduct violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 820.90 et seq.; 21 CFR §§ 814 et seq; 21 CFR §§ 820.198 et seq.; §§ 820. 100 et seq.; 21 CFR §§ 820.20 et seq.; 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.184 et seq.; and 21 CFR §§ 820.30 et seq. Defendants' conduct separately violated their duties under California law.

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

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

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

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

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

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

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

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

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

49. Upon obtaining knowledge of these potential device failure modes, the Defendants were required under the Essure® CPMA, 21 CFR §§ 820.30 et seq., 21 CFR §§ 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 Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

50. Defendants' conduct violated these FDA regulations and also separately violated its duties under California state law, thereby jeopardizing the health of patients, including Plaintiff.

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

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

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



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d. Conceptus' failure to submit MDRs 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

e. 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.

53. The FDA Establishment Inspection Report for the inspection that ended on January 6, 2011 states the following:

a. "My inspection of the complaint system of Conceptus Inc. found that the firm was not reporting complaints of loose micro-insert coils in the peritoneal or abdomino-pelvic cavity (See FDA483 Observation #2). . . . In some of these cases the micro-insert coil will migrate through the perforation in the tube and will be found on x-ray to be outside the female reproductive tract in the peritoneal cavity. Such cases will be reported as an MDR by the firm if the patient is complaining of pain and a second procedure is required to remove the coil. However, the firm will not report such complaints if an abdominal located coil is removed during a laparoscopic tubal ligation performed because of failure of the Essure procedure."

b. During this inspection, Conceptus gave the FDA inspector "an Excel spreadsheet with all of the complaints opened since Jan. 1, 2008 [and] there were 16,581 complaint[s] from 1/1/08 until 12/6/10 listed. There were 182 MDRs reported in the same time period."

c. Conceptus also gave the FDA inspector a more detailed complaint spreadsheet "that starts at 7/20/2010 and goes to 12/10/2010. That spreadsheet [had] a total of 2,752 complaints."

d. The FDA inspector looked at the complaints for perforation and noted that "none of the perforation complaints were reported as MDRs."



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54. 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.

55. These actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Conceptus, including, but not limited to, 21 CFR §§ 803.50 et seq.; 21 CFR §§ 814 et seq.; 21 CFR §§ 820.30 et seq.; 21 CFR § 820.198; 21 CFR §§ 820.100 et seq; and 21 CFR § 820.20. Defendants' actions also separately violated duties under California law governing the post-marketing conduct of Conceptus.

56. In May and June 2013, the FDA conducted another inspection that included an evaluation of Conceptus' and Bayer's complaint handling and adverse event reporting practices. During that inspection, the FDA inspector requested a complete list of complaints since January 2011. Defendants provided the FDA inspector with a spreadsheet that contained 16,047 complaints from January 2011 to May 2013.

57. The inspector reviewed 29 random complaint forms received by Defendants. Of 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.

58. Upon information and belief, from January 1, 2008 through May 2013, Defendants were receiving on average over 15 complaints per day about their product, and thousands of complaints each year. Defendants timely reported only a tiny fraction of these complaints to the FDA.

59. Defendants' actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Defendants, including, but not limited to, 21 CFR §§ 803.50 et seq.; 21 CFR § 820.198; 21 CFR §§ 820.100 et seq.; and 21 CFR §§ 820.20 et seq. Defendants' actions also separately violated duties under California law governing their post-market conduct.

60. Defendants had unique knowledge concerning the frequency, severity and permanence of the complications and risks associated with the Essure® device. Despite this unique knowledge, as outlined above, Defendants failed to unilaterally update its labeling through the CBE Process to advise Essure® users of the defects and risks described above.



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61. Defendants' actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Defendants, including, but not limited to, 21 C.F.R. § 814.39(d). Defendants' actions also separately violated duties under California law governing their post-market conduct.

62. Conceptus also failed to timely submit Post-Approval Studies under the Essure® CPMA. The six month report was due on August 24, 2012 but was not received by the FDA until December 14, 2012; the one year report was due February 23, 2013 but was not received by the FDA until March 8, 2013; and the eighteen month report due August 24, 2013 but was not received by the FDA until September 12, 2013.

63. Defendants' actions violated the conditions of the Essure® CPMA and federal regulations and requirements governing the post-marketing conduct of Defendants, including, but not limited to, 21 CFR §§ 814.80 et seq. Defendants' actions also separately violated duties under California law governing their post-market conduct.

64. 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."

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

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

67. By failing to update their labeling as new post-marketing information became available to ensure that its labeling remained both accurate and adequate, Defendants also rendered Essure® a "misbranded" device under the FDCA and thus not allowed to be marketed. Despite this, Defendants continued to improperly market Essure® for use in women, including the Plaintiff, at a time that they were prohibited from doing so under federal law. Defendants' actions separately violated duties under California law governing their post-market conduct.

68. By failing to comply with several CPMA conditions and federal regulations and requirements prior to implant into Plaintiff, Essure® was also considered to be an "adulterated" device under § 501(f) of the FDCA and not allowed to be marketed. 21 U.S.C. § 351(h); 21 CFR §§ 814.80 et seq. Despite this, Defendants continued to improperly market Essure® for use in women, including the Plaintiff, at a time that they were prohibited from doing so under federal law. Defendants' actions separately violated duties under California law governing their post-market conduct.

69. Defendants' failure to timely file MDRs and to report to the FDA complaints not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which Defendants knew of from the more than 32,000 complaints that they received, violated the CPMA, FDA post-marketing regulations, and parallel state law. Defendants' violations prevented Plaintiff, her physicians, and the public from understanding the true nature of Essure®'s adverse events, risks, and ineffectiveness.

70. Defendants did not provide any true medical training to physicians prior to selling their products, including Plaintiff's implanting physician. Instead, the training consisted of a printed manual and guidance / instruction from sales representatives who did not have any formal medical training.

71. Contrary to Defendants' representations, there was no meaningful Essure® training program provided to or required for prospective implanting physicians, including Plaintiff's physician. Defendants sold its Essure® system without regard to physicians' knowledge, training, or experience with hysteroscopes and the Essure® system itself, including, but not limited to the Essure® Instructions for Use and Physician Training Manual.

72. Defendants' actions violated duties under California law governing their post-market conduct.

## VI. DEFENDANTS ENGAGED IN FALSE AND MISLEADING SALES AND MARKETING TACTICS

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

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

75. The marketing campaign for Essure® was described 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.*"

76. 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.

77. Defendants advertised, promoted and marketed on its website, in its print and/or video advertisements, brochures and fact sheets the following representations 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



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clinical trials and five pregnancies during the first year of commercial experience. Additionally, several pregnancies have been reported subsequent to Essure® implantation. Between 1997 and 2005, 64 pregnancies were reported to Defendants. Adverse Event Report ESS 205 dated October 3, 2006 evidences a pregnancy after the three-month Confirmation Test was confirmed. Furthermore, a recent study indicates that women implanted with Essure® have a ten times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater.

b. The Essure® website, print advertising, and patient brochure described Essure® as a "[s]urgery-free" permanent birth control option, 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 actively concealed and failed to report complaints of perforations and pain which occurred as a result of Essure® as noted above. Essure® can cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and



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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 not reported by the Defendants.

e. The Essure® website, print advertising, and patient brochure stated "[t]he Essure® inserts are made from the same trusted, silicone free material used in heart stents" or words to that effect. However, the micro-inserts are not made from the same material as heart stents and do not elicit tissue growth. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure® micro-insert is not known." The Essure® inserts also contain nickel, which can cause severe reactions in patients.

f. The Essure® website, print advertising, and patient brochure stated "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure® is not "surgery-free" and can cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications. Defendants failed in their post-market obligations to monitor and report these serious adverse events.



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g. 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 stated, "We did not conduct a clinical trial to compare the Essure® procedure to laparoscopic tubal ligation."

h. 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 placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in one out of seven clinical participants. Moreover, Defendants failed to warn of the dangers associated with the hysteroscopic procedure, a necessary part of implantation of the device.

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

79. Defendants advertised, promoted, and marketed on its websites, in print and/or video advertisements, brochures, and fact sheets the following 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.

c. "[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.

d. "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.

e. 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.

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

81. 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."

## VII. THE FDA HEARINGS AND RESULTING FDA ACTION

82. Defendants not only violated federal regulatory duties and duties under California law, but also buried a massive amount of information that should have been shared with the medical and scientific community and the public. Because the Defendants failed to timely, completely, or accurately

report their knowledge of the risks and complications associated with the Essure® device, the public's knowledge of the risks associated with the Essure® device were seriously hampered and delayed. This endangered patient safety, including Plaintiff's safety.

83. As the FDA continued to force Defendants to provide additional information known to them that had been withheld, more information belatedly was made known to the medical community, including information concerning the frequency, severity and permanence of complications associated with the prescription and implementation of the Essure® device.

84. This belated and untimely release of relevant and important information led to an increasing number of adverse events being reported to the FDA about Essure® from patients and physicians. Because of these complaints, the FDA convened a public hearing concerning the safety and efficacy of the Essure® device on September 24 and 25, 2015. At that public hearing, Defendants continued to misrepresent the safety and efficacy of Essure®:

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

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 complaints of adverse events that it had received.

85. On February 29, 2016, the FDA announced "actions to provide important information about the risks of using Essure® and to help women and their doctors be better informed of the potential complications associated with" the device. The FDA took the following actions:

a. The FDA is requiring a black box warning on Essure® to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure® also warns: "Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure device during discussion of the benefits and risks of the device."

b. The FDA is requiring Defendants to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure®. The FDA's draft Patient Decision Checklist is a five-page document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ('perforation'), or movement of the device into the abdomen or pelvis ('intra-peritoneal migration')"; "allergy or hypersensitivity reactions"; symptoms such as changes in skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that "there is no reliable test to predict ahead of time who may develop a reaction to

the device"; the possibility that the Essure device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure device has to be removed after placement, it will require surgery to remove and possibly a hysterectomy.

c. The FDA has also ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." The study must provide data on "the risks associated with Essure and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure device. The study will also evaluate how much these complications affect a patient's quality of life. . . . The FDA will use the results of this study to determine what, if any, further actions related to Essure are needed to protect public health."

86. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Plaintiff of the true risks of Essure®. Had the Defendants complied with their federal regulatory duties and their duties under California law by adequately assessing the true risks of their device and appropriately reporting the known risks and complications in a timely fashion, the Plaintiff and her physicians would have had this relevant, critical information available to them prior to the implant of the Essure® device.

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

## VIII. PLAINTIFF'S HISTORY

88. On December 8, 2011, Myrna "Betty" Migliaccio sought care for permanent birth control to prevent pregnancy. Mrs. Migliaccio was offered Essure® after being provided information about the procedure.

89. Mrs. Migliaccio relied on the representations made about Essure® and in the Essure® paperwork provided to her in reaching her decision to have the Essure® procedure.



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90. On January 17, 2012, Mrs. Migliaccio underwent the Essure® procedure during an office/outpatient visit at Anupam Garg, M.D., a Medical Corporation in San Diego, California.

91. Following the Essure® procedure, Mrs. Migliaccio began to experience right side pelvic cramping, excruciating pelvic pain, abnormal bleeding, allergic reactions including urticaria (hives), inflammation of the fallopian tubes, and other symptoms.

92. Mrs. Migliacco has been unable to work since approximately February 2014 due to the complications resulting from the Essure® procedure.

93. Following the Essure® procedure, Mrs. Migliaccio was diagnosed with pelvic pain, chronic salpingitis associated with Essure® implants, severe adhesive disease, and endometrial polyps by her health care provider.

94. On January 27, 2016, Mrs. Migliaccio underwent a surgical procedure to remove a portion of each fallopian tube and both of the implanted Essure® devices.

95. 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.

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 could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendants' tortious conduct. Defendants' misconduct and fraudulent concealment of the relevant facts, as described *infra*, tolls any relevant statute of limitations. Under appropriate application of the discovery rule, Plaintiff's suit is filed well within the applicable statutory limitations period.

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

## FIRST CAUSE OF ACTION

## NEGLIGENT FAILURE TO WARN

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

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

100. As set forth, Defendants breached their duty in that they failed to timely warn Plaintiff and her physicians by, among other things, not timely reporting the risk of serious defects and life-altering complications described herein that they knew or should have known were associated with Essure®; failing to timely communicate adverse events to the FDA, including the roughly 32,000 complaints that it had internally received about Essure®; and failing to inform physicians and patients about known and knowable complications through their product labeling.

101. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiff's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiff and/or Plaintiff's physician, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

102. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiff has experienced due to Essure®.

103. Defendants' delay in timely reporting their known complications prevented the Plaintiff and her physicians from having timely information concerning the real life risks associated with the Essure® device. Had the Plaintiff received timely and adequate information of these serious risks and adverse events, she would not have agreed to the Essure® implant.

104. Defendants breached their duty of care to Plaintiff under California 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.

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

**SECOND CAUSE OF ACTION**

**NEGLIGENCE**

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

107. Defendants had a duty under California law to exercise reasonable care in the manufacture, development, marketing, labeling, distributing, and sale of Essure® after it was approved for sale by the FDA in 2002.

108. 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.

109. Defendants also undertook a duty under California law to certify and train physicians on the proper use and surgical technique associated with the Essure® device.

110. As set forth above, Defendants breached their duties under California law by, among other things: (1) manufacturing actual Essure® devices that differ from the specifications set forth in the CPMA, its Supplements, the Conditions of Approval and/or other federal regulations; (2) failing to correctly monitor its products to ensure that it complied with appropriate quality control procedures and to track nonconforming products; (3) failing to conduct regular risk analysis of its Essure® device, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes and failing to exercise appropriate post-market quality controls; (4) failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two-year report schedules; (5) failing to comply with applicable federal and state regulations; (6) failing to adequately train Defendants' employees who provided recommendations and advice to physicians who implanted the device; (7) making false, inaccurate and misleading statements

concerning the properties and effects of the Essure® device; and (8) failing to properly train and educate physicians on the use of the Essure® device.

111. Defendants knew or should have known that consumers such as Plaintiff, physicians, the medical community, and the public, would reasonably rely on the false, inaccurate and misleading statements concerning the properties and effects of the Essure® device.

112. 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®.

113. Plaintiff and/or Plaintiff's physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended. Specifically, Plaintiff would have never had the Essure® implanted had she been aware that there had been over 30,000 complaints regarding Essure®, or the falsity of the representations specifically delineated in the preceding paragraphs.

114. 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.

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

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

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

## THIRD CAUSE OF ACTION

## STRICT PRODUCTS LIABILITY

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

119. 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 the product did not adequately warn of the risks involved in its use and in that the system differed from Defendants' intended result and design specifications.

120. The defects inherent in the Essure® device were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physicians.

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

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

123. 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.

124. 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.

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

**FOURTH CAUSE OF ACTION**

**FRAUD**

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

127. 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.

128. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of section 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.

129. As set forth above, the Defendants willfully deceived the Plaintiff and her healthcare providers, the medical community, and the public in general, by making representations 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 the Defendants had a duty to disclose.

130. At the time Essure® was manufactured, distributed, and sold to Plaintiff, the 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.

131. 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 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 were not misled.

132. 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 had been over 32,000 complaints regarding Essure®, the vast majority of which were not timely reported to the FDA, the medical community, or the public. In addition, Plaintiff would have never had the Essure implanted had she been aware of the falsity of the representations specifically delineated in the foregoing section, "Defendants Engaged in False and Misleading Sales and Marketing Tactics."

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

134. 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 losses and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

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

**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:



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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 an award of attorneys' fees and costs;
4. For prejudgment interest and the costs of suit;
5. Punitive or exemplary damages according to proof; and
6. 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 28, 2016

Respectfully submitted,

**GIBBS LAW GROUP LLP**

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