UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MAYBELLE GARCIA Plaintiff v. BAYER ESSURE®, INC., BAYER U.S. LLC, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC. Defendants	::	**COMPLAINT FOR DAMAGES** **C.A. NO.**

COMPLAINT OF PLAINTIFF, MAYBELLE GARCIA

COMES NOW the Plaintiff, MAYBELLE GARCIA ("Plaintiff"), who, by and through undersigned counsel, hereby files her Complaint, seeking judgment against Defendants BAYER ESSURE®, INC., BAYER CORPORATION, BAYER U.S. LLC, BAYER HEALTHCARE LLC, and BAYER HEALTHCARE PHARMACEUTICALS, INC. (hereafter collectively, "the BAYER Defendants", "Defendants", "BAYER" or "Defendant") for the personal injuries she sustained as a result of being prescribed, receiving, and subsequently using the defective and unreasonably dangerous permanent birth control device Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Defendants or Conceptus, Inc., which was acquired by Defendants on or about April 28, 2013. In support therefor, Plaintiff further states as follows:

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I. PARTIES

A. PLAINTIFF

1. Plaintiff, MAYBELLE GARCIA is a citizen of the state of Alabama.

B. DEFENDANTS

2. BAYER CORPORATION is a for-profit corporation incorporated in the State of Indiana. At all relevant times, BAYER CORPORATION's principal office was located at 100 Bayer Rd. Building 4, Pittsburgh, Allegheny County, PA 15205. BAYER CORPORATION is a wholly-owned subsidiary of Bayer AG. On or around January 1, 2017, BAYER CORPORATION changed its principal office to New Jersey. However, BAYER CORPORATION's officers are located in Pittsburgh, Pennsylvania. Defendant, BAYER CORPORATION, is currently a citizen of New Jersey and Indiana, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, BAYER CORPORATION, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

3. BAYER CORPORATION is the parent corporation of BAYER HEALTHCARE, LLC, BAYER ESSURE®, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC. (the "Bayer subsidiaries"). Defendant BAYER CORPORATION owns 100% of the Bayer subsidiaries.

4. BAYER U.S. LLC has its principal place of business at 100 Bayer Road, Pittsburgh, Allegheny County, PA 15205, an address registered with the Pennsylvania Secretary of State in Dauphin County, PA. Defendant BAYER U.S. LLC is a citizen of Pennsylvania, either through incorporation in Pennsylvania or through having its principal place of business in Pennsylvania, and is authorized to do and does business throughout the Commonwealth of

Pennsylvania. Defendant, BAYER U.S. LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

5. BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the State of Delaware and is a wholly-owned subsidiary of Bayer AG. Defendant, BAYER HEALTHCARE LLC, has a principal office at 100 Bayer Blvd., Whippany, NJ 07981. Defendant, BAYER HEALTHCARE LLC, is a citizen of Delaware, Pennsylvania, New Jersey, Germany, and the Netherlands, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, BAYER HEALTHCARE LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

6. BAYER ESSURE®, INC. (f/k/a Conceptus, Inc.) is a for-profit corporation incorporated in the State of Delaware and is a wholly-owned subsidiary of Bayer AG and/or BAYER HEALTHCARE LLC. On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with BAYER HEALTHCARE LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly-owned subsidiary of BAYER HEALTHCARE LLC and/or Bayer AG, and thereafter renamed "BAYER ESSURE®, INC." For purposes of this Complaint, Conceptus, Inc. and BAYER ESSURE®, INC. are one and the same. BAYER ESSURE®, INC. has a principal office at 100 Bayer Boulevard, Whippany, NJ 07981. Defendant, BAYER ESSURE®, INC., is a citizen of Delaware and New Jersey, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, BAYER ESSURE®, INC., is engaged in the

business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

7. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the State of Delaware and is a wholly-owned subsidiary of Bayer AG. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., has a principal office of 100 Bayer Blvd., Whippany, NJ 07981. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is a citizen of Delaware and New Jersey, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

8. At all relevant times, the Bayer subsidiaries are agents or apparent agents of BAYER CORPORATION. Each Defendant acted as the agent of the other Defendant and acted within the course and scope of the agency, regarding the acts and omissions alleged. Together, the Defendants acted in concert and or abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves and creating an injustice at the expense of Plaintiff.

9. In addition, the Bayer subsidiaries, individually and/or collectively, are "Alter Egos" of BAYER CORPORATION as, *inter alia,* they are wholly owned by BAYER CORPORATION; share the same trademark; share management and officers; and in other ways were dominated by BAYER CORPORATION.

10. Moreover, there exists and at all times mentioned herein there existed a unity of interest in ownership and among all Defendants such that individuality and separateness between

and among them has ceased. Because Defendants are "Alter Egos" of one another and exert control over each other, adherence to the fiction of the separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud, and promote injustice. Defendant, BAYER CORPORATION, wholly ignored the separate status of the Bayer subsidiaries and so dominated and controlled its affairs that its separate entities were a sham.

11. Defendants BAYER CORPORATION, BAYER U.S. LLC, BAYER HEALTHCARE LLC, BAYER ESSURE®, INC (f/k/a Conceptus, Inc.), and BAYER HEALTHCARE PHARMACEUTICALS, INC. are hereafter collectively referred to as "the BAYER Defendants", "Defendants", "BAYER" or "Defendant".

12. At all times herein mentioned, the BAYER Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the Essure® device, and processing, reporting, and storing adverse events related to the device. These products were for use by the Plaintiff and Plaintiff's physicians. As such, each of the BAYER Defendants are individually, as well as jointly and severally, liable to the Plaintiff for their damages.

13. The harm caused to Plaintiff resulted from the conduct of one or various combinations of the Defendants, and through no fault of Plaintiff. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one, or which combination of, the

Defendants caused Plaintiff's injuries. Thus, the burden of proof should be upon each Defendant to prove that the Defendants have not caused the harms suffered by the Plaintiff.

14. "Defendant" as used herein means each Defendants listed above independently and/or jointly, unless noted otherwise.

II. JURISDICTION

15. During all relevant times, BAYER CORPORATION was held out as the "US headquarters of pharmaceuticals and materials giant Bayer AG," which oversaw "The US subsidiaries of Bayer's three global divisions: Bayer Healthcare (pharmaceuticals, animal health, and over-the counter medicines), Material Science (plastics, coatings and polyurethanes), and Bayer CropScience (herbicides, fungicides and insecticides)." At all relevant times, BAYER CORPORATION was located at 100 Bayer Rd., Pittsburgh, PA 15205.

16. Defendant, BAYER HEALTHCARE LLC, is a citizen of Pennsylvania.

17. Defendant BAYER U.S. LLC has its principal office in Pittsburgh, Pennsylvania.

18. As alleged herein, the BAYER entities herein are unitary, so that jurisdiction over the parent would draw jurisdiction over the subsidiaries.

19. Defendants engaged in conduct in the State of Pennsylvania that was so "continuous and systematic" as to render them "at home" in the forum state, including but not limited to business, marketing, regulatory and research activities.

20. At all times relevant, Defendants were engaged in the business of designing, researching, developing, testing, licensing, manufacturing, marketing, advertising, promoting, selling, distributing, and/or introducing into interstate commerce throughout the United States, which necessarily includes the Commonwealth of Pennsylvania, and Philadelphia, either directly or indirectly through third parties, subsidiaries or related entities, the Essure® device.

21. Furthermore, key officers and employees of the BAYER Defendants are located in Pennsylvania, including but not limited to Keith Abrams, who is an officer of BAYER CORPORATION, manager of BAYER U.S. LLC and Assistant Secretary of BAYER ESSURE®, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER HEALTHCARE LLC.[1]

a. Helmut Hegger, President of Bayer Business and Technology Services LLC (BBTS), is located in Pennsylvania.[2] BBTS is listed with the Pennsylvania Secretary of State as a prior name to BAYER U.S. LLC, which now (as of January 2017) maintains employees from multiple BAYER entities, including Defendant BAYER ESSURE®, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER HEALTHCARE LLC.

b. Also, Dan Cella, the treasurer for Bayer AG, is located in Pennsylvania.[3]

c. BAYER CORPORATION maintains officers in Pennsylvania, including: Jon R. Wyne, Treasurer; Klaus H. Risse, President; Melvyn A. Silver, Vice President; and Stephen B. Paige, Secretary.[4]

22. There is also "specific" personal jurisdiction, because Defendants used the State of Pennsylvania to develop, create a marketing strategy for, label, and/or work on the regulatory approval for Essure®, and all of the Plaintiff's claims arise out of or relate to the Defendants' contacts with Pennsylvania.

23. For example, at all relevant times, Pennsylvania was the site of clinical studies regarding Essure®.

a. Pennsylvania was a site of the ESS305 Post-Approval Study whose purpose was to document the bilateral placement of the ESS305 model. The data obtained from this study was intended to be used to update labeling and training procedures.[5]

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[1] *See* https://www.corporationwiki.com/Pennsylvania/Pittsburgh/keith-r-abrams-P7498713.aspx (last visited January 29, 2018); *and* https://www.americanconference.com/speakers/mr-keith-abrams/ (last visited January 29, 2018).
[2] *See* http://www.bayer.us/en/about-bayer/leadership/helmut-hegger/ (last updated August 18, 2017).
[3] *See* January 23, 2018 FEC filing available at http://docquery.fec.gov/pdf/531/201801239090524531/201801239090524531.pdf#navpanes=0.
[4] *See* https://www.corporations.pa.gov/Search/CorpSearch (last visited February 8, 2018).
[5] *See* Clinical Data Final Report: Ess305 Post-Approval Study, located at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm413805.pdf (last visited January 29, 2018).

b. Pennsylvania was also a site for the ESS-NSPAS Study to Evaluate the Effectiveness of Essure® Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure® Confirmation Test.[6]

c. Ben Zhang, located in Pennsylvania, was the "Head of Business Transformation and Change Management" from 2009-2015, where he was responsible for overseeing a consultant team, team management, development and training, recruiting, and business development. He also served as "Interim Head of Consumer Relations" where he was responsible for "resolution of product liability, adverse event and crisis management issues."[7] Additionally, Mr. Zhang was on the HealthCare Management Board, where he "[s]upported commercial due diligence and led the post-merger integration for Bayer's $1.1bn Conceptus acquisition."[8]

d. Further, BAYER HEALTHCARE LLC, which is a citizen of Pennsylvania, is and was at all relevant times, responsible for the manufacturing of Essure®.

e. BAYER CORPORATION was, at all relevant times, responsible for the finance administration of Essure®.

f. Defendants and their agents, located in Pennsylvania, were involved with the acquisition of Conceptus, Inc. by Bayer AG, Defendants' parent company.

g. The BAYER Defendants also conducted sales and marketing activities in Pennsylvania, including but not limited to those activities conducted through sales representatives such as Matthew Hladek and Monica Anderson.

i. Additionally, Pennsylvania was home to Key Opinion Leaders, or "KOLs" for BAYER, including Carl R. Della Badia, D.O. of Drexel University – College of Medicine in Philadelphia, Pennsylvania. Dr. Della Badia was a 2008 member of the Speaker's Bureau for Conceptus, Inc.[9] Larry R. Glazerman, M.D., MBA of Mainline Health System in Wynnewood, Pennsylvania, was also a member.[10] Further, Dr. John Roizin was a KOL for BAYER, and received payments for Essure®.[11]

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[6] *See* https://clinicaltrials.gov/ct2/show/study/NCT01740687?show_locs=Y#contacts (last visited January 29, 2018).
[7] *See* Linkedin page for Ben Zhang, available at https:www.linkedin.com/in/benzhang2009/.
[8] *Id*.
[9] *See* https://www.aagl.org/files/08FinalProgram_No%20Ads.pdf (last visited January 28, 2018).
[10] *See* https://www.aagl.org/2012syllabus/12FinalProgram.pdf.
[11] *See* payments made on behalf of Bayer to Dr. Roizin at http://doctors.healthgrove.com/l/610867/John-Roizin-in-Bethlehem-Pennsylvania#Open%20Payments&s=2GU8tV (last visited January 29, 2018).

24. At all relevant times, the BAYER Defendants transacted, solicited, and conducted business in Pennsylvania through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Pennsylvania, and committed torts in whole or in part against Plaintiff in Pennsylvania including but not limited to negligent and wrongful conduct in connection with the design, development, testing, promoting, marketing, distribution, labeling and/or sale of Essure®.

25. Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

26. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because complete diversity in citizenship exists between Plaintiff and the Defendants, and the amount in controversy exceeds seventy-five thousand dollars ($75,000) exclusive of interest and costs.

27. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) and (3) because Defendants have their principal place of business in this district, and/or a substantial part of the events or omissions giving rise to the claim occurred in this district, and/or Defendants regularly transact substantial business in this district and are subject to personal jurisdiction in this district. Additionally, Defendants have advertised in this district and have received substantial revenue and profits from their sales of Essure® devices in this district; therefore, a substantial part of the events and/or omissions giving rise to the claims occurred, in part, within this district.

III. FACTUAL ALLEGATIONS

28. This Complaint is brought by Plaintiff who was implanted with a female birth control device known as "Essure®." In short, the device is intended to cause bilateral occlusion

(blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in reality, the device migrates from the tubes, perforates organs, breaks into pieces and/or corrodes, wreaking havoc on the female body.

29. As a result of (1) Defendant's negligence described *infra* and (2) Plaintiff's reliance on Defendant's warranties and representations, Defendant's Essure® devices migrated, fractured, punctured internal organs, and/or caused other serious injuries.

30. Essure® had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, Essure® became "adulterated" and "misbranded" due to (1) Defendant's failure to conform to the FDA requirements prescribed in the CPMA and (2) violations of federal statutes and regulations noted *infra.*

31. Pursuant to Defendant's CPMA (which reads: "Failure to comply with conditions of approval invalidates this approval order"), the C.F.R., and Federal Food, Drug and Cosmetic Act ("FDCA"), the product is "adulterated" and "misbranded" and, thus, should not have been marketed or sold to Plaintiff.

32. Specifically, Essure® was adulterated and misbranded as Defendant (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with federal laws regarding marketing and distribution as specifically described *infra.*

33. The fact that Defendant failed to comply with these conditions is not a mere allegation made by Plaintiff. These failures to comply with both the CPMA and federal regulations are memorialized in several FDA findings, including Notices of Violations and Form 483s issued by the FDA.

34. As discussed in greater detail *infra*, Defendant was cited by the FDA and the Department of Health for:

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

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

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

d. manufacturing Essure® at an unlicensed facility; and

e. manufacturing Essure® for three (3) years without a license to do so.

35. Defendant was also found, by the FDA, to be:

a. Not reporting complaints in which their product migrated;

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

c. Only disclosing twenty-two (22) perforations while having knowledge of one hundred and forty-four (144) perforations;

d. Not considering these complaints in their risk analysis for the design of Essure®;

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

f. Failing to analyze or identify existing and potential causes of non-confirming product and other quality problems;

g. Failing to track the non-conforming product;

h. Failing to follow procedures used to control products which did not conform to specifications;

i. Failing to have complete Design Failure Analysis;

j. Failing to document CAPA activities for a supplier corrective action;

k. Failing to disclose 16,047 complaints to the FDA as Medical Device Reports ("MDR"); and

l. Failing to provide the FDA with timely post-approval reports for its six (6) months, one (1) year, eighteen (18) months, and two (2) years report schedules.

36. Most egregiously, on May 30, 2013, the FDA uncovered an internal excel spreadsheet with 16,047 entries of complaints which were not properly reported to the FDA. Here, Defendant did not disclose to the FDA complaints where its product migrated outside of the fallopian tube. Defendant's excuse was that those complaints were not reported because the patients were "not at last contact experiencing pain….and were mere trivial damage that does not rise to the level of a serious injury." The FDA again warned Defendant for violations of the FDCA.

37. As a result, the "adulterated" and "misbranded" product, Essure®, which was implanted in Plaintiff, should never have been marketed or sold to Plaintiff pursuant to federal law.

38. Lastly, Defendant concealed and altered the medical records of its own clinical trial participants to reflect favorable data. Specifically, Defendant altered medical records to reflect less pain than what was being reported during the clinical studies for Essure® and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process. Subsequently, Defendant failed to disclose this and concealed it from Plaintiff and her implanting physicians.

39. Plaintiff's causes of action are all based on deviations from the requirements in the CPMA and/or violations of federal statutes and regulations.

40. Plaintiff's causes of action are also based entirely on the express warranties, misrepresentations, and Defendant's deceptive conduct, which were relied upon by Plaintiff prior to having the device implanted. Under Pennsylvania law, Plaintiff's claims for breach of express warranties are not preempted by the Medical Device Act ("MDA").

41. In addition, Defendant failed to comply with the following express conditions and federal regulations:

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

b. "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

c. Report Due Dates – six (6) months, one (1) year, eighteen (18) months, and two (2) year reports.

d. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

e. Effectiveness of Essure® is established by annually reporting on the 745 women who participated in the clinical tests.

f. Successful bilateral placement of Essure® is documented for newly trained physicians.

g. Warranties are truthful, accurate, and not misleading.

h. Warranties are consistent with applicable federal and state law.

42. These violations rendered the product "adulterated" and "misbranded" – precluding Defendant from marketing or selling Essure® and, more importantly, endangered the lives of Plaintiff and hundreds of thousands of women.

43. Defendant actively concealed these violations and never advised Plaintiff of the same. Had Plaintiff known that Defendant was concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license, they never would have had Essure® implanted into their bodies.

A. DESCRIPTION OF ESSURE® AND HOW IT WORKS

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

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

46. The micro-inserts are comprised of two (2) metal coils which are placed in a woman's fallopian tubes via Defendant's disposable delivery system and under hysteroscopic guidance (camera).

47. The hysteroscopic equipment needed to place Essure® was manufactured by a third party, is not a part of Defendant's CPMA, and is not a part of Essure®. However, because Plaintiff's implanting physicians did not have such equipment, Defendant provided it so that it could sell Essure®.

48. The coils are comprised of nickel, steel, nitinol, and PET fibers. In other words, the coils are metal-on-metal.

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

50. After placement of the coils in the fallopian tubes by Defendant's disposable delivery system, the micro-inserts expand upon release and are intended to anchor into the

fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

51. The coils are supposed to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

52. Three (3) months after implant, patients are to receive a "Confirmation" test to determine if the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpingogram ("HSG Test" or "Confirmation Test").

53. Regardless of the Confirmation Test, Defendant warranted that Essure® allows for visual confirmation of each inserts' proper placement during the procedure.

54. Essure® was designed, manufactured, and marketed to be used by the average gynecologist as a "quick and easy" and "non-surgical" outpatient procedure to be done without anesthesia.

B. EVOLUTION OF ESSURE®

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

56. Conceptus and Defendant merged on or about April 28, 2013.

57. For purposes of this lawsuit, Conceptus and Defendant are one in the same.

58. Essure®, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendant.

59. Defendant trained physicians, including Plaintiff's implanting physicians, on how to implant Essure® and use hysteroscopic equipment.

60. Prior to the merger between Conceptus and the BAYER Defendant, Conceptus obtained CPMA for Essure®.

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

62. PMA is intended to be a stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA.

63. An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device if it complies with federal laws and is not "adulterated" or "misbranded".

64. FDA regulations provide one hundred and eighty (180) days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's Recommendation on whether the FDA should approve the submission.

65. However, the PMA process for Essure® was "expedited", and several trial candidates' medical records were altered to reflect favorable data.

66. According to the FDA, a Class III device that fails to meet CPMA requirements is considered to be adulterated under section 501(f) of the FDCA and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.

67. Regarding the PMA, devices can either be "approved", "conditionally approved," or "not approved."

68. Essure® was "conditionally approved". It had CPMA, not PMA, which is the "gold standard".

69. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval invalidates this approval order[12]." The following were conditions of approval:

a. "Effectiveness of Essure® is established by annually reporting on the seven hundred and forty-five (745) women who took part in clinical tests."

b. "Successful bilateral placement of Essure® is documented for newly trained physicians."

c. "Within ten (10) days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

d. "Report to the FDA whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

e. Warranties are truthful, accurate, and not misleading.

f. Warranties are consistent with applicable federal and state law.

g. Conduct a post approval study in the United States to document the bilateral placement rate for newly trained physicians.

h. 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.

i. 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.

j. Submit a PMA supplement whenever there are changes to the performance of the device.

12 Note: The CPMA order does not read…failure to comply *may* invalidate the order.

C. REQUIREMENTS UNDER FEDERAL REGULATIONS

70. The CPMA also required Defendant to comply with the Medical Device Reporting regulations and post market requirements for Class III medical devices:

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;

b. Report to the FDA within thirty (30) days whenever they receive notice of serious injury;

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

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

e. Submit a PMA Supplement for any change in manufacturing site, 21 CFR §§ 814.39 et seq.;

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

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

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

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

j. Establish Quality Management System (QMS) procedures to assess potential causes of non-conforming products and other quality problems, 21 CFR §§ 820.70 et seq. and 21 CFR §§ 27 820.90 et seq.;

k. Report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80;

l. Advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

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

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

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

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

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

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

D. FAILURES OF ESSURE®

73. After obtaining the CPMA, Defendant became aware of potential quality and failure modes associated with Essure® and failed to warn Plaintiff and/or her implanting physicians. Defendant became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

a. The stainless steel used in Essure® can become un-passivated;

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

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

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

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

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

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

h. PET fibers are also known endocrine disruptors. Endocrine Disrupting Chemicals ("EDCs") like PET often disrupt endocrine systems by mimicking or blocking a natural hormone. In the case of hormone mimics, an EDC can "trick" that hormone's receptor into thinking that the EDC is the hormone, and this can inappropriately activate the receptor and trigger processes normally activated only by a natural hormone.

i. PET fibers found on the Essure® device (that were intended to cause an inflammatory response) are also causing endocrine disruption which has "unmasked" and caused autoimmune diseases and other autoimmune like symptoms in women who have been implanted with the Essure® device.

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

E. VIOLATIONS OF FEDERAL REQUIREMENTS

74. In June 2002, the FDA found the following objectionable conditions:

a. Design outputs were not completely identified.

b. Corrective and preventative action activities were not being documented, including implementation of corrective and preventative actions.

c. Procedures addressing verification of corrective and preventative actions were not implemented.

75. In July 2002, during an inspection of Defendant's facility, the FDA observed that adverse events were not captured in the data.

76. In July of 2002, the FDA found that Defendant "does not have an assurance/quality control unit."

77. In June 2003, the following observations were made by the FDA which resulted in the FDA issuing Form 483s:

a. Two (2) lot history records showed rejected raw materials which was not documented and, therefore, could not be tracked.

b. Procedures were not followed for the control of products that did not conform to specifications.

78. In December 2010, the FDA found that Defendant was "not reporting complaints of their product being seen radiographically in the patient's abdominal cavity" and "did not have a risk analysis of the coils being in the abdominal cavity."

79. Defendant failed to comply with several conditions, including:

a. Defendant failed to timely provide the FDA with reports after twelve (12) months, eighteen (18) months and then a final report for one (1) schedule. Defendant also failed to timely submit post approval reports for its six (6) month, one (1) year, eighteenth (18th) month and two (2) year reports. All reports failed to meet the respective deadlines.

b. Defendant failed to document successful placement of Essure®, concealing the failure rates.

c. Defendant failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report eight (8) perforations, which occurred as a result of Essure®, and was cited for the same by the FDA via Form 483.[13]

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

e. As outlined *infra*, Defendant's warranties were not truthful or accurate, and were, in fact, misleading.

f. Defendant's warranties were not consistent with applicable federal and state law.

g. Defendant failed to notice the FDA of their internal Excel file containing sixteen thousand and forty-seven (16,047) entries of complaints.

80. Defendant was also found to be:

a. Erroneously using non-conforming material in the manufacturing of Essure® and not tracking where it went.

b. Failing to use pre-sterile and post-sterile cages.

c. Manufacturing Essure® at an unlicensed facility.

d. Manufacturing Essure® for three (3) years without a license to do so.

e. Not reporting … complaints in which their product migrated.

f. Not considering these complaints in their risk analysis for the design of Essure®.

g. Failing to document CAPA activities for a supplier corrective action.

81. Specifically, it was determined that:

a. On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within thirty (30) days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." These failures included

13 Form 483 is issued to firm management at the conclusion of inspections when an FDA investigator has observed any conditions that violate the FDCA rendering a device "adulterated".

incidents regarding perforation of bowels, Essure® coils breaking into pieces, and Essure® coils migrating out of the fallopian tubes. Defendant was issued these violations for dates of incidents 5/11/10, 9/1/10, 10/1/10, 10/5/10, 10/26/10, 11/3/10, 11/5/10, and 11/16/10.

b. Defendant had notice of 168 perforations, but only disclosed twenty-two (22) to the FDA.

c. On January 6, 2011, Defendant was cited for their risk analysis of Essure® being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure® did not include, as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

d. On January 6, 2011, Defendant was cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendant's design. The FDA also found that Defendant's CAPA did not mention the non-conformity of materials used in Essure® or certain detachment failures. The FDA found that Defendant's engineers learned of this, and it was not documented.

e. On July 7, 2003, Defendant was cited for not analyzing and identifying existing and potential causes of non-conforming product and other quality problems. Specifically, two (2) lot history records showed rejected raw material was not documented on a quality assurance form which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

f. On July 7, 2003, Defendant was cited for not following procedures used to control products which did not conform to specifications.

82. In response, Defendant admitted that "the device may have caused or contributed to a death or serious injury, and an MDR Report is required to be submitted to FDA."

83. In addition, Defendant's failure to timely file MDRs 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 it received, violated the CPMA, FDA post-marketing regulations and parallel state law.

84. Moreover, Defendant did not provide the requisite training to the implanting physicians prior to selling it to the same.

F. FDA HEARINGS AND RESULTING ACTION

85. Defendant's conduct not only violated its federal regulatory duties and its duties under state 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 Defendant failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure® device, the public's knowledge of the risks associated with Essure® were seriously hampered and delayed. This endangered patient safety, including Plaintiff's safety.

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

87. As described by Sanket S. Dhruva, M.D., and co-authors in the *New England Journal of Medicine*, "[g]iven the limitations of the relevant studies, it's not surprising that so many years passed before safety issues with Essure were recognized." They continued:

> To identify adverse events occurring in day-to-day practice, the FDA examines reports voluntarily submitted to its MAUDE database. Although passive adverse-event reporting is known to underestimate adverse-event rates, as of June 2015, a total of 5093 adverse-event reports related to Essure had been made to MAUDE, most of which listed multiple safety concerns. **These reports led the FDA to update the device label in 2013 to include information about risks of chronic pain and device migration and to reconvene its Obstetrics and Gynecology Devices Panel to reassess safety and effectiveness**.[14]

88. These belated and untimely releases of relevant and important information lead to an increasing number of adverse events being reported to the FDA about Essure® from patients

[14] Sanket S. Dhruva, M.D., et al., "Revisiting Essure – Toward Safe and Effective Sterilization," NEJM 373:15 at e17(2) (Oct. 8, 2015) (emphasis added).

and physicians. Because of these complaints, the FDA convened a public hearing concerning the safety and efficacy of Essure®. At that hearing, Defendant continued to misrepresent the safety and efficacy of Essure®. For example, Defendant stated that:

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

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

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

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

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

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

b. The FDA is requiring Defendant to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure®. The FDA's draft Patient Decision Checklist is a five (5) 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 the skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that "there is no reliable test to predict ahead of time who may develop a reaction to the device"; the possibility that the Essure® device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure® device has to be removed after placement, it will require surgery to remove and, possibly, a hysterectomy.

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

90. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Plaintiff of the true risks of Essure®. Had Defendant complied with their federal regulatory duties and their duties under state law by reporting the known risks and complications in a timely fashion, Plaintiff and their physicians would have had this relevant, critical information available to them prior to the implant of Essure®. At all relevant times, Defendant's Essure® product was prescribed and used as intended by Defendant and in a manner reasonably

foreseeable to Defendant. Moreover, Defendant's misrepresentations regarding Essure® discussed *infra*, in effect, over-promoted Essure® and nullified otherwise adequate warnings.

91. Lastly, although Essure® appears at first glance to be a "medical device", Defendant actually categorizes it as a "drug".

92. In short, Essure® is considered an "adulterated" and "misbranded" product that could not have been marketed or sold to Plaintiff per the FDA and federal law, and all of Plaintiff's claims center around violations of the CPMA requirements and/or federal regulations and statutes.

93. FDA scrutiny of Bayer's handling of Essure safety continued long after 2016. As Scott Gottlieb, M.D., Commissioner of the FDA, explained,

> In April [2018], when the FDA became aware that many patients were not being adequately counseled, we required a restriction (/news-events/press-announcements/fda-restricts-sale-and-distribution-essure-protect-women and require-patients-receive-risk) which limits the sale and distribution of the device to only health care providers and facilities that provide information to patients about the risks and benefits of this device and gives patients the opportunity to sign an acknowledgement that they fully understood these potential risks before having the device implanted.[15]

94. As provided by the FDA:

> Bayer, the device manufacturer is required to implement these restrictions immediately and ensure that the process going forward results in health care provider compliance with the sales restriction. The FDA will review and monitor Bayer's plan to ensure the company complies with the restriction. **The FDA plans to enforce these requirements and will take appropriate action for a failure to comply, including applicable criminal and civil penalties.**[16]

[15] FDA.gov, "Statement from FDA Commissioner Scott Gottlieb, M.D., on manufacturer announcement to halt Essure sales in the U.S.; agency's continued commitment to postmarket review of Essure and keeping women informed," https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-manufacturer-announcement-halt-essure-sales-us-agencys, (last accessed on Feb. 1, 2020).

[16] FDA.gov, "FDA restricts sale and distribution of Essure to protect women and to require that patients receive risk information," https://www.fda.gov/news-events/press-announcements/fda-restricts-sale-and-distribution-essure-protect-women-and-require-patients-receive-risk (last accessed on Feb. 1, 2020) (emphasis added).

95. More recently, on July 20, 2018, Defendants withdrew Essure from the market in the United States after having withdrawn from foreign markets in 2017. Defendants issued a press release the same day, claiming the decision was based on a "decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable."[17] FDA Commissioner Scott Gottlieb, M.D., issued a statement the same day, explaining that Defendant's decision:

> follows the FDA's patient safety action in April, in which the agency issued an order (/news-events/press-announcements/fda-restricts-sale-and-distributionessure-protect- women-and-require-patients-receive-risk) restricting the sale and distribution of Essure; it was a unique type of restriction where the FDA used its authority to impose additional requirements to provide a reasonable assurance of the device's safety and effectiveness. The decision today to halt Essure sales also follows a series of earlier actions that the FDA took to address the reports of serious adverse events associated with its use.
>
> [. . .]
>
> Since the FDA ordered Bayer (/news-events/press-announcements/fda-takes-additional-action-betterunderstand-safety-essure-inform-patients-potential-risks) to conduct the post-market study and then to add a boxed warning and a Patient Decision Checklist to the labeling, there has been an approximate 70 percent decline in sales of Essure in the U.S. The company stated its decision to halt sales and distribution of the device was due to commercial reasons.[18]

G. DEFENDANT'S TRAINING AND DISTRIBUTION PLAN

96. Defendant (1) failed to abide by FDA approved training guidelines when training Plaintiff's implanting physicians; (2) provided specialized hysteroscopic equipment to the implanting physicians who were not qualified or competent to use the same; and (3) created an

[17] Bayer.us, "Bayer to voluntarily discontinue U.S. sales of Essure at the end of 2018 for business reasons," https://www.bayer.us/en/newsroom/press-releases/article/?id=123229, (last accessed on Feb. 1, 2020).

[18] FDA.gov, "Statement from FDA Commissioner Scott Gottlieb, M.D., on manufacturer announcement to halt Essure sales in the U.S.; agency's continued commitment to postmarket review of Essure and keeping women informed," https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-manufacturer-announcement-halt-essure-sales-us-agencys (last accessed on Feb. 1, 2020).

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

97. Because Essure® was the first device of its kind, the implanting physicians were trained by Defendant on how to properly insert the micro-inserts using the disposable delivery system and were given hysteroscopic equipment by Defendant.

98. In order to capture the market, Defendant independently undertook a duty of training physicians outside of FDA guidelines, including the implanting physicians, on how to properly use its own mechanism of delivery and the specialized hysteroscopic equipment manufactured by a third party.

99. Defendant's Senior Director of Global Professional Education stated, "training is the key factor when clinicians choose a new procedure" and, "For the Essure® procedure, the patient is not under anesthesia, therefore a skilled approach is crucial."

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

101. Defendant provided no training to the implanting physicians on how to remove Essure® should it fail.

102. Defendant also kept training records on all physicians "signed-off to perform Essure® procedures."

103. In order to sell its product and because the implanting physicians did not have access to the expensive hysteroscopic equipment, Defendant provided the implanting physicians with hysteroscopic equipment which, although is not a part of Essure®, is needed to implant Essure®. The entrustment of this equipment is not part of any CPMA.

104. In fact, Defendant entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc. to obtain specialized hysteroscopic equipment to then give to physicians and to increase its sales force to promote Essure®.

105. According to Defendant, these agreements allowed Defendant to "gain market presence…and expand … market opportunity by driving adoption among a group of physicians."

106. In regard to the entrustment of such specialized equipment, Defendant admitted: "We cannot be certain how successful these programs will be, if at all."

107. Defendant "handed out" this hysteroscopic equipment to unqualified physicians, including Plaintiff's implanting physicians, in an effort to sell its product.

108. Defendant knew or failed to recognize that the implanting physicians were not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physicians in order to capture the market.

109. In return for providing the expensive hysteroscopic equipment, Defendant required that the implanting physicians purchase two Essure® "kits" per month. This was part of Defendant's unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff.

110. The physicians had to purchase the kits regardless of whether they used them or not. This distribution plan created an environment which induced the implanting physicians to "push" Essure® and implant the same into Plaintiff.

111. Defendant used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as bait. Once the implanting physicians "took the bait", they were required to purchase two (2) Essure® "kits" per month, regardless of whether they sold any Essure® "kits".

112. Defendant's distribution plan also included (1) negligently distributing Essure® in violation of FDA orders and federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure® through representatives of the hysteroscopic equipment manufacturers who were not adequately trained, nor had sufficient knowledge regarding Essure®; (4) failing to report and actively concealing adverse events which occurred as a result of Essure®; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure®; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure® at an unlicensed facility; and (8) manufacturing Essure® for three (3) years without a license to do so.

113. In short, Defendant (1) failed to abide by FDA approved training guidelines when training Plaintiff's implanting physicians; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use it; and (3) created an unreasonably dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

114. All of this was done in violation of federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiff's safety, health, and bodies.

H. PLAINTIFF'S HISTORY

115. On June 12, 2006 Plaintiff underwent the Essure® procedure by Dr. Rosalind Jackson in Middletown, Ohio.

116. As a result of Essure®, Plaintiff suffered from severe and permanent injuries.

117. Plaintiff believes she underwent an HSG test, which confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

118. Shortly after undergoing the Essure® procedure, Plaintiff MAYBELL GARCIA began to suffer from pain, bleeding, infection, urinary problems, migration of device, post-implant pregnancy and other symptoms related to Essure®.

119. Plaintiff continues to suffer from ongoing pain and other injuries as described above, to this day.

120. Plaintiff relied on representations from her doctor that Essure® is a surgery free permanent birth control; Essure® is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy; Essure® eliminates the risks, discomfort and recovery time associated with surgical procedures; the inserts are made from safe, trusted material; worry free; once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy. Plaintiff relied on these representations as to the safety and effectiveness of Essure®, and based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied upon the representations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on these representations concerning Essure®.

I. FRAUDULENT CONCEALMENT / DISCOVERY RULE / EQUITABLE TOLLING / EQUITABLE ESTOPPEL

121. Defendant's fraudulent acts and/or omissions prevented Plaintiff and/or Plaintiff's physicians from discovering the injuries or causes thereof as alleged in this complaint until after February 29, 2016.

122. Defendant's failure to report, document, or follow up on the known adverse event complaints, and concealment and altering of adverse events, serious increased risks, dangers, and complications, constitutes fraudulent concealment that tolls Plaintiff's statutes of limitations.

123. Defendant also is estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure®, actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure®, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiff. As a result of Defendant's concealment of the true character, quality, history, and nature of their product, it is estopped from relying on any statute of limitations defense.

124. Defendant furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in Essure® and/or arising out of the use of Essure® and a continued and intentional, systematic failure to disclose and/or conceal such information from/to Plaintiff, Plaintiff's physicians, and the FDA.

125. In short, Defendant:

a. Actively and intentionally concealed from Plaintiff that her physicians were not trained pursuant to FDA-approved training.

b. Actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure®, and

failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiff.

c. Actively and intentionally concealed from Plaintiff and Plaintiff's physicians' risks by making the misrepresentations/warranties discussed herein knowing they were false. In short, Defendant knew the misrepresentations were false because they had studies and reports which showed the opposite, yet altered and concealed the same from Plaintiff, the FDA and Plaintiff's physicians. Defendant made the misrepresentations with the intent of misleading Plaintiff into relying on them because they had studies and reports which showed the opposite, yet decided to conceal the same (collectively "the acts and omissions").

126. If Defendants had met their duties under the applicable federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiff and Plaintiff's physicians, of the increased risks and serious dangers associated with Essure® in time to have lessened or prevented Plaintiff's injuries, which is evidenced by the fact that the FDA is now mandating a new clinical trial, a "black box" warning, and a "patient decision checklist" which discusses and warns in detail about the risks of the very same injuries Plaintiff suffered. Had Defendant satisfied their obligations, these FDA mandates would have been implemented prior to Plaintiff's implantations. However, Defendant's continued to misrepresent the safety and efficacy of Essure® at the FDA Hearings.

127. In short, Defendants manipulated their reports to the FDA and presented false and misleading information, which, in turn, resulted in Plaintiff's consent to implant not being informed because critical facts regarding the nature and quality of side effects from Essure® were concealed from Plaintiff and her physician.

128. Defendants did this in an effort to maintain the impression that Essure® had a positive risk/benefit profile, to guard sales, and to ensure that Plaintiff and her physician did not have the salient facts in order to bring the claims alleged in this complaint.

129. Defendants' conduct was malicious, intentional, and outrageous, and constitutes a willful and wanton disregard for the rights and safety of Plaintiff and others.

J. FDA CALLS ESSURE® MEETING

130. The FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and plan recommendations for Essure®.

131. On February 29, 2016, the FDA first announced that it will force a major change to the Essure® warning label and also require all women considering receiving Essure®, to fill out a "Patient Decision Checklist" to ensure that they are fully informed of the true risks.[19]

132. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.[20]

133. The new warning and checklist changed the risk/benefit profile of Essure® for Plaintiff and gave rise to new salient facts which Plaintiff and her physicians did not and could not have had prior to February 29, 2016.

134. In its current form, this patient decision checklist requires a patient's initials and signature fifteen separate times, recognizing new risks previously not disclosed.

135. Finally, women considering Essure® will have the chance to be fully informed of its true risks.

136. This result is why Defendant withheld and actively concealed safety information from the FDA and the public for years.

19 *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm.

20 *Id.*

137. Upon information and belief, Defendant knew that if the true risks of Essure® were known to the FDA, they should or would inevitably be communicated to physicians and Plaintiff.

138. The checklist specifically warns of device migration, perforation of organs, and new side effects that Defendant had been cited for hiding from the FDA, Plaintiff, and Plaintiff's physician and/or enhances prior inadequate warnings.

139. The checklist enhances the sufficiency of the warnings given to potential Essure® patients and completely alters the process of undergoing the procedure.

140. The checklist has a major impact on the risk/benefit profile of the device, and Plaintiff would not have had the device implanted if she was aware of the true risks of Essure®.

141. On February 29, 2016, the FDA also announced that it would require a detailed boxed warning for the Essure® device. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events. Boxed warnings indicate the highest level of risk.

142. The FDA suggested the following warning:

> **WARNING: Some patients implanted with the Essure® System for Permanent Birth Control have 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. 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.**[21]

21 *FDA Draft Guidance on Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, issued March 4, 2016.*

143. This boxed warning directly addresses side effects that Defendant had been cited for hiding from the FDA and the public for years.

144. Still, in April 2018, the FDA concluded that Essure patients were still not being sufficiently warned despite the FDA-mandated boxed warning and patient-physician checklist. As a result, the FDA issued a sales restricting limiting the sale and distribution of the device to only doctors and facilities that "that provide information to patients about the risks and benefits of this device and gives patients the opportunity to sign an acknowledgement that they fully understood these potential risks before having the device implanted."[22]

K. DISCOVERY RULE – TOLLING

145. Plaintiff did not know of the claims and their underlying facts asserted in this complaint, nor could any reasonable prudent person know of such claims until after February 29, 2016.

146. Plaintiff did not possess the sufficient critical facts to put her on notice that the wrongs and the acts and omissions discussed herein had been committed until such date. This is because it was not until the FDA hearing that Essure®'s safety and Defendant's acts and omissions were publicly called into question by the FDA and the medical community and the FDA required the "black box warning," "patient decision checklist," and "new clinical trials."

147. In fact, no reasonable person in Plaintiff's position would have been aware of the salient facts set out in this complaint until after February 29, 2016.

148. Plaintiff did not have the opportunity to discover the harm inflicted because Defendant was and are continuing to conceal the acts and omissions noted above.

[22] FDA.gov, "Statement from FDA Commissioner Scott Gottlieb, M.D., on manufacturer announcement to halt Essure sales in the U.S.; agency's continued commitment to postmarket review of Essure and keeping women informed," https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-manufacturer-announcement-halt-essure-sales-us-agencys, (last accessed on Feb. 1, 2020).

149. At all times material hereto, Plaintiff exercised reasonable diligence in investigating potential causes of her injuries by discussing her injuries with her healthcare providers. None of the conversations gave Plaintiff a reason to suspect, or reasonably should have given Plaintiff a reason to suspect, that Essure® or Defendant's tortious conduct was the cause of such injuries until after February 29, 2016.

150. Regardless of the exercise of reasonable diligence, Plaintiff did not know, or reasonably should not have known, that she suffered injuries and that her injuries were caused by Defendant's conduct until after February 29, 2016.

151. Plaintiff neither suspected nor knew of Defendant's wrongdoings as alleged herein until after February 29, 2016.

152. In sum, Plaintiff was reasonably unaware, and had no reasonable way of knowing, that her injuries described above were caused by Defendant's conduct until after February 29, 2016.

153. As such, Plaintiff's statute of limitations did not begin to run until after February 29, 2016.

L. FRAUDULENT CONCEALMENT – EQUITABLE TOLLING

154. Defendant committed affirmative independent acts of concealment (including the acts and omissions) and intentionally mislead Plaintiff as noted above upon which Plaintiff and Plaintiff's physician relied on.

155. These acts and omissions misled Plaintiff in regard to her causes of action and prevented them from asserting such rights because the facts which would support their causes of action as alleged in this complaint were not apparent to a reasonably prudent person until after February 29, 2016.

156. Defendants also prevented Plaintiff from asserting her rights by committing affirmative independent acts of concealment as noted above upon which Plaintiff relied.

157. Due to the acts and omissions of concealment, Plaintiff was not cognizant of the facts supporting her causes of action until after February 29, 2016.

158. As such, Plaintiff's statutes of limitations were tolled in light of Defendants' fraudulent concealment and their statutes began to run starting from the date that facts supporting their causes of action in this complaint became apparent, which was on or after February 29, 2016.

159. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiff and her physician of vital information essential to the pursuit of the claims in this complaint, without any fault or lack of diligence on their part. Plaintiff relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendant's tortious conduct.

M. EQUITABLE ESTOPPEL

160. In the alternative, Defendants are estopped and may not invoke the statute of limitations as a defense because, through the fraud or concealment noted above, specifically the acts and omissions, Defendants caused Plaintiff to relax her vigilance and/or deviate from her right of inquiry into the facts as alleged in this complaint.

161. Defendants affirmatively induced Plaintiff to delay bringing this complaint by and through their acts and omissions.

162. In addition to the acts and omissions noted above, Defendants consistently represented to Plaintiff and/or Plaintiff's physician that Essure® was not the cause of any of Plaintiff's injuries to delay her bringing a claim against Defendants.

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

N. FACTS AND WARRANTIES

164. Defendant failed to abide by FDA approved training guidelines when training Plaintiff's implanting physician on how to use Essure® and the necessary hysteroscopic equipment.

165. The skills needed to place the micro-inserts, as recognized by the FDA panel in the PMA process, "are way beyond the usual gynecologist".

166. Defendant went out and attempted to train the implanting physicians on how to use its device and the necessary hysteroscopic equipment. Defendant (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendant observed physicians until Defendant believed they were competent; (4) created Essure® Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure® procedures". Defendant had no experience in training others in hysteroscopy.

167. Defendant failed to abide by FDA approved training guidelines when training Plaintiff's implanting physicians and provided hysteroscopic equipment to the implanting physicians who were not qualified to use such complicated equipment.

168. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendant's training methods were failing[23].

169. Defendant provided hysteroscopic equipment to the implanting physicians who were not competent to use such equipment. Defendant knew the implanting physicians were not competent to use such sophisticated equipment, yet provided the equipment regardless in order to sell its product.

170. Defendant's distribution plan of requiring the implanting physicians to purchase two (2) Essure® kits a month was an unreasonably dangerous plan, as it compelled the implanting physicians to insist that Essure® be used in Plaintiffs.

171. Defendant's distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and federal law; (2) the promotion of Essure® through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure®; (3) failing to report and actively concealing perforations which occurred as a result of Essure®; (4) erroneously using non-conforming material in the manufacturing of Essure® and failing to keep track of the non-conforming material; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure® at an unlicensed facility and (7) manufacturing Essure® for three (3) years without a license to do so.

172. Lastly, as indicated above, Plaintiff relied on several warranties which were directly given by her implanting physician prior to implantation.

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23 *Learning curve of hysteroscopic placement of tubal sterilization micro inserts*, US National Library of Medicine, Janse, JA.

I. GROSS NEGLIGENCE/RECKLESS CONDUCT

173. In addition to the facts pled above, plaintiff alleges the following:

174. At all material times hereto, Defendants represented to Plaintiff that Essure® was made out of "safe, trusted material" and that the product was "worry free" when the company knew or should have known that Essure® contained materials that were not intended to be permanently implanted in the human body, including known carcinogens.

175. In order to train the implanting physician on how to place the device and comply with the CPMA training requirements, Defendants hired and employed non-doctors (including salespersons) to train the implanting physician on how to place the device.

176. Subsequently, when patients began to file and report complaints, Defendants dismissed the patients concerns by criticizing the women voicing the complaints. Instead of reaching out to the women, Defendants actively spied on the women under false pretenses on several online forums. Instead of reaching out to the women, Defendants desired to stop the women's complaints and began an intentional and/or reckless plan to hide and conceal adverse event reports from the FDA, the implanting doctor, and Plaintiff.

177. When a few doctors began to voice their concerns with Essure®, BAYER then created a list of concerned doctors and implemented a plan to convince those doctors to become supporters of Essure®.

178. Once the FDA was finally able to obtain a substantial amount of adverse events and complaints, it ordered the 2015 ADCOM hearing which eventually resulted in the mandated Black Box Warning, Patient-Decision checklist, and post market 522 study (requiring 1400 women to be implanted with Essure® and studied in comparison to tubal ligation).

179. Instead of complying with the original post market study requirement of implanting 1400 women with Essure®, Defendants pulled the product from the market, knowing full well that this action would result in BAYER not being able to enroll 1400 women in the required study, further concealing relevant data from the FDA, the implanting physician, and the Plaintiff.

COUNTS

A. NEGLIGENT TRAINING – COUNT I

180. Plaintiff re-alleges and re-incorporates the preceding paragraphs.

181. First, Defendant undertook an independent duty to train physicians on how to properly use Essure® and place the micro-inserts which failed to abide by FDA training guidelines.

182. In fact, Defendant (1) created an Essure® Training Program; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendant observed physicians until Defendant believed they were competent; (4) created Essure® Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure® procedures."

183. As part of Defendant's training, Defendant had a duty to abide by the FDA training guidelines for the implanting physicians on how to place Essure® using its own delivery system, certify the implanting physicians, and oversee this particular procedure. Defendant also had a duty to disclose adverse events to the physicians so that they, in turn, could properly advise their patients of the actual risks.

184. Specifically, pursuant to the FDA approved training regulations and guidelines, Defendant had a duty to comply with the following federal requirements so that implanting

physicians performed "competent procedures" and would be able to "manage possible technical issues":

(a) Ensure that the implanting physicians completed the required preceptoring (generally five [5] cases) in Essure® placement until competency;

(b) Ensure that the implanting physicians had read and understood the Physician Training Manual; and

(c) Ensure that the implanting physicians had "successful completion of Essure® Simulator Training."

185. As outlined in the Physicians Manual these requirements were necessary in order to:

(a) Ensure that the implanting physicians were selecting appropriate patients for Essure®;

(b) Ensure that the implanting physicians were appropriately counseling Plaintiff on the known risks; and

(c) Ensure the implanting physicians were qualified and competent to perform the Essure® procedure to ensure proper placement to preclude migration, perforation and fracturing of coils.

186. Defendant breached this duty and parallel state laws, thereby departing from the FDA approved guidelines by:

(a) Not ensuring that the implanting physicians completed the required preceptoring in Essure® placement until competency. The implanting physicians did not complete the required preceptoring until competency;

(b) Not ensuring that the implanting physicians had read and understood the Physician Training Manual. The Implanting Physicians did not understand the Physician Training Manual; and

(c) Not ensuring that the implanting physicians had "successful completion of Essure® Simulator Training." The implanting physicians did not successfully complete the Essure® Simulator Training.

187. This departure from the training guidelines caused the Essure® coils to migrate/fracture and/or perforate organs because:

(a) The Essure® Training Program ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(b) The required preceptoring ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above; and

(c) The requirement to read and understand the Physician Training Manual ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above.

188. This breach caused Plaintiff's damages as noted above.

189. As a result, Plaintiff suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against Defendant for an amount in excess of $75,000.00, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

B. NEGLIGENCE – RISK MANAGEMENT – COUNT II

190. Plaintiff re-alleges and re-incorporates the preceding paragraphs.

191. In short, Defendant had a duty, under both state and federal law, to have in place a reasonable risk management procedure to ensure that, *inter alia*, (1) adverse events were being reported to the FDA so that it could be relayed to the implanting physicians and/or Plaintiff; (2)

adverse reports were considered in its risk analysis and that the risk analysis was updated to reflect the same so that it could be relayed to the implanting physicians and/or Plaintiff; (3) Defendant investigated information about the risks Essure® posed so that it could be relayed to the implanting physicians and/or Plaintiff; (4) the continued sale of Essure® was appropriate and reasonable despite information being withheld from the public by Defendant; (5) Defendant monitored the product after pre-market approval to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.; (6) Defendant had internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq., and §§ 820.20 et seq.; and (7) Defendant maintained the labeling of Essure® by filing a "Special PMA Supplement – Changes Being Effected" ("CBE") which allowed Defendant to unilaterally update the labeling of Essure® to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d).

192. Specifically, Defendant had a duty to comply with the following federal regulations, but breached its duties promulgated by these regulations by the subsequent violations noted directly below (which Defendant was cited for by the FDA):

(a) 21 C.F.R. 814.80 – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a condition of approval specified in the PMA approval order for the device. (Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians. This failure to disclose and include the information in their risk management analysis was a breach of a condition of approval in its CPMA.)

(b) 21 C.F.R. 803.1(a) – This part establishes the requirements for the medical device reporting for device user facilities, manufacturers, importers, and

distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow up information. These reports help us to protect the public health by helping to ensure that the devices are not adulterated or misbranded and are safe and effective for their intended use.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(c) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose

coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(d) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(e) 21 C.F.R. 803.53 – You must submit a five (5) day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than five (5) work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a five (5) day report. If you receive such a written request from us, you must submit, without further requests, a five (5) day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(f) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device, which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven-digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven-digit registration number will be assigned a seven-digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC),

model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations,

pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(g) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(h) 21 C.F.R. 820.65 – Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.
(Defendant breached this federal standard by failing to establish and maintain procedures for identification of each Essure® unit which in turn precluded proper corrective actions and led to the failure to disclose and include in their risk management analysis thousands of adverse events and complaints for migrations, perforations, pregnancies, and device failures

and malfunctions, which in turn were never disclosed to Plaintiff and Implanting Physicians. This failure to disclose and include in their risk management analysis was a condition of approval in its CPMA).

(i) 21 C.F.R. 822 – Post market surveillance. This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA) by providing procedures and requirements for post-market surveillance of class II and class III devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is intended to be implanted in the human body for more than one (1) year; The purpose of this part is to implement our post-market surveillance authority to maximize the likelihood that post-market surveillance plans will result in the collection of useful data. This data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.
(Defendant was cited for and breached this federal standard by failing to comply with post-market surveillance plans. Specifically, by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians. Defendant further breached this federal standard by not withdrawing its product from the market.)

(j) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those notes stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(k) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(l) FDA requirement in CPMA order – "Within ten (10) days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(m) FDA requirement in CPMA order – "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(n) Monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

(o) Establish internal procedures for reviewing complaints and event reports, 21 CFR §§820.198, §§ 820.100 et seq. and §§ 820.20 et seq.
(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiff and Implanting Physicians.)

193. Due to these breaches, Defendant was cited by the FDA as Defendant "did not consider these complaints in their risk analysis" and "for their risk analysis of Essure® being incomplete."

194. This was an unreasonably dangerous and negligent risk analysis plan which was required by federal law as it put Plaintiff at unnecessary risk of injury due to Defendant's failure to report adverse reports to the FDA, to track non-conforming product, update its labeling of Essure®, and to consider adverse reports in its risk analysis.

195. This breach caused Plaintiff's damages because but for Defendant's failure to comply with federal law and disclose, consider, and include in their risk management plans and/or labeling the thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, Plaintiff would not have been implanted with Essure® and therefore would also not have been injured by Essure®. Instead, Defendant failed to have a complete Risk Management Plan in place, thereby precluding Plaintiff and her implanting physician from knowing of the thousands of migrations, perforations, pregnancies, device failures and malfunctions. This was actively concealed by Defendant.

196. This breach caused Plaintiff's injuries and damages noted above.

197. As a result, Plaintiff suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against Defendant for an amount in excess of $75,000.00, including compensatory damages,

punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

C. BREACH OF EXPRESS WARRANTY – COUNT III

198. Plaintiff re-alleges and re-incorporates the preceding paragraphs.

199. The FDA's CPMA order confirms that: the FDA "does not evaluate information related to contractual 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."

200. This claim arises out of injuries caused by Defendant's express warranties to Plaintiff which were specifically negotiated and expressly communicated to Plaintiff by Defendant or their agents in such a manner that Plaintiff understood and accepted them.

201. Defendant made, and Plaintiff relied on, the following actual affirmations of fact or promises which formed the bases of the bargain between Plaintiff and Defendant:

a. "Worry free: Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy."

i. Plaintiff relied on this warranty and believed it to be true. Plaintiff relied on this warranty and believed it to be true. Specifically, Plaintiff was provided with this information from the implanting physician.

ii. This warranty created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendant concealed this information from Plaintiff. Between 1997 and 2005, sixty-four (64) pregnancies were reported to Defendant. Defendant concealed this information from Plaintiff. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three (3) month Confirmation Test was performed. Defendant concealed this

information from Plaintiff. There have been over thirty (30) pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure® have a ten (10) times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten (10) years, the risk of pregnancy is almost four (4) times greater.[24] Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

b. "Essure® is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy."

i. Plaintiff relied on this warranty and believed it to be true. Specifically, Plaintiff was provided with this information from the implanting physician.

ii. This warranty created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendant's SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendant. Defendant stated, "We did not conduct a clinical trial to compare the Essure® procedure to laparoscopic tubal ligation." Defendant concealed this information from Plaintiff. In fact, women who have Essure® have a ten (10) times greater risk of pregnancy after one (1) year than those who use laparoscopic sterilization. At ten (10) years, the risk of pregnancy is almost four (4) times greater[25].

c. "Essure® is a surgery-free permanent birth control."

i. Plaintiff relied on this warranty and believed it to be true. Specifically, Plaintiff was provided with this information from the implanting physician.

ii. This warranty created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure® is not permanent because the coils migrate, perforate organs and are expelled by the

24 *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

25 *Id.*

body. Moreover, all Essure® procedures are done under hysteroscopy, which is a surgical procedure.

d. "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiff relied on this warranty and believed it to be true. Specifically, Plaintiff was provided with this information from the implanting physician.

ii. This warranty created the basis of the bargain as Plaintiff relied upon this warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure® is not "surgery-free"; rather, surgery is not required. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

e. "The inserts are made from…safe, trusted material."

i. Plaintiff relied on this warranty and believed it to be true. Specifically, Plaintiff was provided with this information from the implanting physician.

ii. This warranty created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control that was made of safe material which would not cause serious health problems.

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendant refers to Essure® and classify it as a "drug."

202. Defendant's "affirmations of fact or promise" and "descriptions" created a basis of the bargain for Plaintiff as noted above.

203. The warranties were specifically negotiated, directed, intended, and expressly communicated to Plaintiff in such a manner that Plaintiff understood and accepted them. Moreover, Plaintiff provided reasonable notification of the breach.

204. These warranties, in effect, over-promoted Essure® and nullified otherwise adequate warnings.

205. As a result of Defendant's warranties and Plaintiff's reliance on same, Plaintiff has suffered damages. Specifically, the Essure® device did not perform as warranted and instead migrated, perforated, broke, and/or caused other injuries noted above.

206. As a result of Defendant's breaches individually, jointly, and severally, Plaintiff sustained the injuries and damages noted above.

207. As a result, Plaintiff suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

D. NEGLIGENT MISREPRESENTATION – COUNT IV

208. Plaintiff re-alleges and re-incorporates the preceding paragraphs.

209. Defendant made the following misrepresentations:

a. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. This specific or similar language to it created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control.

ii. However, this warranty was false as Defendant also state that it is only after "The Confirmation" that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three-month confirmation test was confirmed. Between 1997 and 2005, sixty-four (64) pregnancies were reported to Defendant. Defendant concealed this information from Plaintiff. There have been over thirty (30) pregnancies after "doctors confirmed the tubes were blocked."

210. Moreover, these misrepresentations, in effect, over-promoted Essure® and nullified otherwise adequate warnings.

211. As a result of Defendant's misrepresentations and Plaintiff's reliance on same, Plaintiff has suffered damages. Specifically, the Essure® device did not perform as represented and instead migrated, perforated, broke and/or caused other injuries, all to Plaintiff's damage.

212. As a result of Defendant's negligence individually, jointly, and severally, Plaintiff sustained the injuries and damages noted above.

213. As a result, Plaintiff suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

E. NEGLIGENCE – FAILURE TO WARN – COUNT V

214. Plaintiff re-alleges and re-incorporates the preceding paragraphs.

215. Plaintiff's injuries were caused by the negligent and reckless conduct of Defendant in failing to warn Plaintiff or her implanting physicians, all of which hinge on violations of federal law and its CPMA.

216. Defendant had a duty to warn Plaintiff and/or her implanting physicians consistent with federal law and its CMPA which included:

(a) 21 C.F.R. 814, governing premarket approval of medical devices, a Statement of material fact means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(b) 21 C.F.R. 814.80 – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a condition of approval specified in the PMA approval order for the device.

(c) 21 C.F.R. 820.65 – establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

(d) 21 C.F.R. 803.1(a) – This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified follow up. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(e) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that

you become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than thirty (30) calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than thirty (30) calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than five (5) work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(f) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(g) 21 C.F.R. 803.53 – You must submit a five (5) day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than

five (5) work days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a five (5) day report. If you receive such a written request from us, you must submit, without further requests, a five (5) day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(h) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within ten (10) working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven (7) digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven (7) digit registration number will be assigned a seven (7) digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a pre-amendments device, and the device listing number. A manufacturer or

importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within ten (10) working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63

FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(i) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(j) 21 C.F.R. 820.65 – Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

(k) 21 C.F.R. 822 – Post market surveillance – This part implements section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA) by providing procedures and requirements for post-market surveillance of class II and class III devices that meet any of the following criteria: (a) Failure of the device would be reasonably likely to have serious adverse health consequences; (b) The device is intended to be implanted in the human body for more than one (1) year;… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

(l) 21 C.F.R. 820.100(a) 6-7 – Corrective and Preventive Action – (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems; (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.

(m) 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include: (1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; (2) Monitoring and control of process parameters and component and device characteristics during production; (3) Compliance with specified reference standards or codes; (4) The approval of processes and process equipment; and (5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. (b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40. (e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. (h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on

product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(n) 21 C.F.R. 820.90 – (a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented. (b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

(o) 21 C.F.R. 820.90 – (a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate. (b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

(p) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(q) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(r) 21 C.F.R. 820.30 – Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall

establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(s) 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a) – A drug or device shall be deemed to be misbranded…if its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

(t) 21 U.S.C. 351(a) (h) – A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if it is…not in conformity with…an applicable condition prescribed by an order.

(u) 21 U.S.C. 352 (q) (r) – Restricted devices using false or misleading advertising or used in violation of regulations. In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

(v) FDA requirement in CPMA order – "Within ten (10) days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

(w) FDA requirement in CPMA order – "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(x) FDA requirement in CPMA order – Report Due Dates – six-month, one year, eighteenth month, and two (2) year reports.

(y) FDA requirement in CPMA order – A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

(z) FDA requirement in CPMA order – Warranties are truthful, accurate, and not misleading…Warranties are consistent with applicable federal and state law.

217. Defendant breached these duties by not complying with the CPMA or federal law:

(a) Defendant failed to timely provide the FDA with reports after twelve (12) months, eighteen (18) months and then a final report for one (1) schedule. Defendant also failed to timely submit post approval reports for its six (6) month, one (1) year, eighteenth (18th) month and two (2) year reports. All reports failed to meet the respective deadlines.

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

(c) Defendant failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report eight (8) perforations which occurred as a result of Essure® and was cited for the same by the FDA via Form 483.

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

(e) Defendant failed to notice the FDA of their internal excel file containing 16,047 entries of complaints.

(f) Defendant excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendant had violated the FDCA.

(g) Erroneously using non-conforming material in the manufacturing of Essure®.

(h) Failing to use pre-sterile and post-sterile cages.

(i) Manufacturing Essure® at an unlicensed facility.

(j) Manufacturing Essure® for three (3) years without a license to do so.

(k) Not reporting … complaints in which their product migrated.

(l) Not considering these complaints in their risk analysis for the design of Essure®.

(m) Failing to document CAPA activities for a supplier corrective action.

(n) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within thirty (30) days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." Form 483/Violation form issued by Timothy Grome on January 6, 2011. These failures included incidents regarding perforation of bowels, Essure® coils breaking into pieces, and Essure® coils migrating out of the fallopian tubes. Defendant was issued these violations for dates of incidents 5/11/10, 9/1/10, 10/1/10, 10/5/10, 10/26/10, 11/3/10, 11/5/10, and 11/16/10.

(o) Defendant had notice of one hundred and sixty-eight (168) perforations but only disclosed twenty-two (22) to the FDA.

(p) On January 6, 2011, Defendant was cited for their risk analysis of Essure® being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure® did not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

(q) On January 6, 2011, Defendant was cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendant's Design. The FDA also found that Defendant's CAPA did not mention the non-conformity of materials used in Essure® or certain detachment failures. The FDA found that Defendant's engineers learned of this and it was not documented.

(r) On July 7, 2003, Defendant was cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

(s) On July 7, 2003, Defendant was cited for not following procedures used to control products which did not confirm to specifications.

(t) Defendant failed to disclose to Plaintiff and her implanting physicians the fact that Defendant's altered medical records to reflect less pain then was being reported during the clinical studies for Essure® and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

218. Had Defendant disclosed such information as was required by the CPMA and federal law to Plaintiff or the Implanting Physician, Plaintiff would never have had Essure® implanted and would have avoided her injuries.

219. At all times referenced herein, Defendant and each of them were acting as agents and employees of each of the other Defendant and were acting within the scope, purpose and authority of that agency and employment and with full knowledge, permission and consent of each other Defendant.

220. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiff sustained the injuries noted above.

221. As a result, Plaintiff suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

F. FRAUDULENT MISREPRESENTATION – COUNT VI

222. Plaintiff re-alleges and re-incorporates the preceding paragraphs.

223. Defendant made a misrepresentation, a fraudulent utterance thereof, which are specifically mentioned below:

a. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. This specific or similar language to it created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control.

ii. This warranty, received by Plaintiff shortly before Essure was implanted at her physicians' office, created the basis of the bargain as Plaintiff relied upon the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendant also state that it is only after "The Confirmation" pregnancy cannot occur. i.e. the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three-month confirmation test was confirmed. Between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiff. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[26].

224. Under Pennsylvania law, fraud may be established even where there is an innocently made misrepresentation so long as it relates to a material matter. Pleading the materiality of the misrepresentation substitutes for pleading the fraudulent utterance thereof.

225. The representations were material to Plaintiff having Essure® placed as she would not have had the device inserted had she known of the misrepresentations

226. Defendants intentionally made the statements so that Plaintiff would be induced to have Essure® implanted in her.

227. Plaintiff justifiably relied on the misrepresentations. Specifically, Plaintiff would have never had Essure® implanted had she been aware of the falsity of the representations specifically delineated in the preceding paragraphs which violate both Federal law and the CPMA.

[26] *Essure insert expulsion after 3-month hysterosalpingogram*, US National Library of Medicine, Garcia, Al.

228. These misrepresentations, in effect, over-promoted Essure® and nullified otherwise adequate warnings. Furthermore, these misrepresentations provided Defendant with financial gain as they were able to sell more of their product.

229. As a proximate result, Essure® device did not perform as warranted and Plaintiff suffered damages.

230. As a result of Defendant's fraud, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: severe and persistent pelvic pain and chronic back pain, and other symptoms related to Essure®.

231. As a result, Plaintiff suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of enjoyment of life, expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, for the above reasons, Plaintiff demands judgment in her favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

G. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiff, as follows:

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

2. Past and future economic and special damages according to proof at trial;

3. Medical expenses, past and future, according to proof at the time of trial;

4. Equitable relief as the Court deems just and proper;

5. Declaratory judgment that Defendants are liable to Plaintiff for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendant's wrongdoing;

6. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

7. Punitive or exemplary damages according to proof at the time of trial;

8. Costs of suit incurred herein;

9. Pre-judgment interest as provided by law; and

10. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

WHEREFORE, Plaintiff MAYBELL GARCIA demands a jury trial with regards to all claims.

Dated: September 24, 2020

Respectfully submitted,

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