UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

BRITTANY DAVENPORT,

Plaintiffs,

Civil Action No.

v.

BAYER CORPORATION., an Indiana corporation; BAYER HEALTHCARE LLC, a Delaware company; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.), a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation

Defendants.

COMPLAINT

COMES NOW BRITTANY DAVENPORT, Plaintiff herein, complaining of BAYER CORPORATION, an Indiana corporation; BAYER HEALTHCARE LLC, a Delaware company; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.), a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation, Defendants herein, and for cause of action say:

I. PARTIES AND JURISDICTION

1. Plaintiff Brittany Davenport ("Plaintiff") is, and at all times material hereto was a resident and citizen of the State of Louisiana.
2. Defendant Bayer Corporation is, and at all times material hereto was, a corporation organized under the laws of the State of Indiana, with its principal place of business in

3. Pennsylvania, a citizen of Indiana and Pennsylvania; and may be served with process by serving its registered agent for service,

4. Defendant Bayer Healthcare, LLC is, and at all times material hereto was, a limited liability company organized under the laws of the State of Delaware, a wholly owned subsidiary of Bayer AG, a citizen of Germany (Therefore, Bayer Healthcare, LLC is a citizen of Delaware and Germany); and may be served with process by serving its registered agent for service, Corporation Service Company, 501 Louisiana Avenue, Baton Rouge, LA 70802.

5. Defendant Bayer Essure, Inc. is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of California, a citizen of Delaware and California; and may be served with process by serving its registered agent for service, Corporation Service Company, 2711 Centerville Rd., Suite 400, Wilmington, DE 19808.

6. Defendant Bayer Healthcare Pharmaceuticals, Inc. is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey, a citizen of Delaware and New Jersey; and may be served with process by serving its registered agent for service, Corporation Service Company, 2711 Centerville Rd., Suite 300, Wilmington, DE 19808.

7. Defendant Bayer Corporation, Defendant Bayer Healthcare, LLC, Defendant Bayer Essure, Inc., and Bayer Healthcare Pharmaceuticals, Inc. shall hereinafter, jointly and severally be referred to as "Bayer" or "Defendant."

8. This is a lawsuit for personal injury damages in excess of $75,000.00. There is complete diversity of citizenship between Plaintiff and all of the Defendants as the parties are

citizens/entities of different states. Accordingly, subject matter jurisdiction in proper in this Court pursuant to 28 U.S.C. 1332. Further, this Court has personal jurisdiction over the Defendants because they have done business in the State of Louisiana, have committed a tort in whole or in part in the State of Louisiana, have substantial and continuing contact with the State of Louisiana, and derive substantial revenue from goods used and consumed within the State of Louisiana. The Defendants actively sell, market and promote their Mesh to physicians and consumers in this state on a regular and consistent basis.

9. Defendants are subject to *in personam* in the U.S. District Court for the Eastern District of Louisiana because they placed a defective product in the stream of commerce and that product caused personal injuries to Plaintiff (who resides in Louisiana) in Louisiana. Further, venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants conduct substantial business in this District.

II. INTRODUCTION

1. This action arises from Defendants' failures to warn about serious health risks associated with their permanent birth control device, Essure®. Essure® is a Class III medical device that has been approved by the U.S. Food and Drug Administration (FDA) for sale in the United States. When the FDA approved the device, the FDA was not aware that the device could cause serious health risks, such as perforation of the uterus, chronic pain, and prolonged bleeding, as well as unintended pregnancies.
2. After the FDA approved the device for sale and it began to be implanted in patients, Defendant became aware of serious adverse events that should have led Defendants to (a) directly inform healthcare providers and consumers of these risks by revising the warning

label for the device and (b) reported the adverse events that should have led Defendants to (a) directly inform healthcare providers and consumers of these risks by revising the warning label for the device and (b) Reported the adverse events to the FDA. Defendants failed to warn healthcare providers and consumers about roughly 16,000 complaints of serious injuries associated with Essure after the device was approved for sale. Defendants also failed to timely report this new information to the FDA, which, upon evaluating the information, required a black box warning to reflect serious health risks that were ultimately suffered by Plaintiffs. If the Defendants had timely and adequately warned plaintiffs' health care provider and Plaintiffs of this new risk information, Plaintiffs' injuries would have been avoided.

3. Not only did Defendants fail to warn about Essure's serious health risks, they also falsely advertised, warranted and represented that Essure® was safer and more effective than other methods of permanent birth control.

4. 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, as well as Bayer's duties under Louisiana Law.

III. DESCRIPTION OF ESSURE®

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

2. 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.

3. Essure® is touted as a form of permanent female birth control (Female sterilization) with a 99.74% effectiveness rate of preventing pregnancy. Defendants market the device as being safer and more effective than alternative forms of birth control. 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 tum, bilateral occlusion (blockage) of the fallopian tubes. Defendants intended the device to be implanted "permanently," i.e., for each patient's lifetime.
4. 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.
5. 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.
6. 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 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 Defendants to physicians for free if the physician purchased twenty-five Essure® units.
7. The hysteroscopic equipment is not part of the Essure® device or any pre-market approval process, but the equipment is necessary for proper implantation of the Essure® device.

8. Defendant Bayer's website warned physicians, "[i]n order to be trained in Essure® you must be a skilled operative hysteroscopist." But Bayer's training materials did not include a training manual for hysteroscopic equipment. The Defendants' training was provided not by physicians but by unqualified sales representatives.

9. After placement of the coils in the fallopian tubes, the micro-inserts expand and anchor into the fallopian tubes. Defendants claim in their physician training manual and patient information booklets that the expanded coils and a chronic inflammatory and fibrotic response to the PET fibers elicit tissue growth that blocks the fallopian tubes and prevents pregnancy. According to Defendants, "the tissues in-growth into the insert caused by the PET fibers results in both inserts retention and pregnancy prevention."

10. Defendants claim that "correct placement" of Essure® "is performed easily because of the design of the micro-insert," and the physician training manual suggests the system and hysteroscope allow for visual confirmation of each insert's proper placement during the implant procedure. 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 a "proven permanent birth control procedure that works with your body to create a natural barrier against pregnancy" and that it is "not reversible."

11. The Instructions for Use ("IFU") accompanying the Essure® device provide that patients should be counseled to receive 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 hysterosalpingograrn (HSG Test") and is part of the Essure® product.

12. 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.

13. Essure® was manufactured, marketed, and promoted by Defendants to be used by gynecologists throughout the world. In advertisements and patient information booklets, Defendants claimed their product entailed a "quick and easy," "surgery-free" outpatient "simple" procedure that did not require general anesthesia and "requires no downtime for recovery." If Defendants had not so promoted the Essure, Plaintiffs physician and Plaintiff would not have chosen to use the Essure device. If the Essure device had not been used in Plaintiff, Plaintiff would not have suffered the injuries described herein.

IV. PRE-MARKET APPROVAL

1. In April 2002, Conceptus submitted its Pre-Market Approval Application to the United States Food and Drug Administration ("FDA") for the Essure® device.
2. Pre-Market Approval "PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices based on the information available at the time. *See* 21 U.S.C. *§* 360(e); 21 C.F.R. § 814.3(e).
3. 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 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 any 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.

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

5. The FDA's Conditional Premarket Approval (CPMA) Order for Essure included the following requirements:

a. conduct a post approval study in the U.S. to "document the bilateral placement rate{of Ensure®} fore newly trained physicians";

b. establish the effectiveness of Ensure® 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 when unanticipated adverse effects, increases in 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 with 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. "report to the FDA whenever it received information from any source that reasonably suggested that the device may have caused or contributed to a

serious injury";

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.

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

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.

7. The CPMA Order acknowledged the Defendants' ability to update safety warnings for Essure® without prior FDA approval by utilizing the "Changes Being Effected "provision in 21C.F.R. §814.39(d)(2).

V. A Manufacturer's Obligation to Update Its Product Labeling To Account for New Safety Information Arising After the Device Received Pre-Market Approval

1. 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 Louisiana law. The FDA's initial approval of a device label amounts to a finding by the FDA that the label is adequate for purposes of gaining initial approval to market the device. It does not represent a finding by the FDA that the label can never be deemed inadequate after approval as new safety information from the real world experience with the device becomes available to the manufacturer. Sound reasons support these principles: there are cases such as Essure® where evidence of the device's defects comes to light only after the device received premarket approval.

2. After Essure® received pre-market approval, Defendants were at all times responsible for maintaining the labeling of Essure(s) in light of the most current risk information obtained from the real world clinical experience with the device. There is no federal requirement that a manufacturer maintaining its original warning language in the face of new safety information. Nor does federal law give device manufacturers a right to market their device using the label originally approved by the FDA when new post-market information bearing on the safety of the device comes to light. To the contrary, the FDA required Defendants not to sell a device that was accompanied by an inadequate warning or had a label that was false or misleading in any respect, 21 U.S.C.§325(a),(f)(2), because such a deficient warning rendered the device "misbranded" under 21 U.S.C.§331.
3. Defendants had the ability under federal law, and the duty under state law and federal law, to directly warn healthcare providers and consumers by unilaterally updating the labeling of Essure® to reflect newly acquired safety information without advance approval by the FDA 21 C.F.R.§814.39(d). These updates include:

4. 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;
5. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;
6. Labeling changes that ensure it is not misleading, false, or contains unsupported indication; and
7. 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.
8. Defendants breached their duties under federal law and state law to maintain labeling that (a) added warnings about the adverse reactions alleged herein for which there was reasonable evidence of a causal association; (b) added instructions for use that would enhance the safe use of the device; and (c) added descriptions of adverse events to ensure that the labeling was not false or misleading.
9. Defendants post-approval obligations under federal law also included 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 m 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 analysis, 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.;

10. Report on Post Approval studies in a timely fashion, 21 C.F.R§§801, et seq.

11. Had Defendants fulfilled these Obligations in a timely fashion, which federal and state law required them to do, Plaintiffs' injuries would not have occurred. Defendants failed to do so. If Defendants fulfilled these obligations, Plaintiffs physician and Plaintiff would have been aware of the foregoing risks of the Essure device and would not have chosen to use the Essure device. If the Essure device had not been used in Plaintiff, Plaintiff would not

have suffered the injuries described herein.

12. The claims in this case concern Defendants' duties that arose after premarket approval of Essure®, when Defendants learned of new information bearing on the safety of its device. Defendants breached these duties to take reasonable steps to prevent foreseeable and intended risks, including to the Plaintiffs, in multiple ways, as discussed below.

VI. Defendants Engaged in False and Misleading Sales and Marketing Tactics

1. Defendants violated the Essure® CPMA and §§502(q) and ® of the FDCA and parallel state laws by engaging in false and misleading advertising of Essure®.
2. Defendants continue to sell their product with misleading and false advertising in violation of the conditions of the Essure® CPMA and state laws.
3. The marketing campaign for Essure(s) 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(f) 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(f) as the main topic. In early April 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 tum, 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"*
4. 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.

5. 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:

6. 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.

7. 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.

8. 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.

9. 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.

10. 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 fibers 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.

11. 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.

12. 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 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."

13. 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 gynecologist 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.

14. 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,

15. Doctors and patients, including Plaintiffs and their implanting physicians, relied on these misrepresentations by Defendants. If these misrepresentations had not been made to Plaintiff or her physician, Plaintiff or her physician would not have chosen to use the Essure device, and Plaintiff would not have suffered the injuries set forth herein.

16. Defendants advertised, promoted, and marketed on their website, 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.

17. "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.

18. 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 effec.t. 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 representative to "train" physicians.

19. "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.

20. Doctors and patients, including Plaintiffs and their implanting physicians, also relied on these omissions and/or misrepresentations by Defendants.

21. 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."

22. The Defendants conduct not only violated its federal regulatory duties and its duties under Louisiana law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. 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 risk associated with the Essure® device were seriously hampered and delayed. This endangered patient safety, including Plaintiffs' safety.

23. As the FDA continued to force Defendants to provide additional information known to them that had been withheld, more information elated 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.

24. 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.

25. 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®.

26. 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 ligation and higher than the rates reporter by Bayer to the FDA at the public hearing.

27. 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 represented to physicians and patients that a nickel sensitivity test was sufficient to determine whether a patient was a suitable candidate for an Essure® device.

28. Defendants testified that the 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.

29. 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 to adverse events that they had received.

30. 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. If Defendants had complied with the Essure® CPMA and parallel state laws, Plaintiff or her physician would have chosen not to use the

Essure device and Plaintiff would not have suffered the injuries and damages alleged herein.

VII. FDA REQUIRES BLACK BOX WARNING FOR ESSURE®

1. 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:

2. 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."

3. 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 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.

4. 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 the public health."

5. 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 Louisiana law by warning about and reporting the known risks and complications in a timely fashion, the Plaintiffs and their physicians would have had this relevant, critical information available to them before the implant of the Essure® device. If they had this information before the Essure was placed in Plaintiff, Plaintiff or her physician would have chosen not to use the Essure device, and Plaintiff

would not have suffered the injuries and damages caused by the Essure device alleged herein.

VIII. DEFENDANTS WERE ARE OF DEFECTS AND SERIOUS ADVERSE EVENTS ASSOCIATED WITH ESSURE® AND FAILED TO COMPLY WITH THE FDA AND OTHER REGULATIONS VIOLATION LOUISIANA STATE LAW

1. Defendants have a duty under Louisiana law to exercise reasonable care in warning Plaintiff and/or Plaintiffs' 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 risk associated with its device.

2. 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 risk associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to monitor, warn, or otherwise ensure the safety and the efficacy of its users in violation of Louisiana state law and FDA regulations.

3. 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 the FDA-regulated product may be in violation of FDA requirements.

4. 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.

5. The FDCA requires that medical device manufactures 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 even 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.

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

See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf'MAUDE/search.cfm

7. Defendants have a duty under Louisiana law to exercise reasonable care in warning Plaintiffs and/or Plaintiffs' physicians about the dangers of Essure® that were known or knowable to Defendants at the time of distribution. Defendants here failed to do so.

8. Defendants also have a duty under Louisiana 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. Defendants here failed to do so. If Defendants had complied with its obligations under Louisiana law, which parallel its obligations under federal law, Plaintiff or her physician would have chosen not to use the Essure device and Plaintiff would not have suffered the injuries and damages caused by the Essure device as set forth

herein.

9. 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 manufacturing issues that arise from the device; and to ensure that any labeling warranties, or representations Defendants made were not false or misleading in any respect. Defendants here failed to do so. If Defendants had done so, Plaintiff or her physician would have chosen not to use the Essure device and Plaintiff would not have suffered the injuries and damages caused by the Essure device as set forth herein.

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

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

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

13. 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 quality sources to identify existing and potential causes of nonconforming product- such as a 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.

14. Defendants' conduct violated the conditions of the Essure® CPMA, a 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.

15. 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.

16. 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 action- 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 Louisiana state law, thereby jeopardizing the health of patients. If Defendants had complied with these obligations, Plaintiff or her physician would have chosen not to use the Essure device and Plaintiff would not have suffered the injuries and damages caused by the Essure device as set forth herein.

17. 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.

18. 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.

19. 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.

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

21. This conduct violated parallel Louisiana state laws governing the post-marketing conduct by Conceptus.

22. 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.

23. 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;

24. 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 document 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 CPA an incident involving the erroneous use of uncertified material by Conceptus' contract manufacturer in a validation protocol.

25. 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 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. I, 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 for the perforation complaints were reported as MDRs."

26. 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.

27. Defendants' actions set forth above violated the conditions of the Essure® CPMA. Defendants' actions violated parallel state laws governing the post-marketing conduct of

Conceptus. If Defendants had complied with these obligations, the FDA would have required Defendants to inform physicians and patients of these risks, Plaintiff or her physician would have been aware of these risks, and Plaintiff or her physician would have chosen not to use the Essure device and Plaintiff would not have suffered the injuries and damages caused by the Essure device as set forth herein.

28. 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.

29. 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, the FDA requested a complete list of complaints since January 2011. Defendants provided the FDA inspector with a spreadsheet containing 16,047 complaints Conceptus received on the Essure® device between January 2011 and the date of the inspection, only 183 of which were reported by Defendants to the FDA as MDRs.

30. 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.

31. 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.

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

33. Defendants had unique knowledge concerning the frequency, severity and permanence of

the complications and risks associated with Essure® device. Despite this unique knowledge, 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 Louisiana state law.

34. 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 Louisiana law governing their post-market conduct.

35. 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.

36. Defendants' action 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.

37. The FDA also requires that upon purchase of the 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."

38. 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 C.F.R.§§814.39 et seq, Defendants' actions also separately violated duties under Louisiana law governing their post-market conduct.

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

40. 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. These actions also violated parallel state laws governing Defendants; marketing representations and warnings. 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 Louisiana law governing their post-market conduct.

41. 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(:t) of the FDCA and not allowed to be marketed 21 U.S.C.§351(h); 21 C.F.R.§§814.90, et seq. However, Defendants continued to market Essure®. Despite this, Defendants Continued to improperly market Essure® for use in women, including the Plaintiffs; at a time that they were prohibited from doing so under Federal law. Defendants' actions separately violated duties under Louisiana law governing their post-market conduct.

42. Defendants' failure to timely file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from the more than 32,000 complaints that it 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.

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

44. Contrary to Defendants' representations, there was no meaningful Essure® training program, provided to, let alone required for, prospective implanting physicians, including Plaintiffs physician, to complete prior to selling its Essure® system. 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 TrainingManual.

45. Defendants' actions violated duties under Louisiana law governing their post-market conduct.

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

47. Prescribing and implanting physicians, healthcare providers and patients, including Plaintiffs 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.

IX. PLAINTIFF'S HISTORY

90. Plaintiff received her device on May 13, 2016. Following the implantation of her Essure device, plaintiff has suffered with heavy bleeding with large clots, severe abdominal cramping and pelvic pain, painful stomach bloating, leg pain, heavy menstrual cycles, severe itching, headaches, fatigue, as well as other things.

91. Plaintiff underwent a surgery on October 20, 2016 to have the Essure device removed.

COUNT I: FAILURE TO WARN LA. R.S. 9:2800.57

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

93. Defendants 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.

94. Defendants had a duty under Louisiana 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.

95. 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 Plaintiffs' implant, including failure to communicate adverse events similar to the injuries suffered by Plaintiffs.

96. Specifically, Defendants breached these duties and violated federal and state law by, inter alia: receiving and failing to warn of or report Essure®'s failure to meet its performance specifications or perform as intended under 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.

97. 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 Louisiana state law, the Essure® CPMA and FDA regulations.

98. 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.

99. 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.

100. 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.

101. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physicians, 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 Plaintiffs and/or Plaintiffs' physicians, 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 Plaintiffs 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 could have included this information in its labeling, physician use materials and patient pamphlets, which Plaintiffs and their 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.[1] This information would have been available for review by Plaintiffs and Plaintiffs' physicians.

105. Indeed, if Plaintiffs had been adequately warned of these serious risks and adverse events, they would 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 Plaintiffs under state law and caused Plaintiffs past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other

[1] 1 See "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization; an observational cohort study" available online at: http://www.bmj.com/content/35l/bmj.h5162.com : See "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: http://www.con traceptionioumal.org/pb/assets/raw/Health%20Advance/ioumal/contra/CON-8309-FINAL.pdf; See "Revisiting Essure- Toward Safe and Effective Sterilization" available online at http://www.ne jm.org/doi/ full/10.1056/NEJMpl S10514

injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

106. WHEREFORE, Plaintiffs pray for judgement against Defendants as hereinafter set forth.

COUNT II: STRICT LIABILITY – DESIGN DEFECT, MARKETING DEFECT, CONSTRUCTION OR COMPOSITION DEFECT & MANUFACTURING DEFECT: LA. R.S. 9:2800.55 AND 9:2800.56

1. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
2. Essure® was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Essure® could cause injuries such as those suffered by Plaintiff during foreseeable use. This fact was known to Defendant at the time Essure® was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including Plaintiff. Nonetheless, Defendant failed to warn that Essure® was designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Such a failure to warn rendered the Essure® unreasonably dangerously defective as designed and marketed.
3. At all times material to these allegations, Defendant manufactured, distributed, tested, packaged, promoted, marketed, labeled, designed, and sold Essure® as alleged herein.
4. Defendant, as manufacturers of healthcare products, are held to the level of knowledge of an expert in the field.
5. The Essure® implanted in Plaintiff was defective in design and formulation in the following respects:

a. When it left the hands of the Defendant, this device was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff or Plaintiff's physicians;

b. Any benefit of this device was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendant intended;

c. There are no patients for whom the benefits of Essure® outweighed the risks;

d. The subject product was not made in accordance with the Defendant's specifications or performance standards;

e. There are no patients for whom Essure® is a safer and more efficacious device than other products in its class; and/or

f. There were safer alternatives that did not carry the same risks and dangers that Defendant' Essure® had.

6. The Essure® implanted in Plaintiff was defective at the time it was distributed by the Defendant or left their control.

7. The Essure® implanted in Plaintiff was expected to reach user without substantial change in the condition in which it was sold.

8. The Essure® implanted in Plaintiff reached Plaintiff without substantial change in the condition to which it was sold.

9. There were safer alternative methods and designs for Defendant's Essure®.

10. Plaintiff was a patient who the Defendant reasonably expected would be administered Essure®.

11. Defendant were at liberty to withdraw Essure® from the market at any time, but failed to do so.

12. The defective and unreasonably dangerous design and marketing of Essure® was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability

theories set forth in Restatement (Second) of Torts, Defendant are liable to Plaintiff for all damages claimed in this case to which Plaintiffs are legally entitled.

13. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Essure®, Plaintiff was injured as described herein. All of said injuries caused and/or continue to cause Plaintiff's damages, for which Plaintiff is entitled to damages.

14. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Essure®, Plaintiff was required to obtain reasonable and necessary health care treatment and services and incurred expenses for which Plaintiffs are entitled to damages.

15. As a direct and proximate result of the design, marketing and manufacturing defects of Defendant's product, Essure®, Plaintiff suffered serious and permanent injury, and the harms as previously alleged herein.

COUNT III: NEGLIGENCE/NEGLIGENCE PER SE

107. Plaintiff incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follow:

108. 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, developments, promotion, marketing, labeling, distribution, and sale of Essure®. See Essure® CPMA; 21 U.S.C. ch.9§§301, et seq.

109. Violations of the following federal regulations also constitute violations of Defendants' state law duties and give rise to negligence *per se:* 21 U.S.C *§* 352(a), (f)(2), (q); 21 U.S.C *§* 360(e), (q), (r); 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.P.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.P.R.§ 820.22; 21 C.P.R.§ 820.25; 21 *§* C.F.R. 820.70; 21 C.F.R. 820, 198; 21 C.P.R. 820.100. Said violations include but are not limited to:

a. 21 U.S.C. § 352(a) because Conceptus and Bayer promoted for sale of misbranded and adulterated products because the Essure® label is false and misleading because Essure® is not a safer more effective method of permanent sterilization than alternative methods, evidenced by the over 1 0,000 reported adverse events consisting of serious injuries and pregnancies, by numerous Essure® studies consisting of thousands of women reporting that patients who undergo the Essure® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

b. 21 U.S.C. § 352(q) because Conceptus and Bayer created and distributed false and misleading advertising for Essure® which is a "Restricted Device" because Essure® is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure® studies consisting of thousands of women reporting that patients who undergo the Essure® procedure are more likely to experience injuries and complications which require or will require surgical intervention or reoperation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

c. 21 C.F.R. *§* 820.3(z) (x), 21 C.F.R. § 820.22, 21 C.F.R. *§* 820.5, 21 C.F.R. §820.l (a), 21 C.F.R. *§* 820.22, 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198(a) and 21 C.F.R. *§* 820:1 70(a) because Conceptus and Bayer failed to comply with the general quality control standards found in these regulations.

d. 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i (a), because as discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury and/or may require Plaintiffs to undergo surgical intervention in the future to prevent further injury.

e. 21 C.F.R. § 814.84(b)(2) because as discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known about, including but not limited to the Cornell

study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure® abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

f. 21 U.S.C. §§ 360(q); 360(r) because Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure® in order to convince physicians and patients to use Essure® over other methods of permanent birth control, thereby gaining market share.

g. 21 C.F.R. § 820.198 because Conceptus and Bayer failed to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure® device.

h. 21 C.F.R. § 820.198 and 21 C.F.R. § 803.3 because Conceptus and. Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure® device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to sell Essure® into the stream of interstate commerce when they knew, or should have known, that the Essure® was malfunctioning or otherwise not responding to its Design Objective Intent.

1. 21 C.F.R. § 814.80 because Conceptus and Bayer manufactured, packaged, stored,

labeled, distributed, and/or advertised in a manner that is inconsistent with the conditions for approval specified in the PMA approval for it.

j. 21" C.F.R. § 820.100 because upon obtaining knowledge of device failure modes, Conceptus and Bayer: (1) failed *to* routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventative Actions ("CAP A") necessary to address non-conformance and other internal quality control issues.

k. 21 C.F.R. § 820.70 because Conceptus and Bayer failed to establish Quality

Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure® device.

1. 21 C.P.R.§ 814.39 because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association; such evidence is the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, by the numerous Essure® studies consisting of thousands of women reporting that patients who undergo the Essure® procedure are more likely to experience injuries and complications which require or will require surgical intervention or reoperation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

132. Plaintiff is within the class of persons the statutes and regulations protect and regulations protect and Plaintiffs' injuries are of the type of injuries these statutes and regulations are intended to prevent.

133. Defendants' violations of these statutes and regulations proximately caused Plaintiffs' injuries alleged herein.

134. 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).

135. Defendants had a parallel duty under Louisiana law to exercise reasonable care in testing and inspecting their product, in monitoring the design of the Essure® placed into Plaintiff, 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.

136. Defendants were negligent under Louisiana state law in their development, promotion,

marketing, manufacture, distribution, and/or sale of Essure® in one or more of the following particulars:

a. 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;

b. 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 process;

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

d. Carelessly and negligently selling and distributing Essure® in violation of the CPMA and federal law;

e. Negligently incorporating components into Essure® that could not stand up to normal usage;

f. Failing to exercise reasonable care in its inspecting and testing of the product;

g. Failing to exercise reasonable care in its manufacturing and quality control processes; and

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

137. 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.

138. Defendants also had a duty under Louisiana state law to exercise ordinary care in the

manufacture of Essure® consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval.

139. 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.

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

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

142. 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.

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

144. 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.

145. 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 hysteroscope.

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

147. 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.

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

149. 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.

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

forth.

COUNT IV: BREACH OF EXPRESS WARRANTY: LA R.S. 9:2800.58

16. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

17. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Essure® in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

18. Essure® materially failed to conform to those representations made by Defendant in package inserts, and otherwise, concerning the properties and effects of Essure®, respectively manufactured and/or distributed and sold by Defendant, and which Plaintiff purchased implanted into her body in direct or indirect reliance upon these express representations. Such failure by Defendant constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Essure® sold to Plaintiff.

19. As a direct, foreseeable and proximate result of Defendant's breaches of express warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such express warranties, prescribed for Plaintiff the use of Essure®. Plaintiff purchased and was implanted with Essure® by Plaintiff's physician leading to Plaintiff's injuries.

COUNT V: REDHIBITION

20. Defendant is by operation of law presumed to know that their products contained redhibitory defects which they failed to declare, so that Defendant is further liable unto Plaintiffs under Articles 2520 et seq. of the Louisiana Civil Code. Such liability includes return of the purchase

price, damages, including, but not limited to, mental anguish, and attorney's fees pursuant to Article 2545 of the Louisiana Civil Code and the presumption contained therein.

21. Separate and apart from, and in the alternative to, their status as manufacturers of their products, Defendant entered into a contract of sales with Plaintiff as a result of Plaintiff's purchase of their products.

Damages Applicable to All Counts

Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follow:

As a producing cause, proximate cause, or both, of Defendants' conduct, Defendants' defective product, or both, more particularly set forth above, Plaintiff suffered, sustained and incurred, and in reasonable medical probability will continue to suffer, sustain and incur, the following injuries and damages, among others:

a. Surgery to remove the Essure device
b. Allergic reaction/adverse event in connection with the Essure device
c. Physical pain and mental suffering
d. Physical impairment
e. Physical disfigurement
f. Loss of earning capacity
g. Reasonable and necessary medical expenses.

Demand for Jury Trial

Plaintiffs hereby demand a trial by jury as to all claims in this action.

Respectfully submitted,

s:/John D. Sileo
John D. Sileo (La. Bar No.: 17797)
Casey W. Moll (La. Bar No.: 35925)
320 North Carrollton Avenue, Suite 101
New Orleans, Louisiana 70119
(504) 486-4343

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

BRITTANY DAVENPORT

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

JOHN D. SILEO, 320 N. CARROLLTON AVE. SUITE 101
NEW ORLEANS, LA 70119

DEFENDANTS

BAYER CORPORATION

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding | ❒ 2 Removed from State Court | ❒ 3 Remanded from Appellate Court | ❒ 4 Reinstated or Reopened | ❒ 5 Transferred from Another District *(specify)* | ❒ 6 Multidistrict Litigation - Transfer | ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 uSC 1332 AND 1391

Brief description of cause:
Plaintiff sustained injuries due to a defective product.

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
11/29/2017

SIGNATURE OF ATTORNEY OF RECORD
JOHN D. SILEO

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.