IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MARIA ALFARO, BRIDGET AMOS, CHRISTINA ANDERSON, REBECCA ARBOLEDA, ANNETTE ARNOLD, PAOLA ASTUDILLO, SUKHJIWAN ATHWAL, DEBORHA BALL, MARQUITTE BARLOW, DEBORAH BASCOM, KELLY BATESON, E. NICOLE BAXLEY, KANDACE BEAM, LINDSAY BEAMIS, TAMMY BELLARD, JAMIE BENNETT, KATHLEEN BERGET, TAMEEKA BEY, KRISTY BLACKBURN, SHANTAI BORUM, KATIE BOUCHER, LESLIE BOUDREAU, VICTORIA BOURQUE, JULIA BRAZZIL-MANNINGS, APRIL BROOKS, PERRICA BROWN, LACEY BROWN, DEBORAH BRUCATO, REVONDA BURNEY, WENDY CABRERA, JENNIFER CAMPBELL, YAJAIRA CAMPOS, AMY CANTU, CHRISTINA CASTELLANOS, NANCY CERVANTES, IISHA CLEMENTS, AMBER CLINGER, ILIANA CONTRERAS, SHASTEVIA COOK, DONNA COTTRELL, LOUANN COX, PRESTENA CRANE, DEQUITA CRAWFORD, SHERETHA CRAWFORD, MONICA CREATH, AMBER CRIGLER, JENNIFER DARGONNE, AURORA DARNELL, PAULA DAVIS, BRANDI DAVIS, KRISTINE DAYWALT, JENNIFER DECHENEY, CATHERINE DENNISON, CONNIE DEROSIER, AMY DETTY, AGNES DEW, JENNIFER DEWALT, MISTY DICKERSON, KRISTI DOYLE, JESSICA DUCLO, DAWN EDWARDS, ABIGAIL FERSTEIN, JENNIFER FINNEY, MECCA FISHER, STACY FLORES, FAITH FORDE, JAYME FOX, ALYSSA FRANKLIN, MELISSA FULKERSON, and ASHLEY GADSON,

Plaintiffs,

vs.

CASE NO: 18 838

JURY TRIAL DEMAND

PETITION FOR DAMAGES

FILED
FEB 23 2018
KATE BARKMAN, Clerk
By_____Dep. Clerk

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC.

Defendants.

COMPLAINT

PLAINTIFFS, by and through undersigned counsel, file this Complaint against Defendants, BAYER CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC. and BAYER HEALTHCARE, PHARMACEUTICALS, INC. (Collectively the "Bayer Defendants" or "Defendants") and in support thereof make the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, Maria Alfaro, is a resident of CA.
2. Plaintiff, Bridget Amos, is a resident of GA.
3. Plaintiff, Christina Anderson, is a resident of CO.
4. Plaintiff, Rebecca Arboleda, is a resident of NY.
5. Plaintiff, Annette Arnold, is a resident of NE.
6. Plaintiff, Paola Astudillo, is a resident of FL.
7. Plaintiff, Sukhjiwan Athwal, is a resident of CA.
8. Plaintiff, Deborha Ball, is a resident of MI.
9. Plaintiff, MarQuitte Barlow, is a resident of MI.
10. Plaintiff, Deborah Bascom, is a resident of NJ.
11. Plaintiff, Kelly Bateson, is a resident of FL.
12. Plaintiff, E. Nicole Baxley, is a resident of TX.
13. Plaintiff, Kandace Beam, is a resident of AL.

14. Plaintiff, Lindsay Beamis, is a resident of NY.

15. Plaintiff, Tammy Bellard, is a resident of LA.

16. Plaintiff, Jamie Bennett, is a resident of GA.

17. Plaintiff, Kathleen Berget, is a resident of WI.

18. Plaintiff, Tameeka Bey, is a resident of GA.

19. Plaintiff, Kristy Blackburn, is a resident of KY.

20. Plaintiff, Shantai Borum, is a resident of IL.

21. Plaintiff, Katie Boucher, is a resident of WI.

22. Plaintiff, Leslie Boudreau, is a resident of IL.

23. Plaintiff, Victoria Bourque, is a resident of TX.

24. Plaintiff, Julia Brazzil-Mannings, is a resident of IL.

25. Plaintiff, April Brooks, is a resident of CA.

26. Plaintiff, Perrica Brown, is a resident of GA.

27. Plaintiff, Lacey Brown, is a resident of UT.

28. Plaintiff, Deborah Brucato, is a resident of VA.

29. Plaintiff, Revonda Burney, is a resident of GA.

30. Plaintiff, Wendy Cabrera, is a resident of CT.

31. Plaintiff, Jennifer Campbell, is a resident of CA.

32. Plaintiff, Yajaira Campos, is a resident of NY.

33. Plaintiff, Amy Cantu, is a resident of OH.

34. Plaintiff, Christina Castellanos, is a resident of CA.

35. Plaintiff, Nancy Cervantes, is a resident of CA.

36. Plaintiff, Iisha Clements, is a resident of FL.

37. Plaintiff, Amber Clinger, is a resident of OH.

38. Plaintiff, Iliana Contreras, is a resident of TX.

39. Plaintiff, Shastevia Cook, is a resident of TX.

40. Plaintiff, Donna Cottrell, is a resident of TN.

41. Plaintiff, Louann Cox, is a resident of OH.

42. Plaintiff, Prestena Crane, is a resident of TX.

43. Plaintiff, Dequita Crawford, is a resident of GA.

44. Plaintiff, Sheretha Crawford, is a resident of TX.

45. Plaintiff, Monica Creath, is a resident of NC.

46. Plaintiff, Amber Crigler, is a resident of NC.

47. Plaintiff, Jennifer Dargonne, is a resident of CT.

48. Plaintiff, Aurora Darnell, is a resident of OK.

49. Plaintiff, Paula Davis, is a resident of TN.

50. Plaintiff, Brandi Davis, is a resident of AZ.

51. Plaintiff, Kristine Daywalt, is a resident of MD.

52. Plaintiff, Jennifer DeCheney, is a resident of MI.

53. Plaintiff, Catherine Dennison, is a resident of VA.

54. Plaintiff, Connie Derosier, is a resident of MN.

55. Plaintiff, Amy Detty, is a resident of MI.

56. Plaintiff, Agnes Dew, is a resident of GA.

57. Plaintiff, Jennifer Dewalt, is a resident of OH.

58. Plaintiff, Misty Dickerson, is a resident of AR.

59. Plaintiff, Kristi Doyle, is a resident of TX.

60. Plaintiff, Jessica Duclo, is a resident of CA.

61. Plaintiff, Dawn Edwards, is a resident of NC.

62. Plaintiff, Abigail Ferstein, is a resident of IL.

63. Plaintiff, Jennifer Finney, is a resident of OH.

64. Plaintiff, Mecca Fisher, is a resident of TX.

65. Plaintiff, Stacy Flores, is a resident of AZ.

66. Plaintiff, Faith Forde, is a resident of NC.

67. Plaintiff, Jayme Fox, is a resident of WI.

68. Plaintiff, Alyssa Franklin, is a resident of CT.

69. Plaintiff, Melissa Fulkerson, is a resident of KY.

70. Plaintiff, Ashley Gadson, is a resident of MI.

71. BAYER CORP. is a for-profit corporation incorporated in the state of Indiana with its principal place of business in the Commonwealth of PA at 100 Bayer Road, Building 4, Pittsburgh, PA 15205. Defendant is authorized to do and does business throughout the Commonwealth of PA.

72. BAYER CORP. is the parent corporation of BAYER HEALTHCARE, LLC, BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC. (the "Bayer subsidiaries"). BAYER CORP. owns 100% of the Bayer subsidiaries.

73. BAYER CORP. is wholly owned by BAYER A.G.

74. BAYER A.G. is a German for-profit corporation. Defendant is authorized to do and does business throughout the Commonwealth of PA.

75. At all relevant times, the Bayer subsidiaries are agents or apparent agents of BAYER CORP. and/or BAYER A.G. 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 Plaintiffs.

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

77. 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. BAYER CORP. and BAYER A.G. wholly ignored the separate status of the Bayer subsidiaries separate status and so dominated and controlled its affairs that its separate entities were a sham.

78. BAYER HEALTHCARE, LLC. is a for-profit corporation incorporated in the state of DE. Defendant is authorized to do and does business throughout the Commonwealth of PA.

79. BAYER ESSURE, INC. is a for-profit corporation incorporated in the state of DE. Defendant is authorized to do and does business throughout the Commonwealth of PA.

80. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of DE. Defendant is authorized to do and does business throughout the Commonwealth of PA.

81. Diversity jurisdiction is invoked pursuant to 28 U.S.C. §1332.

82. The amount in controversy exceeds $75,000, exclusive of interest and costs, as specified by 28 U.S.C. §1332.

83. The parties to this action are citizens of a State and citizens or subjects of a foreign state or different states, as specified by 28 U.S.C. §1332.

84. Venue is proper in the United States District Court of the Eastern District of Penn. pursuant to 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to the claims asserted below occurred within this judicial district and the parties have stipulated to the same.

INTRODUCTION

85. This Complaint is brought by Plaintiffs who were 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.

86. As a result of (1) Defendants' negligence described *infra* and (2) Plaintiffs' reliance on Defendants' warranties and representations, Defendants' Essure device migrated/fractured and/or punctured internal organs.

87. Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, Essure became "adulterated" and "misbranded", pursuant to (1) the FDA due to Defendants' failure to conform with the FDA requirements prescribed in the CPMA and (2) violations of Federal Statutes and Regulations noted *infra*.

88. Pursuant to Defendants' CPMA (which reads: "Failure to comply with conditions of approval invalidates this approval order"), the C.F.R, and the Federal Food, Drug and Cosmetic Act ("FD&C Act"): the product is "adulterated" and "misbranded" and thus, could not have been marketed or sold to Plaintiffs.

89. Specifically, Essure was adulterated and misbranded as Defendants (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.*

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

91. As discussed in greater detail *infra*, Defendants were cited by the FDA and the Department of Health for:

(a) failing to report and actively concealing 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 years without a license to do so.

92. Defendants were 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 22 perforations while having knowledge of 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 confirm 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 MDR's (Medical Device reports which are suspected from device malfunction or associated with injury); and

(l) Failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two year report schedules.

93. Most egregiously, on May 30, 2013, the FDA uncovered an internal excel spreadsheet with 16,047 entries for complaints which were not properly reported to the FDA. *See Exhibit "H."* Here, Defendant did not disclose to the FDA complaints where its product migrated outside of the fallopian tube. Defendants 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." Accordingly, the FDA again warned Defendants for violations of the FD&C Act.

94. As a result, the "adulterated" and "misbranded" product, Essure, which was implanted in Plaintiffs should never have been marketed or sold to Plaintiffs pursuant to Federal law.

95. Lastly, Defendants concealed and altered the medical records of its own trial participants to reflect favorable data. Specifically, Defendants 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. Subsequently, Defendants failed to disclose this and concealed it from Plaintiffs and their implanting physicians.

96. Plaintiffs' causes of action are all based on deviations from the requirements in the CPMA and/or violations of Federal statutes and regulations.

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

98. In addition, Defendants failed to comply with the following express conditions and Federal regulations:

(a) "Within 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 month, one year, eighteenth month, and two 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 took place 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.

99. These violations rendered the product "adulterated" and "misbranded"- precluding Defendants from marketing or selling Essure per the FDA, and, more importantly endangered the lives of Plaintiffs and hundreds of thousands of women.

100. Defendants actively concealed these violations and never advised Plaintiffs of the same. Had Plaintiffs known that Defendants were 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 to do the same, they never would have had Essure implanted.

DESCRIPTION OF ESSURE AND HOW IT WORKS

101. 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.

102. 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. *See Exhibit "A" for a description of Essure.*

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

104. The hysteroscopic equipment needed to place Essure was manufactured by a third party, is not a part of Defendants' CPMA, and is not a part of Essure. However, because Plaintiffs' implanting physicians did not have such equipment, Defendants provided it so that it could sell Essure. *See Exhibit "A" for a description of hysteroscopic equipment.*

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

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

107. After placement of the coils in the fallopian tubes by Defendants' 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.

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

109. After three months following the device being implanted, patients are to receive a "Confirmation" test to determine that the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpinogram ("HSG Test" or "Confirmation Test").

110. Regardless of the Confirmation Test, Defendants warrant that Essure allows for visual confirmation of each insert's proper placement during the procedure.

111. Essure was designed, manufactured, and marketed to be used by the average gynecologists throughout the world, as a "quick and easy" and "non-surgical" outpatient procedure to be done without anesthesia.

EVOLUTION OF ESSURE

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

113. Conceptus and Defendants merged on or about April 28, 2013.

114. For purposes of this lawsuit, Conceptus and Defendants are one in the same.

115. Essure, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendants.

116. Defendants also trained physicians on how to use its device and other hysteroscopic equipment, including Plaintiffs' implanting physicians.

117. Prior to the merger between Conceptus and Bayer defendants, Conceptus obtained CPMA for Essure.

118. 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.

119. 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.

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

121. FDA regulations provide 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 FDA with the committee's recommendation on whether FDA should approve the submission.

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

123. 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 Federal Food, Drug, and Cosmetic Act ("FD&C Act") and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.

124. Regarding the Premarket Approval Process, devices can either be "approved," "conditionally approved," or "not approved."

125. Essure was "conditionally approved" or in other words, had only CPMA not outright PMA, the "gold standard."

126. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval invalidates this approval order[1]." The following were conditions of approval:

(a) "Effectiveness of Essure is established by annually reporting on the 745 women who took part in clinical tests."

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

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

(c) "Within 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) Effectiveness of Essure is established by annually reporting on the 745 women who took place 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.

(i) Conduct a post approval study in the US to document the bilateral placement rate for newly trained physicians.

(j) 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.

(k) Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device facilitates, necessitate a labeling, manufacturing, or device modification.

(l) Submit a PMA supplement whenever there are changes to the performance of the device.

REQUIREMENTS UNDER FEDERAL REGULATIONS

127. The CPMA also required Defendants 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 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.;

(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.

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

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

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

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

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

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

FAILURES OF DEVICE

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

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

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

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

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

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

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

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

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

VIOLATIONS OF FEDERAL REQUIREMENTS

131. 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 preventative actions were not implemented.

132. In July 2002, during an inspection of Defendants facility, the FDA observed that adverse events were not captured in the data.

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

(a) Two 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.

134. In July of 2002, the FDA found that:

(a) Defendant "does not have an assurance/quality control unit.

135. In December 2010, the FDA found that Defendants were "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."

136. Defendants failed to comply with *several* conditions:

(a) Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month and two year reports. All reports failed to meet the respective deadlines. *Post approval Studies- ESS-305 Schedule attached as Exhibit "B."*

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

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report 8 perforations which occurred as a result of Essure and was cited for the same by the FDA via Form 483.[2] *See Investigative Report attached as Exhibit "C."*

(d) Defendants 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, Defendants failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. *See Investigative Report attached as Exhibit "C."*

(e) As outlined *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

(f) Defendants' warranties were not consistent with applicable Federal and State law.

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

[2] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

137. Defendants also were found to be:

(a) erroneously using non-conforming material in the manufacturing of Essure and not tracking where it went; *See Investigative Report attached as Exhibit "C."*

(b) failing to use pre-sterile and post-sterile cages; *See Exhibit "D."*

(c) manufacturing Essure at an unlicensed facility; *See Exhibit "D."*

(d) manufacturing Essure for three years without a license to do so. *See Exhibit "D."*

(e) Not reporting … complaints in which their product migrated; See *Exhibit "E."*

(f) Not considering these complaints in their risk analysis for the design of Essure; See *Exhibit "E."*

(g) Failing to document CAPA activities for a supplier corrective action; See *Exhibit "E."*

138. Specifically,

(a) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 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." See Exhibit "F." 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. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

(b) Defendants had notice of 168 perforations but only disclosed 22 to the FDA. *Id.*

(c) On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(d) On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain

detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(e) On July 7, 2003, Defendants were 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) See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

(f) On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications. See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

139. In response Defendants 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."

140. In addition, Defendants' failure to timely file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from the more than 32,000 complaints it received, violated the CPMA, FDA post-marketing regulations, and parallel state law.

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

FDA HEARINGS AND RESULTING ACTION

142. The Defendants 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 the Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure device, the public's knowledge of the risks associated with the Essure

device were seriously hampered and delayed. This endangered patient safety, including Plaintiffs' safety.

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

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

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

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

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

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

(c) The FDA has also ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's

> quality of life. . . .The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

146. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Plaintiffs of the true risks of Essure. Had the Defendants complied with their federal regulatory duties and their duties under state law by reporting the known risks and complications in a timely fashion, the Plaintiffs and their physicians would have had this relevant, critical information available to them prior to the implant of the Essure device. At all relevant times, Defendants' Essure product was prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants. Moreover, Defendants misrepresentations regarding Essure discussed *infra*, in effect, over promoted Essure and nullified otherwise adequate warnings.

147. Lastly, although Essure appears at first glance to be a "medical device," Defendants actually categorize it as a "drug."

148. In short, (1) Essure is considered an "adulterated" and "misbranded" product that could not have been marketed or sold to Plaintiffs per the FDA and Federal law and (2) all of Plaintiffs' claims center around violations of the CPMA requirements and/or Federal regulations and statutes.

DEFENDANTS' TRAINING AND DISTRIBUTION PLAN

149. Defendants (1) failed to abide by FDA-Approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to the implanting physicians who was not qualified or competent to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiffs' safety and well-being.

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

151. In order to capture the market, Defendants independently undertook a duty of training physicians outside of FDA guidelines, including the implanting physicians, on how to properly use (1) its own mechanism of delivery and (2) the specialized hysteroscopic equipment manufactured by a third party.

152. Regarding Essure, Defendants' 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."

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

154. Defendants provided no training to the implanting physicians on how *to remove* Essure should it fail.

155. Defendants also kept training records on all physicians "signed-off to perform Essure procedures."

156. In order to sell its product and because the implanting physicians did not have access to the expensive hysteroscopic equipment, Defendants 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.

157. In fact, Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc. (1) to obtain specialized hysteroscopic equipment to then give to physicians and (2) to increase its sales force to promote Essure.

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

159. In regard to the entrustment of such specialized equipment, Defendants admitted: "We cannot be certain how successful these programs will be, if at all." *See US SEC Form 10-Q: Quarterly Report Pursuant to Section 13 or 15(d)of the SEC Act of 1934.*

160. Defendants "handed out" this hysteroscopic equipment to unqualified physicians, including Plaintiffs' implanting physicians, in an effort to sell its product.

161. Defendants 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 physician in order to capture the market.

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

163. Defendants' distribution plan included requiring the implanting physicians to purchase two (2) Essure "kits" per month, regardless of whether he used them or not. This

distribution plan created an environment which induced the implanting physicians to "push" Essure and implant the same into Plaintiffs.

164. In short, Defendants used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as "bait." Once the implanting physicians "took the bait" they was required to purchase two (2) Essure "kits" per month, regardless of whether they sold any Essure "kits".

165. This was an unreasonably dangerous distribution scheme as it compelled the implanting physicians to sell two (2) devices per month at the expense of Plaintiffs' safety and well-being.

166. 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 years without a license to do so.

167. In short, Defendants (1) failed to abide by FDA-Approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (3) created an unreasonably dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

168. All of this was done in violation of Federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiffs' safety.

PLAINTIFFS' HISTORY

169. Plaintiff, Maria Alfaro, is a resident of CA. She was implanted on or about September, 2012. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

170. Plaintiff, Bridget Amos, is a resident of GA. She was implanted on or about April, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

171. Plaintiff, Christina Anderson, is a resident of CO. She was implanted on or about April, 2013. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

172. Plaintiff, Rebecca Arboleda, is a resident of NY. She was implanted on or about July, 2016. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

173. Plaintiff, Annette Arnold, is a resident of NE. She was implanted on or about October, 2006. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

174. Plaintiff, Paola Astudillo, is a resident of FL. She was implanted on or about October 16, 2013. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

175. Plaintiff, Sukhjiwan Athwal, is a resident of CA. She was implanted on or about July, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

176. Plaintiff, Deborha Ball, is a resident of MI. She was implanted on or about 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

177. Plaintiff, MarQuitte Barlow, is a resident of MI. She was implanted on or about November 8, 2012. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

178. Plaintiff, Deborah Bascom, is a resident of NJ. She was implanted on or about October 10, 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

179. Plaintiff, Kelly Bateson, is a resident of FL. She was implanted on or about June, 2008. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

180. Plaintiff, E. Nicole Baxley, is a resident of TX. She was implanted on or about February 3, 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

181. Plaintiff, Kandace Beam, is a resident of AL. She was implanted on or about August 21, 2017. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

182. Plaintiff, Lindsay Beamis, is a resident of NY. She was implanted on or about January, 2013. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

183. Plaintiff, Tammy Bellard, is a resident of LA. She was implanted on or about June, 5 2008. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

184. Plaintiff, Jamie Bennett, is a resident of GA. She was implanted on or about 2012. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

185. Plaintiff, Kathleen Berget, is a resident of WI. She was implanted on or about June, 2007. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

186. Plaintiff, Tameeka Bey, is a resident of GA. She was implanted on or about July 22, 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

187. Plaintiff, Kristy Blackburn, is a resident of KY. She was implanted on or about October, 2009. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

188. Plaintiff, Shantai Borum, is a resident of IL. She was implanted on or about October 20, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

189. Plaintiff, Katie Boucher, is a resident of WI. She was implanted on or about January, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

190. Plaintiff, Leslie Boudreau, is a resident of IL. She was implanted on or about September, 2009. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

191. Plaintiff, Victoria Bourque, is a resident of TX. She was implanted on or about July, 2013. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

192. Plaintiff, Julia Brazzil-Mannings, is a resident of IL. She was implanted on or about December, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

193. Plaintiff, April Brooks, is a resident of CA. She was implanted on or about December, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

194. Plaintiff, Perrica Brown, is a resident of GA. She was implanted on or about December, 2005. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

195. Plaintiff, Lacey Brown, is a resident of UT. She was implanted on or about May, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

196. Plaintiff, Deborah Brucato, is a resident of VA. She was implanted on or about December, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

197. Plaintiff, Revonda Burney, is a resident of GA. She was implanted on or about April, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

198. Plaintiff, Wendy Cabrera, is a resident of CT. She was implanted on or about February, 2004. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

199. Plaintiff, Jennifer Campbell, is a resident of CA. She was implanted on or about 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

200. Plaintiff, Yajaira Campos, is a resident of NY. She was implanted on or about February 21, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

201. Plaintiff, Amy Cantu, is a resident of OH. She was implanted on or about August 15, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

202. Plaintiff, Christina Castellanos, is a resident of CA. She was implanted on or about March, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

203. Plaintiff, Nancy Cervantes, is a resident of CA. She was implanted on or about March, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

204. Plaintiff, Iisha Clements, is a resident of FL. She was implanted on or about February, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

205. Plaintiff, Amber Clinger, is a resident of OH. She was implanted on or about 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

206. Plaintiff, Iliana Contreras, is a resident of TX. She was implanted on or about July 14, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

207. Plaintiff, Shastevia Cook, is a resident of TX. She was implanted on or about April, 2013. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

208. Plaintiff, Donna Cottrell, is a resident of TN. She was implanted on or about July, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

209. Plaintiff, Louann Cox, is a resident of OH. She was implanted on or about January 20, 2008. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

210. Plaintiff, Prestena Crane, is a resident of TX. She was implanted on or about January 14, 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

211. Plaintiff, Dequita Crawford, is a resident of GA. She was implanted on or about April, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

212. Plaintiff, Sheretha Crawford, is a resident of TX. She was implanted on or about April 4, 2015. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

213. Plaintiff, Monica Creath, is a resident of NC. She was implanted on or about February 7, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

214. Plaintiff, Amber Crigler, is a resident of NC. She was implanted on or about July, 2009. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

215. Plaintiff, Jennifer Dargonne, is a resident of CT. She was implanted on or about 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

216. Plaintiff, Aurora Darnell, is a resident of OK. She was implanted on or about October, 2009. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

217. Plaintiff, Paula Davis, is a resident of TN. She was implanted on or about 2012. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

218. Plaintiff, Brandi Davis, is a resident of AZ. She was implanted on or about March 4, 2012. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

219. Plaintiff, Kristine Daywalt, is a resident of MD. She was implanted on or about August, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

220. Plaintiff, Jennifer DeCheney, is a resident of MI. She was implanted on or about 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

221. Plaintiff, Catherine Dennison, is a resident of VA. She was implanted on or about July 26, 2013. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

222. Plaintiff, Connie Derosier, is a resident of MN. She was implanted on or about 2011. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

223. Plaintiff, Amy Detty, is a resident of MI. She was implanted on or about June, 2009. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

224. Plaintiff, Agnes Dew, is a resident of GA. She was implanted on or about July 7, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

225. Plaintiff, Jennifer Dewalt, is a resident of OH. She was implanted on or about October 31, 2008. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

226. Plaintiff, Misty Dickerson, is a resident of AR. She was implanted on or about December, 2006. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

227. Plaintiff, Kristi Doyle, is a resident of TX. She was implanted on or about June, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

228. Plaintiff, Jessica Duclo, is a resident of CA. She was implanted on or about 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

229. Plaintiff, Dawn Edwards, is a resident of NC. She was implanted on or about May, 2005. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

230. Plaintiff, Abigail Ferstein, is a resident of IL. She was implanted on or about January 24, 2017. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

231. Plaintiff, Jennifer Finney, is a resident of OH. She was implanted on or about March, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

232. Plaintiff, Mecca Fisher, is a resident of TX. She was implanted on or about May, 2008. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

233. Plaintiff, Stacy Flores, is a resident of AZ. She was implanted on or about October 15, 2008. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

234. Plaintiff, Faith Forde, is a resident of NC. She was implanted on or about November, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

235. Plaintiff, Jayme Fox, is a resident of WI. She was implanted on or about June, 2012. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

236. Plaintiff, Alyssa Franklin, is a resident of CT. She was implanted on or about August, 2014. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

237. Plaintiff, Melissa Fulkerson, is a resident of KY. She was implanted on or about March, 2010. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

238. Plaintiff, Ashley Gadson, is a resident of MI. She was implanted on or about October, 2016. As a result of Essure, this Plaintiff suffered from severe and permanent injuries.

FRAUDULENT CONCEALMENT/DISCOVERY RULE/EQUITABLE TOLLING/EQUITABLE ESTOPPEL

SUMMARY OF ACTIVE CONCEALMENT

239. First, Defendants' fraudulent acts and/or omissions discussed below, before, during and/or after the acts causing Plaintiffs' injuries, prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injuries or causes thereof as alleged in this amended complaint until February 29, 2016.

240. Second, Defendants' 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 Plaintiffs' statute of limitations.

241. Third, and in the alternative, Defendants are also estopped from relying on any statute of limitations defense because it 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 the Plaintiffs. As a result of Defendants' concealment of the true character, quality, history, and nature of their product, they are estopped from relying on any statute of limitations defense.

242. Defendants furthered their fraudulent concealment through act and omission, 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 the Plaintiffs, Plaintiffs' physicians, and the FDA.

243. In short, Defendants:

(a) Actively and intentionally concealed from Plaintiffs that their physicians were not trained pursuant to the FDA-approved training noted *infra*.

(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 the Plaintiffs.

(c) Actively and intentionally concealed from Plaintiffs and Plaintiffs' physician's risks by making the misrepresentations/warranties noted *infra* knowing they were false. In short, Defendants knew the misrepresentations were false because they had studies and reports which showed the opposite yet altered and concealed the same from Plaintiffs, the FDA and Plaintiffs' physicians. Defendants made the misrepresentations with the intent of misleading Plaintiffs 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")

244. If Defendants had met their duties under the above mentioned federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians of the increased risks and serious dangers associated with Essure in time to have lessened or prevent Plaintiffs' 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 discuss and warn in detail, the risks of the very same injuries Plaintiffs suffered and Defendants concealed and altered. Had Defendants satisfied their obligations, these FDA mandates would have been plausible prior to Plaintiffs' implantation. As discussed *infra*, Defendants continued to misrepresent the safety and efficacy of Essure at the FDA Hearings.

245. In short, Defendants manipulated its reports to the FDA and presented false and misleading information, which, in turn, caused or contributed to Plaintiffs' consent not being informed as critical facts regarding the nature and quality of side effects from Essure were concealed from Plaintiffs and their physicians.

246. Defendants did this in an effort to maintain the impression that the Essure device had a positive risk/benefit profile, to guard sales, and to ensure that Plaintiffs and their physicians did not have the salient facts in order to bring the claims alleged in this amended complaint.

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

FDA CALLS ESSURE MEETING

248. 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 the Essure device.

249. 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.[3]

250. 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.[4]

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

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

253. Finally, women considering the device will have the chance to be fully informed of its true risks.

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

255. Upon information and belief, Defendants knew that if the true risks of Essure were known to the FDA, then they should or would inevitably be communicated to physicians and Plaintiffs.

---

[3] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm.
[4] *Id.*

256. The checklist specifically warns of device migration, perforation of organs, and new side effects that Defendants had been cited for hiding from the FDA, Plaintiffs, and Plaintiffs' physicians and/or enhances the sufficiency of the same.

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

258. The checklist has a major impact on the risk/benefit profile of the device, and Plaintiffs would not have had the device implanted with it in place.

259. On February 29, 2016, the FDA also announced that it would also 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.

260. 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.**[5]

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

DISCOVERY RULE- TOLLING

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

---

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

263. Plaintiffs did not possess the sufficient critical facts to put them on notice that the wrongs and the acts and omissions had been committed until such date. This is because it was not until the FDA hearing that Essure's safety and Defendants' 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."

264. In fact, no reasonable person in Plaintiffs' position would have been aware of the salient facts of this complaint until after February 29, 2016.

265. Plaintiffs did not have the opportunity to discover the harm inflicted because Defendants were and are continuing to conceal the acts and omissions noted above.

266. At all times material hereto, Plaintiffs exercised reasonable diligence in investigating potential causes of her injury by discussing her injuries with healthcare providers. None of the conversations gave Plaintiffs a reason to suspect, or reasonably should have given Plaintiffs a reason to suspect that Essure or Defendants' tortious conduct in this complaint was the cause of such injuries until February 29, 2016.

267. Regardless of the exercise of reasonable diligence, Plaintiffs did not know or reasonably should not have known that she suffered injury and that her injury had been caused by Defendants' conduct in this complaint until February 29, 2016.

268. Plaintiffs neither suspected nor knew of Defendants' wrongdoings as alleged in this complaint until February 29, 2016.

269. In sum, Plaintiffs were reasonably unaware, and had no reasonable way of knowing, that their injuries described above were caused by Defendants' conduct as alleged in this complaint until February 29, 2016.

270. As such, Plaintiffs' statute of limitations did not begin to run until February 29, 2016.

FRUADULENT CONCEALMENT – EQUITABLE TOLLING

271. Defendants committed affirmative independent acts of concealment (including the acts and omissions) and intentionally mislead Plaintiffs as noted above upon which Plaintiffs and Plaintiffs' physicians relied on.

272. The acts and omissions misled Plaintiffs in regard to their 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 February 29, 2016.

273. Defendants also prevented Plaintiffs from asserting their rights in this complaint by committing affirmative independent acts of concealment as noted above upon which Plaintiffs relied on.

274. Due to the acts and omissions of concealment, Plaintiffs were not cognizant of the facts supporting their causes of action in this complaint until February 29, 2016.

275. As such, Plaintiffs' statute of limitations were tolled in light of Defendants' fraudulent concealment and their statute began to run starting from the date that facts supporting their causes of action in this complaint became apparent or February 29, 2016.

276. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs and their physicians of vital information essential to the pursuit of the claims in this complaint, without any fault or lack of diligence on their part. Plaintiffs 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 Defendants' tortious conduct.

EQUITABLE ESTOPPEL

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

278. Defendants affirmatively induced Plaintiffs to delay bringing this complaint by the acts and omissions.

279. In addition to acts and omissions noted above, Defendants consistently represented to Plaintiffs and/or Plaintiffs' physicians that Essure was not the cause of any of Plaintiffs' injuries to delay her bringing this complaint.

280. 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.

FACTS AND WARRANTIES

281. First, Defendants failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physicians, including the implanting physicians, on how to use its device and in hysteroscopy.

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

283. Accordingly, Defendants went out and attempted to train the implanting physicians on (1) how to use its device and (2) in hysteroscopy. Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants 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." Defendants had no experience in training others in hysteroscopy.

284. Defendants failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physicians and provided hysteroscopic equipment to the implanting physicians who was not qualified to use such complicated equipment.

285. 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 Defendants' training methods were failing[6].

286. Second, Defendants provided hysteroscopic equipment to the implanting physicians who was not competent to use such device. Defendants knew the implanting physicians was not competent to use such sophisticated equipment, yet provided the equipment anyway in order to sell its product.

287. Third, Defendants' 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 Plaintiff.

288. Defendants' distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and Federal law; (2) the promotion of

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

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 years without a license to do so.

289. Lastly, Plaintiffs relied on several warranties which were given directly by Defendants to Plaintiffs, prior to implantation, on the internet and in the implanting physicians' office, through Defendant's website and advertising, as outlined in detail *infra*.

NEGLIGENT TRAINING – COUNT I

290. Plaintiffs re-allege and re-incorporate the preceding Paragraphs.

291. First, Defendants undertook an independent duty to train physicians on how to (1) properly use its device to place the micro-inserts which failed to abide by FDA training guidelines.

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

293. As part of Defendants' training: Defendants 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. Defendants

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.

294. Specifically, pursuant to the FDA-approved training regulations and guidelines, Defendants 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 5 cases) in Essure placement until competency;

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

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

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

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

(b) Ensure that the implanting physicians were appropriately counseling Plaintiffs 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.

296. Defendants breached this duty and parallel state law 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 requirement;

(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.

(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.

297. 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, and/or fracture 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, and/or fracture producing the damages noted above;

(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, and/or fracture producing the damages noted above;

298. This breach caused Plaintiffs' damages noted above.

299. As a result of Defendants' negligence individually, jointly, and severally, Plaintiffs sustained the injuries and exacerbations noted above.

300. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

301. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

302. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

303. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $75,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENCE- RISK MANAGEMENT– COUNT II

304. Plaintiffs re-allege and re-incorporate the preceding Paragraphs.

305. In short, Defendants had a duty under both state and Federal law to have in place a reasonable risk management procedure to ensure, *inter alia*, (1) that adverse reports were being reported to the FDA so that it could be relayed to the implanting physicians and/or Plaintiffs; (2) that 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 Plaintiffs; (3) that they investigate information about the risks Essure posed so that it could be relayed to the implanting physicians and/or Plaintiffs; (4) that the continued sale of Essure was appropriate and reasonable despite the information being withheld to the public by Defendants (5) 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.;(6) establish internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.; and (7) maintain the labeling of Essure by filing a "Special PMA Supplement – Changes Being Effected" ("CBE") which allows Defendants to unilaterally update the labeling of Essure to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d).

306. Specifically, Defendants had a duty to comply with the following Federal regulations but breached the same regulations by the subsequent violations noted directly below (which Defendants were 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 conditions of approval specified in the PMA approval order for the device.

(Defendants were 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 Plaintiffs and Implanting Physicians. This failing to disclose and include in their risk management analysis was a condition of approval in its CPMA)

(b) 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.

(Defendants were 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 Plaintiffs 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.

(Defendants were 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 Plaintiffs 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.

(Defendants were 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 Plaintiffs and Implanting Physicians.)

(e) 21 C.F.R. 803.53- You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 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 5-day report. If you receive such a written request from us, you must submit, without further requests, a 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.

(Defendants were 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 Plaintiffs 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 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 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]

(Defendants were 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 Plaintiffs 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.

(Defendants were 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 Plaintiffs 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.

(Defendants 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 failing 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 Plaintiffs and Implanting Physicians. This failing 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 (the act) by providing procedures and requirements for postmarket 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 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.

(Defendants were cited for and breached this federal standard by failing to comply with postmarket 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 Plaintiffs and Implanting Physicians. Defendants 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 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.

(Defendants were 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 Plaintiffs 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.

(Defendants were 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 Plaintiffs and Implanting Physicians.)

(l) FDA requirement in CPMA order- "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(Defendants were 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 Plaintiffs 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."

(Defendants were 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 Plaintiffs 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.;

(Defendants were 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 Plaintiffs and Implanting Physician.)

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

(Defendants were 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 Plaintiffs and Implanting Physicians.)

307. Due to these breaches, Defendants were cited by the FDA as Defendants "did not consider these complaints in their risk analysis" and "for their risk analysis of Essure being incomplete.

308. This was an unreasonably dangerous and negligent risk analysis plan which was required by Federal law as it put Plaintiffs at unnecessary risk of injury due to Defendants' 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.

309. This breach caused Plaintiffs' damages because but for Defendants 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, Plaintiffs would not have been implanted with Essure and therefore would also not have been injured by Essure. Instead, Defendants failed to have a complete Risk Management Plan in place thereby precluding Plaintiffs and their implanting physicians from knowing of the thousands of migrations, perforations, pregnancies, device failures and malfunctions. This was actively concealed by Defendants.

310. This breach caused Plaintiffs' damages noted above.

311. As a result of Defendants' negligence individually, jointly, and severally, Plaintiffs sustained the injuries and exacerbations noted above.

312. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

313. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

314. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their

significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

315. Plaintiffs have suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $75,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

BREACH OF EXPRESS WARRANTY- COUNT III

316. Plaintiffs re-alleges and re-incorporates the preceding Paragraphs and pleads in the alternative to Counts IV.

317. 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."

318. This claim arises out of injuries caused by Defendants' express warranties to Plaintiffs which were specifically negotiated and expressly communicated to Plaintiffs by Defendants or its agents in such a manner that Plaintiffs understood and accepted them.

319. Defendant made, and Plaintiffs relied on, the following actual affirmations of fact or promises which formed the bases of the bargain between Plaintiffs and Defendants[7]:

(a) "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

[7] The warranties and misrepresentations relating to pregnancy apply to only those plaintiffs that became pregnant.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty which was located on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

(b) "There were Zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

(c) "Physicians must be signed-off to perform Essure procedures"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted reliable physicians who were approved to perform her surgery.

iii. However, this warranty was false as Defendants failed to abide by the FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendants concealed this information from Plaintiff.

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

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw 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. Defendants concealed this information from Plaintiffs. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. Defendants concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[8] Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(e) "Essure is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants

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

concealed this information from Plaintiffs. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[9].

(f) "Correct placement…is performed easily because of the design of the micro-insert"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiffs.

(g) "Essure is a surgery-free permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiff encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

(h) "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an

[9] *Id.*

advertisement entitled "Are you Ready?" The circumstances under which Plaintiff encountered this representation was via a brochure given to her at her implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

(i) In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an Essure advertisement. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted reliable physicians who were approved to perform her surgery.

iii. However, this warranty was false as Defendants "signed off" on "Essure physicians who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendants concealed this information from Plaintiff.

(j) You'll never have to worry about unplanned pregnancy again.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

(k) Defendants marketed with commercials stating during the procedure: "the tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiff relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

(l) "Worry free"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that she did not have to worry about working or causing her serious health problems.

iii. However, Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiff. *See Investigative Report attached hereto as Exhibit "C."* Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiffs. *See Investigative Report attached hereto as Exhibit "C.* Defendants' facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages." Defendants actively concealed this from Plaintiffs. *See Notice of Violation attached as Exhibit "D."* Defendants also was issued a notice of violation when it "failed to obtain a valid license…prior to manufacturing medical devices." Defendants were

manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiffs. *See Notice of Violation attached as Exhibit "D."* Defendants were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. *See Notice of Violation attached as Exhibit "D."* Defendants actively concealed this from Plaintiffs. Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. *See Exhibit "H."* Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(m) "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483 issued to Defendants by the FDA. *See Investigative Report attached hereto as Exhibit "C ."* Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(n) "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation when they were researching options of birth control.

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

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiff. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issue another Form 483 for "failing to adequately document the situation." *See Investigative Report attached hereto as Exhibit "C."*

(o) Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants 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 Defendants. Defendants concealed this information from Plaintiffs. 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[10].

(p) "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the 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. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(q) Essure is a …permanent birth control procedure-without … the risks of getting your tubes tied.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the 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 does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

(r) "The inserts are made from…safe, trusted material."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure."

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

The circumstances under which Plaintiff encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause her 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, Defendants refer to Essure and classify it as a "drug."

(s) Defendants' Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiffs encountered this representation was via a brochure given to them at their implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems. Moreover, Plaintiffs wanted a birth control that did not irritate her uterus like other forms of birth control.

iii. However, this warranty was false as the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. *See Investigative Report attached hereto as Exhibit "C ."* Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(t) "there was no cutting, no pain, no scars…"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The

circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that did not cause pain cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiffs have experienced pain as a result of Essure. Defendants concealed this information from Plaintiffs. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain. Defendants altered the records of at least one trial participant to reflect less pain.

320. Defendants' "affirmations of fact or promise" and "descriptions" created a basis of the bargain for Plaintiffs as noted above.

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

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

323. As a result of Defendants' warranties and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure device did not perform as warranted and instead migrated, perforated and/or broke resulting in the injuries noted above.

324. As a result of Defendants' breaches individually, jointly, and severally, Plaintiffs sustained the injuries and exacerbations noted above.

325. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

326. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

327. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

328. Plaintiffs have suffered a significant decrease in her ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $75,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENT MISREPRESENTATION– COUNT IV

329. Plaintiffs re-allege and re-incorporate the preceding Paragraphs.

330. Defendants made the following misrepresentations:

(a) "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty which was located on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

(b) "There were Zero pregnancies in the clinical trials."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiffs.

(c) "Physicians must be signed-off to perform Essure procedures"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable physician who was approved to perform her surgery.

iii. However, this warranty was false as Defendants failed to abide by the FDA guidelines when training the implanting physicians and "signed-off" on the implanting physicians who did not have the requisite training. Defendants concealed this information from Plaintiffs.

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

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs

encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw 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. Defendants concealed this information from Plaintiffs. Between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. Defendants concealed this information from Plaintiffs. There have been over 30 pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater.[11] Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(e) "Essure is the most effective permanent birth control available-even more effective than tying your tubes or a vasectomy."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiffs. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[12].

---

[11] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.
[12] *Id.*

(f) "Correct placement…is performed easily because of the design of the micro-insert"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their own experts in hysteroscopy (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiffs.

(g) "the Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted an implanting physician that was properly trained on placing the device and managing any technical issues.

iii. However, this warranty was false as Defendants failed to train the implanting physicians pursuant to the FDA guidelines. Defendants concealed this information from Plaintiffs.

(h) "In order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted an implanting physician that was properly trained on placing the device and managing any technical issues.

iii. However, this warranty was false as Defendants "signed off" on the implanting physicians who were not a skilled operative hysteroscopist, in order to monopolize and capture the market, including the implanting physicians. Defendants concealed this information from Plaintiffs.

(i) "Essure is a surgery-free permanent birth control."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on Defendants' website www.essure.com. The circumstances under which Plaintiffs encountered this representation was via the internet when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

(j) "Zero pregnancies" in its clinical or pivotal trials.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "Are you Ready?" The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

(k) In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty located on an Essure advertisement. The circumstances under which Plaintiffs encountered this representation was via a brochure given to her at her implanting physicians' office and was read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable Physician who was approved to perform her surgery.

iii. However, this warranty was false as Defendants "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physicians. Defendants concealed this information from Plaintiffs.

(l) You'll never have to worry about unplanned pregnancy again.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

(m) Defendants marketed with commercials stating during the procedure: "the tip of each insert remains visible to your doctor, so proper placement can be confirmed."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a procedure that could be easily performed and ensure that placement of the devices were properly positioned.

iii. However, this warranty was false as Essure does not allow for visual confirmation of proper placement during the procedure.

(n) "Worry free"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that she did not have to worry about working or causing her serious health problems.

iii. However, Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a Form 483 issued by the FDA to Defendants. Defendants actively concealed this from Plaintiffs. *See Investigative Report attached hereto as Exhibit "C ."* Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendants actively concealed this from Plaintiffs. *See Investigative Report attached hereto as Exhibit "C ."*Defendants' facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages." Defendants actively concealed this from Plaintiffs. *See Notice of Violation attached as Exhibit "D."* Defendants also was issued a notice of violation when it "failed to obtain a valid license…prior to manufacturing medical devices." Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiffs. *See Notice of Violation attached as Exhibit "D."* Defendants were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. *See Notice of Violation attached as Exhibit "D."* Defendants actively concealed this from Plaintiffs. Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%." Defendants were issued Form 483's for not

disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(o) "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure" and on www.essure.com. The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed propèrly and would not migrate or cause her other health problems.

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendants actively concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483 issued to Defendants by the FDA. *See Investigative Report attached hereto as Exhibit "C ."* Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(p) "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

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

iii. However, this warranty was false as the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendants actively concealed this from Plaintiffs. PET fibers are not designed or manufactured for use in human implantation. Moreover, Defendants also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known." PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion. Most egregiously, Defendants were issued another Form 483 when it "erroneously used non-conforming material." Defendants actively concealed this and was issue another Form 483 for "failing to adequately document the situation." *See Investigative Report attached hereto as Exhibit "C."*

(q) Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control.

iii. However, this warranty was false as Defendants 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 Defendants. Defendants concealed this information from Plaintiffs. 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[13].

(r) "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure."

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

The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the 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. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

(s) Essure is a …permanent birth control procedure-without … the risks of getting your tubes tied.

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the 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 does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

(t) "The inserts are made from…safe, trusted material."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on an advertisement entitled "When your family is complete, choose Essure." The circumstances under which Plaintiffs encountered this representation was via a brochure when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that was made of safe material which would not cause her 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, Defendants refer to Essure and classify it as a "drug."

(u) Defendants' Essure booklet warrants: "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that would not migrate and that could be visible so that their implanting physicians could confirm they were placed properly and would not migrate or cause her other health problems. Moreover, Plaintiffs wanted a birth control that did not irritate her uterus like other forms of birth control.

iii. However, this warranty was false as the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiffs. Defendants actively concealed and failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in Form 483. *See Investigative Report attached hereto as Exhibit "C ."* Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(v) "there was no cutting, no pain, no scars…"

i. Plaintiffs relied on and actually saw this warranty and believed it to be true. Specifically, Plaintiffs saw and read this warranty on a booklet advertisement entitled "Essure: Permanent Birth Control" The circumstances under which Plaintiffs encountered this representation was via a brochure read when they were researching options of birth control.

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that did not cause pain cutting or scars like other forms of birth control do.

iii. However, this warranty was false as Plaintiffs has experienced pain as a result of Essure. Defendants concealed this information from Plaintiffs. Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive

results in as many as 40%." Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain. Defendants altered the records of at least one trial participant to reflect less pain.

331. Plaintiffs justifiably relied on the misrepresentations. Specifically, Plaintiffs 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.

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

333. As a result of Defendants' misrepresentations and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure device did not perform as represented and instead migrated, perforated and/or broke resulting in the injuries noted above.

334. As a result of Defendants' negligence individually, jointly, and severally, Plaintiffs sustained the injuries and exacerbations noted above.

335. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

336. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, permanent injuries, both physical and mental, and will continue to do so into the indefinite future.

337. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and they may have to endure significant financial expenditures into the foreseeable future.

338. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $75,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENCE-FAILURE TO WARN– COUNT V

339. Plaintiffs re-allege and re-incorporate the preceding Paragraphs.

340. Plaintiffs' injuries were caused by the negligent and reckless conduct of Defendants in failing to warn Plaintiffs or their implanting physicians, all of which hinge on violations of Federal law and its CPMA.

341. Defendants had a duty to warn Plaintiffs and/or their implanting physicians consistent with Federal law and its CMPA and 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 conditions 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 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.

(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 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 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 5-day report. If you receive such a written request from us, you must submit, without further requests, a 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 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 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 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 (the act) by providing procedures and requirements for postmarket 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 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 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 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 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.

342. Defendants breached these duties by not complying with its CPMA or Federal law:

(a) Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month and two year reports. All reports failed to meet the respective deadlines. *Post approval Studies- ESS-305 Schedule attached as Exhibit "B."*

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

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report 8 perforations which occurred as a result of Essure and was cited for the same by the FDA via Form 483.[14] *See Investigative Report attached as Exhibit "C."*

(d) Defendants 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, Defendants failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in Form 483. *See Investigative Report attached as Exhibit "C."*

(e) Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. See Exhibit "E."

(f) Defendants excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendants had violated the FDCCA. *Id.*

(g) erroneously using non-conforming material in the manufacturing of Essure; *See Investigative Report attached as Exhibit "C."*

[14] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

(h) failing to use pre-sterile and post-sterile cages; *See Exhibit "D."*

(i) manufacturing Essure at an unlicensed facility; *See Exhibit "D."*

(j) manufacturing Essure for three years without a license to do so. *See Exhibit "D."*

(k) Not reporting … complaints in which their product migrated; See *Exhibit "E."*

(l) Not considering these complaints in their risk analysis for the design of Essure; See *Exhibit "E."*

(m) Failing to document CAPA activities for a supplier corrective action; See *Exhibit "E."*

(n) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 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." See Exhibit "F." 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. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

(o) Defendants had notice of 168 perforations but only disclosed 22 to the FDA. *Id.*

(p) On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(q) On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(r) On July 7, 2003, Defendants were 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) See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

(s) On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications. See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

(t) Defendants failed to disclose to Plaintiffs and their implanting physicians the fact that it Defendants 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.

343. Had Defendants disclosed such information as was required by its CPMA and Federal law to Plaintiffs or Implanting Physicians, Plaintiffs would have never had Essure implanted in them and would have avoided injuries.

344. At all times referenced herein, Defendants and each of them were acting as agents and employees of each of the other defendants 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.

345. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained the injuries noted above.

346. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

347. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

348. Plaintiffs have been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to their significant financial detriment and loss, and may have to endure significant financial expenditures into the foreseeable future.

349. Plaintiffs have suffered a significant decrease in their ability to earn money in the future, as well as a significant loss of earning capacity.

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $75,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial with regards to all claims.

DATED this 22 day of February, 2018.

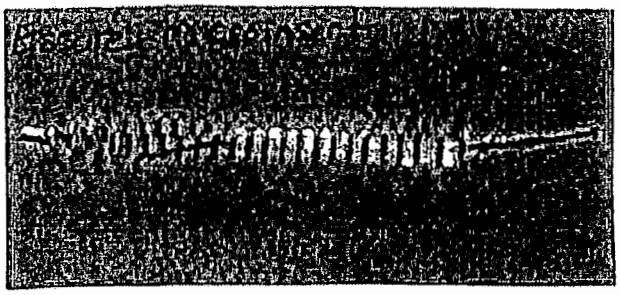
Respectfully submitted,

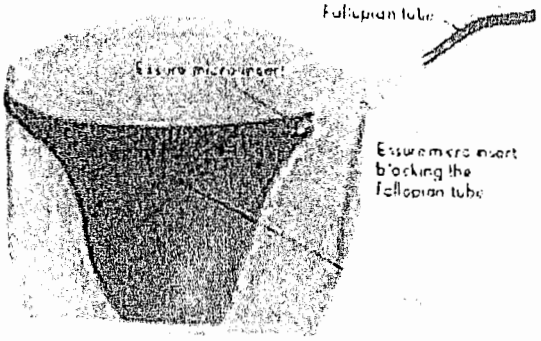
Aylstock, Witkin, Kreis & Overholtz, PLLC

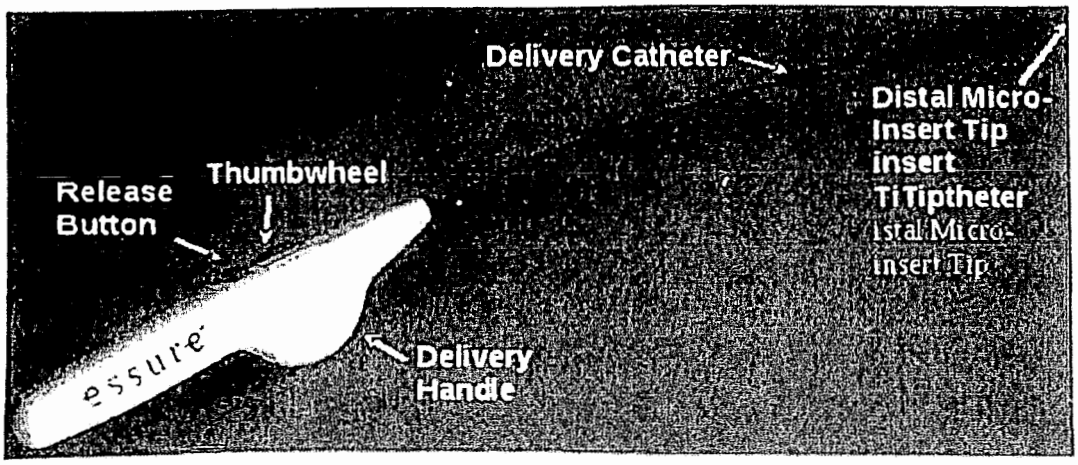
/s/ James D. Barger
James D. Barger - PA Bar No. 310056
17 East Main Street, Suite 200
Pensacola, Florida 32502
(850) 202-1010 (telephone)
(850) 916-7449 (fax)
jbarger@awkolaw.com

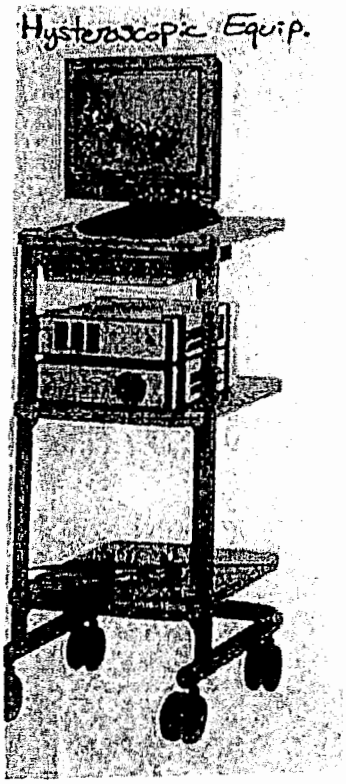
Attorney for Plaintiffs

EXHIBIT A




Fallopian tube
Essure micro-insert
Essure micro-insert blocking the Fallopian tube


Delivery Catheter
Distal Micro-Insert Tip
Release Button
Thumbwheel
Delivery Handle


Hysteroscopic Equip.

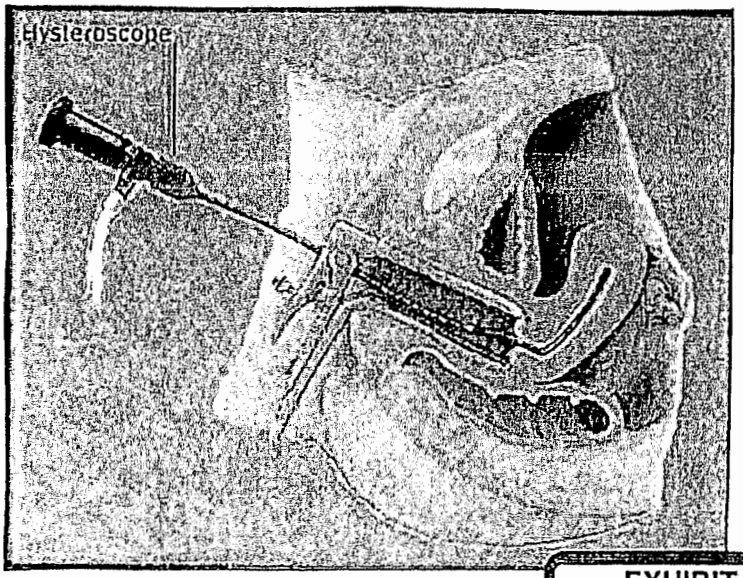

Hysteroscope

EXHIBIT
A

EXHIBIT B

Home[3] Medical Devices[4] Databases[5]

Post-Approval Studies

Post-Approval Studies

- In January 2005, the oversight responsibility of the Post Approval Studies Program was transferred to the Division of Epidemiology (DEPI) of the Office of Surveillance and Biometrics (OSB)/Center for Devices and Radiological Health (CDRH)
- The CDRH Post-Approval Studies Program encompasses design, tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application, protocol development product (PDP) application, or humanitarian device exemption (HDE) application. The program helps ensure that well-designed post-approval studies (PAS) are conducted effectively and efficiently and in the least burdensome manner
- CDRH has established an automated internal tracking system that efficiently identifies the reporting status of active PAS studies ordered since January 1, 2005 based on study timelines incorporated in study protocols and agreed upon by the CDRH and applicants. This system represents CDRH's effort to ensure that all PAS commitments are fulfilled in a timely manner
- In addition, CDRH launched this publicly available webpage to keep all stakeholders informed of the progress of each PAS. The webpage displays general information regarding each PAS, as well as the overall study status (based on protocol-driven timelines and the adequacy of the data) and the applicant's reporting status for each submission due

Links

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[6]
- PAS Webpage FAQs[7]
- Tools for Conducting PAS
  - Letter to IRB Chairs[9] (formerly referred to as "IRB Letter from Dr. Schultz (dated 2/5/09)"
  - Letter to PAS Participants[9]
  - Letter to PAS Investigators[10]
- Post-Approval Studies Workshops
  - Report on Implementation of Post-Approval Studies for Medical Devices Workshop (June 2009)[11]

Contact Information

Julie Unger
Project Manager, Post-Approval Studies Program
Food and Drug Administration
10903 New Hampshire Ave
WO66-4206v Silver Spring, MD
20993-0002

Phone: (301) 796-6134
Fax: (301) 847-8140
julie.unger@fda.hhs.gov

Show All Studies

Export to Excel

General	
Application Number	P020014 S017
Most Recent Protocol Version Approved	02/24/2012
Study Name	Essure/post-NovaSure PAS
Study Status	Progress Adequate
General Study Protocol Parameters	
Study Design	Prospective Cohort Study
Study involve follow-up of premarket cohort (Y/N)	No
Data Source	New Data Collection
Comparison Group	Objective Performance Criterion
Analysis Type	Analytical
Study Population	Transit. Adolescent B (as adults) : 18-21 yrs, Adult >21
Detailed Study Protocol Parameters	
Study Design Description	Single-arm multi-center prospective observational study
Study Population Description	Women aged 21-50 with Essure microinserts properly placed (confirmatory HSG) seeking treatment for menorrhagia
Sample Size	A minimum of 220 female subjects relying on Essure micro-inserts seeking treatment for menorrhagia
Data Collection	Occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure
Followup Visits and Length of Followup	3 years One week post Novasure procedure, then one and three year Post EA Contraception Phone Call

Essure/post-NovaSure PAS Schedule

Report Schedule	Report Data Due	FDA Receipt Date	Reporting Status
six month report	08/24/2012	12/14/2012	Overdue/Received
one year report	02/23/2013	01/08/2013	Overdue/Received
18 month report	08/24/2013	09/12/2013	Overdue/Received
two year report	03/21/2014	03/24/2014	Overdue/Received
three year report	02/23/2015		
four year report	02/23/2016		
five year report	02/22/2017		

Show All Studies

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm

EXHIBIT B

ost-Approval Studies

Post-Approval Studies

- In January 2005 the oversight responsibility of the Post-Approval Studies Program was transferred to the Division of Epidemiology (DEPI) of the Office of Surveillance and Biometrics (OSB)/Center for Devices and Radiological Health (CDRH)
- The CDRH Post-Approval Studies Program encompasses design tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application protocol development product (PDP) application, or humanitarian device exemption (HDE) application The program helps ensure that well designed post-approval studies (PAS) are conducted effectively and efficiently and in the least burdensome manner
- CDRH has established an automated internal tracking system that efficiently identifies the reporting status of active PAS studies ordered since January 1 2005 based on study timelines incorporated in study protocols and agreed upon by the CDRH and applicants This system represents CDRH's effort to ensure that all PAS commitments are fulfilled in a timely manner
- In addition CDRH launched this publicly available webpage to keep all stakeholders informed of the progress of each PAS The webpage displays general information regarding each PAS as well as the overall study status (based on protocol-driven timelines and the adequacy of the data) and the applicant's reporting status for each submission due

Links

- Guidance Document, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[6]
- PAS Webpage FAQs[7]
- Tools for Conducting PAS
  - Letter to IRB Chairs[8] (formerly referred to as "IRB Letter from Dr Schultz (dated 2/3/09)"
  - Letter to PAS Participants[9]
  - Letter to PAS Investigators[10]
- Post-Approval Studies Workshops
  - Report on Implementation of Post-Approval Studies for Medical Devices Workshop (June 2009)[11]

Contact Information

Julie Unger
Project Manager, Post Approval Studies Program
Food and Drug Administration
10903 New Hampshire Ave
WO66-4208v Silver Spring, MD
20993-0002

Phone (301) 796-6134
Fax (301) 847-8140
julie.unger@fda.hhs.gov

Show All Studies | Export to Excel

General	
Application Number	P020014 S012
Most Recent Protocol Version Approved	05/15/2007
Study Name	ESS-305
Study Status	Completed
General Study Protocol Parameters	
Study Design	Cross-Sectional Study
Study involve follow-up of premarket cohort (Y/N)	No
Data Source	New Data Collection
Comparison Group	Historical Control
Analysis Type	Analytical
Study Population	Transit Adolescent B (as adults) 18-21 yrs, Adult >21
Detailed Study Protocol Parameters	
Study Design Description	This is an observational cohort study A new cohort of patients and physicians will be
Study Population Description	Study population is as per device indication This device is indicated for permanent birth control
Sample Size	637 women enrolled - protocol states 20 sites enrolled patients
Data Collection	Study endpoints include: (1) bilateral micro-insert placement rate, (2) identification of factors predictive of micro-insert
Followup Visits and Length of Followup	N/A
Final Study Results	
Actual Number of Patients Enrolled	554 women
Actual Number of Sites Enrolled	75
Patient Followup Rate	81 66%
Final Safety Findings	The sponsor reported only 6 adverse events occurred during and after the Essure placement procedure
Study Strengths and Weaknesses	The study is well designed to evaluate the placement rate among newly trained physicians at
Recommendations for Labeling Changes	Update labeling with the results of the study in the context of patient and physician labeling

ESS-305 Schedule

Report Schedule	Report Data Due	FDA Receipt Date	Reporting Status
6 month report	12/14/2007	12/14/2007	On Time
1 year report	06/14/2008	06/17/2008	Overdue/Received
18 month report	12/13/2008	12/15/2008	Overdue/Received
Final Report	06/14/2009	06/15/2009	Overdue/Received

Show All Studies

Links on this page:

1. http://www.addthis.com/bookmark.php?v=508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

EXHIBIT C

C

STATE OF CALIFORNIA — HEALTH AND HUMAN SERVICES AGENCY

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH
Medical Device Safety & Youth Tobacco Enforcement Section
Medical Device Safety Unit

INVESTIGATIVE REPORT

Inspection Date(s): 1/21/2011

Firm Name: Conceptus, Inc. DBA: N/A

Street Address: 331 East Evelyn Avenue City: Mountain View Zip Code: 94041
Interviewed/Title: Henry Bishop, Quality Manager Phone #: 650-962-4000

INSPECTION TYPE ☐ New License ☐ New Lic Reinsp ☒ Renewal ☐ Reinsp ☐ Complaint ☐ Recall
☐ Other:

LICENSE INFORMATION HMDR License #: _____ Exp Date: _____ FDA CFN #: _____
Other FDB Lic/Reg #: ☒ Device #: 45136 ☐ Drug #: _____ ☐ PFR #: _____

DISCUSSION

The firm, Conceptus Inc., has maintained a medical device manufacturing license, 45136, since 2008. The firm manufactures a Class III medical device, specifically, the Essure System for permanent birth control in women. The current inspection was conducted as a renewal inspection pursuant to HSC 111635(b). Said section states that the Department shall inspect each place of business licensed under Section 111615 once every two years.

Upon initiation of the inspection, credentials were presented to Tarhan Kayihan, Sr Regulatory Quality Engineer, and Henry Bishop, Quality Manager. Mr. Bishop stated that the US FDA had conducted a 15-day, For Cause, inspection in December 2010. Because this recent inspection thoroughly reviewed all aspects of the firm's quality system, the current inspection was limited to the four observations included on the FDA 483 Inspectional Observations [redacted] and the firm's response to the observations.

The FDA's inspection was conducted in response to a discrepancy noted during an inspection of the firm's contract manufacturer [redacted], located in [redacted]. [redacted] had been found to have erroneously used non-conforming material in a validation protocol without adequately documenting the disposition of the material. The FDA then inspected Conceptus to determine if the non-conforming material was properly quarantined at the Mountain View facility.

The FDA inspection did not note any deficiencies with regard the firm's handling of non-conforming material but issued an observation to the firm for failing to adequately document the situation in a separate CAPA. The firm corrected this discrepancy prior to the close of the inspection.

The additional three observations noted on the 483 were all related to a single issue. Specifically, the investigator observed that the firm had not properly evaluated eight complaints of peritoneal perforation for reporting to the FDA as an adverse event. Also, the firm's risk analysis did not include an evaluation of the risk associated with perforation of the peritoneal cavity.

The firm submitted a response to the FDA (Exhibit B) on January 20, 2011, disputing the validity of the observations regarding the reporting of complaints for peritoneal perforation. The firm claims that this condition is a result of the physician's misuse of the device or an error during insertion and not a failure of the device to perform as intended. The FDA has not yet responded to the firm's submission.

The FDA inspection covered all other areas of the firm's quality system. No other observations were noted.

EXHIBIT
C

DISCUSSION WITH MANAGEMENT

The firm was cooperative in providing all requested documents and information. It was explained to the firm that the results of the discussion with FDA regarding the disputed observations would be reviewed at the next renewal inspection.

RECOMMENDATION

No further action is indicated.

Investigator's Name: Lana Widman Badge No. 136

Investigator's Signature: [signature] Report Date: 1/24/11

Supervisor's Review/Comments:

Supervisor's Signature: [signature] Date: 01/25/11

EXHIBIT D

...nia – Health and Human Services Agency

Department of Health Services

NOTICE OF VIOLATION

Food and Drug Branch

Direct responses to: CHRISTINE RODRIGUEZ WITHIN 10 DAYS

Supervisor		Telephone number
HARLAN LOUI.		(916) 650-6500
Address (number, street)	City	ZIP code
1500 CAPITOL AVE, MS 7607	SACRAMENTO	95814
Firm name		Date
CONCEPTUS, INC.		06-11-03
Address (number, street)	City	ZIP code
331 EAST EVELYN AVE	MOUNTAIN VIEW	94041
Person interviewed	Position	
HENRY BISHOP	QUALITY MANAGER	

The conditions or practices noted below were observed on subject premises this date. These are alleged to be violations of one or more provisions of California law pertaining to the manufacture, processing, holding, sale, labeling, or advertising of a food, drug, medical device, cosmetic, or hazardous substance. The Department may seek administrative, civil, or criminal action for each of the violations. This report has been prepared to alert the management of the investigator's findings. It is the responsibility of the firm to assure compliance with all applicable laws and regulations.

(1) THE FIRM FAILED TO OBTAIN A VALID LICENSE FROM THE DEPARTMENT PRIOR TO MANUFACTURING MEDICAL DEVICES. THE FIRM MOVED TO THE ABOVE LOCATION IN 2005 AND HAS BEEN MANUFACTURING MEDICAL DEVICES FROM 2005 TO THE PRESENT AT AN UNLICENSED FACILITY.

(2) THE FIRM FAILED TO MAINTAIN PROCEDURES TO CONTROL DOCUMENTS REQUIRED BY THE QUALITY SYSTEM REGULATION. SPECIFICALLY SOP-CO1454 REVISION Y PERTAINING TO INVENTORY TRANSFER REFERENCES PRE-STERILE AND POST-STERILE QUARANTINE CAGES AND THE SAN CARLOS WAREHOUSE AND THE FACILITY NO LONGER USES PRE-STERILE AND POST-STERILE CAGES AND DOES NOT HAVE A WAREHOUSE.

Signing this notice does not indicate admission of a violation but only receipt of the Notice of Violation.

Firm's authorized representative signature	Authorized representative position
[signature]	Henry Bishop QE Manager
Authorized agent signature	Authorized agent name and badge number (printed)
C Rodriguez	CHRISTINE RODRIGUEZ #155

EXHIBIT tabbies D

EXHIBIT E

ɹlishment Inspection Report	FEI:	1000221357
nceptus, Inc.	EI Start:	05/30/2013
Mountain View, CA 94041-1530	EI End:	06/26/2013

SUMMARY

I initiated this inspection of a manufacturer of a type 3 permanent implantable contraceptive device conducted in accordance with FACTS Assignment 8676539 as part of SAN-DO's FY '13 workplan for medical devices. I conducted this inspection pursuant to CP 7382.845 under PACs 82845A and 81011.

Previous inspection on Dec. 2010 to Jan 2011, covered Corrective and Preventive Actions (CAPA) and Management Controls. That inspection found that the firm was not reporting as MDRs complaints in which their product migrated from the fallopian tube into the peritoneal cavity, the firm did not consider these complaints in their risk analysis for the design of their product, and the firm failed to document CAPA activities for a supplier corrective action. That inspection was classified VAI.

Inspected firm:	Conceptus, Inc.
Location:	331 E Evelyn Ave Mountain View, CA 94041-1530
Phone:	650-962-4000
FAX:	(650)691-4729
Mailing address:	331 E Evelyn Ave Mountain View, CA 94041-1530
Dates of inspection:	5/30/2013, 5/31/2013, 6/3/2013, 6/4/2013, 6/5/2013, 6/6/2013, 6/7/2013, 6/10/2013, 6/11/2013, 6/12/2013, 6/13/2013, 6/17/2013, 6/25/2013, 6/26/2013
Days in the facility:	14
Participants:	Timothy C. Grome, Investigator

On May 22, 2013 I pre-announced the inspection to Henry V. Bishop, Quality Manager. On May 30, 2013, I showed my credentials to and issued an FDA 482 (Notice of Inspection) to D. Keith Grossmann, President & CEO. According to his admission and that of all of the firm officials present at the opening meeting was the most responsible person in charge at the start of the inspection.

During the current inspection Conceptus, Inc. was acquired by Bayer Healthcare Pharmaceutical Division. At the close of the inspection Mr. Grossmann was a consultant contracted by Bayer. The most senior management official on-site by the close of the inspection was Joseph G. Sharpe, Executive Vice President. This was by the admission of Mr. Sharpe, and Mr. Bishop. Also at the close of this inspection the firm was preparing to move their headquarters over the first week of July to the new address.

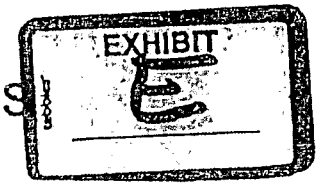


EXHIBIT F

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	12/08/2010 - 01/06/2011*
	FEI NUMBER 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	331 E.Evelyn Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain View, CA 94041	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 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.

Specifically, the following complaints from July 12, 2010 to Dec. 10, 2010 both report a bowel perforation that occurred during the procedure to place the firm's product:

1. (b) (4) incident and aware date of 11/3/2010: Perforation from scope; patient taken to hospital for exploratory laparoscopy. Resolution notes on 12/21/2010 states patient had bowel perforation with some hemorrhage. Patient had a hysterectomy.

2. (b) (4) incident and aware date of 11/16/2010: When doctor attempted to place second device, she used graspers to locate the ostium. She perforated the patients bowel.

In both complaints the firm's device did not directly cause the injury, but the procedure for use required the use of an hysteroscope and visualization of the tubal ostium. There were 41 complaints of perforation from July 12, 2010 to Dec. 10, 2010 the above two complaints were the only two of the 41 that involved perforation of the bowel. The other complaints were for uterus or fallopian tubes.

There was one complaint that was not for a perforation but for which a CT scan showed that the insert was in two pieces with one of the pieces outside of the tube between the uterus and the bowel:

3. (b) (4) incident date 11/05/2010, aware date 12/16/2010: Patient reported pain immediately following the procedure. Essure procedure done on 11/5/10 Performed a CT scan which revealed device was in 2 pieces; proximal part was in isthomal portion; distal between uterus and bowel.Physician plans laparoscopic removal tomorrow and tubal ligation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Timothy C. Grome, Investigator	DATE ISSUED 01/06/2011

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES

EXHIBIT
tabbies
F

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	12/08/2010 - 01/06/2011* FEI NUMBER 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	331 E.Evelyn Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain View, CA 94041	Medical Device Manufacturer

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the firm received complaints that a perforation had occurred with the coil micro-insert being seen radiographically outside of the Fallopian Tube in the abdominal cavity:

1. (b) (4) incident and aware date 10/01/2010: perforation 2 HSGs showed device was located in the peritoneum. The micro-insert was removed during a laparoscopic tubal ligation.

2. (b) (4) incident date 10/05/2010, aware date 10/08/2010: Perforation; 1 micro-insert is in the peritoneal cavity. Essure was placed in June 2010 patient is asymptomatic.

3. (b) (4) incident date 5/11/2010, aware date 10/21/2010: Perforation observed on HSG. Essure procedure done 5/11/10. HSG shows device is outside the tube on the left side in the peritoneal cavity.

4. (b) (4) incident date 10/26/2010, aware date 10/26/2010: Perforation; on HSG micro-insert observed in the peritoneal cavity.

5. (b) (4) incident date 09/01/2010, aware date 12/10/2010: Perforation: micro-insert located outside the tube in the cul-de-sac. Essure done on 09/01/10; no HSG done 12/09/10. Patient is asymptomatic.

During the time period of July 12, 2010 to January 4, 2011 there were 45 complaints for perforation. Two for perforation of bowel, of all the other for perforation of the tube two ((b) (4)) were reported as MDRs in one (b) (4) the patient complained of bleeding, in the other (b) (4) the patient underwent surgery to remove the micro-insert. The five complaints listed above were the other complaints involving a perforation of the uterus or fallopian tube in which the micro-insert was located in the peritoneal cavity.

OBSERVATION 3

Risk analysis is incomplete.

Specifically, Design Failure Modes Effects Analysis (DFMEA) for Essure ESS305 Document Number (b) (4) does not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. Since December 2007 according to complaint database provided by the firm there have been 508 complaints with the subject including perforation. 168 of these complaints were of the subject perforation (micro-insert), and 5 were expulsion/perforation. In the same time period according to the list of Medical Device Reports, there were 3 complaints reported for pain/perforation, 18 complaints for perforation and one for perforation and bleeding. In the database supplied with a complaint description I found 4 complaints of perforation from July 20, 2010 to Dec. 10, 2010 in which the micro-insert coil was found on x-ray to be in

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Timothy C. Grome, Investigator	01/06/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry	12/08/2010 - 01/06/2011* FEI NUMBER 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	331 E.Evelyn Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain View, CA 94041	Medical Device Manufacturer

2007 according to complaint database provided by the firm there have been 508 complaints with the subject including perforation, 168 of these complaints were of the subject perforation (micro-insert), and 5 were expulsion/perforation. In the same time period according to the list of Medical Device Reports, there were 3 complaints reported for pain/perforation, 18 complaints for perforation and one for perforation and bleeding. In the database supplied with a complaint description I found 4 complaints of perforation from July 20, 2010 to Dec. 10, 2010 in which the micro-insert coil was found on x-ray to be in the peritoneal cavity.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, after failures in Design of Experiment for requalification of manufacture of microinsert coil catheters produced failing results on 11/30/2010, (b) (4) your firm's engineers learned from telephone conversations with engineers from your contract manufacturer (b) (4) that delivery wires used for the test lots were taken from quarantine without having the components fully certified. (b) (4) Your firm did not receive the contract manufacturer's CAPA report until 12/21/2010. That CAPA did not mention the non-conformity of your contract manufacturer not following their own SOP for control of non-conforming material. Your firm covered this deviation under CAPA (b) (4) 10/25/10 opened to document actions taken to address the detachment failures noted during lot release (b) (4) ESS305 as documented in (b) (4).

ANNOTATIONS
OBSERVATION 4
(b) (4)
(b) (4)
OBSERVATION 2
(b) (4)
OBSERVATION 3
(b) (4)
OBSERVATION 4
Corrected and Verified 1/6/2011

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Timothy C. Grome, Investigator	01/06/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	12/08/2010 - 01/06/2011* FEI NUMBER 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	331 E.Evelyn Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mountain View, CA 94041	Medical Device Manufacturer

the peritoneal cavity.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, after failures in Design of Experiment for requalification of manufacture of microinsert coil catheters produced failing results on 11/30/2010, (b) (4), your firm's engineers learned from telephone conversations with engineers from your contract manufacturer (b) (4) that delivery wires used for the test lots were taken from quarantine without having the components fully certified. (b) (4). Your firm did not receive the contract manufacturer's CAPA report until 12/21/2010. That CAPA did not mention the non-conformity of your contract manufacturer not following their own SOP for control of non-conforming material. Your firm covered this deviation under CAPA (b) 10/25/10 opened to document actions taken to address the detachment failures noted during lot release of (b) (4) ESS305 as documented in (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Timothy C. Grome, Investigator	01/06/2011

EXHIBIT G

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702	06/25/2003 - 07/07/2003*
	FEI NUMBER: 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: William H. Dippel, Vice President, Operations

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	1021 Howard Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Carlos, CA 94070	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Not all data from quality data sources are analyzed to identify existing and potential causes of nonconforming product and other quality problems.

Specifically, during a review of (b) (4) Lot History Reports (LHRs) for the manufacture of the Essure Permanent Birth Control System, two Lot History Records showed rejected raw materials and/or subassemblies hand-written on the Work Order Picklist. This information/ data was not documented on Page 2 of 3 of the QAF-2335 (Quality Assurance Form) which is used to track and trend in-process data.

Examples are:
LHR (b) (4) shows (b) (4) Inner/Outer Coil Subassemblies rejected (hand-written) on the Work Order Picklist, but not document on Page 2 of 3 of LHR: Essure Sterile 2-Device (b) (4)

LHR (b) (4) shows (b) (4) Inner/Outer Coil subassemblies rejected (hand-written) on the Work Order Picklist, but not document on Page 2 of 3 of LHR: Essure Sterile 2-Device (b) (4)

OBSERVATION 2

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

Specifically, your procedure, SOP-00383, "NONCONFORMING MATERIAL REVIEW", for handling nonconforming materials defines that a nonconforming material under Section 3.0 as "(b) (4)
(b) (4)
for "(b) (4)
(b) (4)
." Your SOP also states that this procedures is to be used

A review of Lot History Records (LHRs) revealed that raw materials and sub-assemblies (i.e., Inner/Outer Coil Sub-

SEE REVERSE OF THIS PAGE		CONTINUED 07/07/2003

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 2 PAGES

EXHIBIT
tabbies
G

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND TELEPHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702	06/25/2003 - 07/07/2003*
	FEI NUMBER 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William H. Dippel, Vice President, Operations

FIRM NAME	STREET ADDRESS
Conceptus, Inc.	1021 Howard Avenue
CITY, STATE, AND ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Carlos, CA 94070	Medical Device Manufacturer

assemblies) were being rejected during manufacturing of the Essure Permanent Birth Control device, but no Material Review Report(s) were initiated/generated for these rejects.

* DATES OF INSPECTION:
06/25/2003(Wed), 06/26/2003(Thu), 06/30/2003(Mon), 07/01/2003(Tue), 07/03/2003(Thu), 07/07/2003(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Mark E. Chan, Investigator

SEE REVERSE OF THIS PAGE		DATE ISSUED 07/07/2003

FORM FDA 483 (07/99) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 OF 2 PAGES

EXHIBIT H

Establishment Inspection Report	FEI:	1000221357
Conceptus, Inc.	EI Start:	05/30/2013
Mountain View, CA 94041-1530	EI End:	06/26/2013

SUMMARY

I initiated this inspection of a manufacturer of a type 3 permanent implantable contraceptive device conducted in accordance with FACTS Assignment 8676539 as part of SAN-DO's FY '13 workplan for medical devices. I conducted this inspection pursuant to CP 7382.845 under PACs 82845A and 81011.

Previous inspection on Dec. 2010 to Jan 2011, covered Corrective and Preventive Actions (CAPA) and Management Controls. That inspection found that the firm was not reporting as MDRs complaints in which their product migrated from the fallopian tube into the peritoneal cavity, the firm did not consider these complaints in their risk analysis for the design of their product, and the firm failed to document CAPA activities for a supplier corrective action. That inspection was classified VAI.

Inspected firm:	Conceptus, Inc.
Location:	331 E Evelyn Ave Mountain View, CA 94041-1530
Phone:	650-962-4000
FAX:	(650)691-4729
Mailing address:	331 E Evelyn Ave Mountain View, CA 94041-1530
Dates of inspection:	5/30/2013, 5/31/2013, 6/3/2013, 6/4/2013, 6/5/2013, 6/6/2013, 6/7/2013, 6/10/2013, 6/11/2013, 6/12/2013, 6/13/2013, 6/17/2013, 6/25/2013, 6/26/2013
Days in the facility:	14
Participants:	Timothy C. Grome, Investigator

On May 22, 2013 I pre-announced the inspection to Henry V. Bishop, Quality Manager. On May 30, 2013, I showed my credentials to and issued an FDA 482 (Notice of Inspection) to D. Keith Grossmann, President & CEO. According to his admission and that of all of the firm officials present at the opening meeting was the most responsible person in charge at the start of the inspection.

During the current inspection Conceptus, Inc. was acquired by Bayer Healthcare Pharmaceutical Division. At the close of the inspection Mr. Grossmann was a consultant contracted by Bayer. The most senior management official on-site by the close of the inspection was Joseph G. Sharpe, Executive Vice President. This was by the admission of Mr. Sharpe, and Mr. Bishop. Also at the close of this inspection the firm was preparing to move their headquarters over the first week of July to the new address.

Joseph G. Sharpe, Executive Vice President
1101 McCarthy Blvd.
Milpitas, CA 95035

Current Inspection on July 9 to 11, 2008 covered CAPA and Design Controls, and reporting of MDRs.

I asked firm officials if Conceptus, Inc. has had any recalls or field corrections since January 2011. Henry V. Bishop, Quality Manager, told me that there have been no recalls or field corrections in the past two years.

I reviewed the firm's procedures for complaints:
Product Returns, Complaints Handling and Reporting SOP-1630 Rev. AE (7/29/11)
MDR Processing WI-03306 Rev. F (8/16/12)

I requested for a complete list of complaints since January 2011. Mr. Bishop provided me with a CD-ROM with an Excel file that contained 16,047 entries for complaints. He also provided me with a list of MDRs. I requested and reviewed 11 random complaint forms (Binomial Staged Sampling Plan, Confidence Limit 0.95 =< 0.25 ucl). I requested and reviewed an additional 18 complaint forms. The additional complaint forms that I reviewed contained the keywords, "peritoneal" or abdominal" cavity with "pain", or pregnancy. All of the complaints in which one or more coils were imaged outside of the fallopian tubes, had documentation that the patient was not -at last contact – experiencing pain. As such those complaints were not reported as MDRs.

The pregnancy complaints that I looked at were the ones in which the patient chose to continue the pregnancy. I asked Henry V. Bishop, Quality Manager, if the firm has data on the outcomes of pregnancies that had occurred after Essure placement. He said that there was no data compiled but had the firm compile data for me (Exhibit #1). This graph was compiled from 132 complaints between January 2011 and March 2013. Three of the categories are for the patient plan at time of last contact by Conceptus: "Plan for live birth", "plan for medical termination", and "undecided". Three other categories were for known outcome of the pregnancy: "Medical termination", "miscarriage", and "Live birth (healthy; uncomplicated)". I searched for "miscarriage" with "migration" of coil or "coil in uterus" and found no results.

I followed up on 3 FDA Consumer Complaints for Conceptus, Inc. These complaints were entered into the firm's data base from MAUDE. These complaints were assessed per the firm's complaint handling procedures.

,olishment Inspection Report	FEI:	1000221357
,nceptus, Inc.	EI Start:	05/30/2013
Mountain View, CA 94041-1530	EI End:	06/26/2013

I reviewed the firm's procedure for Corrective and Preventive Action, Corrective and Preventive Actions SOP-00935 Rev. U (9/22/10); I reviewed the list of all CAPAs since January 2011. From this list I selected 11 random CAPAs (Binomial Staged Sampling Plan, Confidence Limit 0.95 =< 0.25 ucl). Four of these CAPAs were the CAPAs opened in response to the observations of the previous inspection. The current inspection found no objectionable conditions with CAPA system.

Since the previous inspection Conceptus, Inc. has had no completed new full product designs. For design control review I chose the design for the(b) (4) (b) (4) This product is currently between (b) (4) stages. I reviewed the following design procedures: Product Development Process SOP-00799 Rev. V. I reviewed the design history file DHF(b) (4) initiated on(b) (4) The new design(b) (4) (b) (4) is a product of(b) (4) I reviewed customer needs, specifications, and(b) (4) tests. I also reviewed the Risk Management Plan(b) (4) (Exhibit #2).

Since the previous inspection the former Chief Executive Officer and President, Mark M. Sieczkerak was replaced with D. Keith Grossmann (Exhibit #3). By the close of the inspection Conceptus, Inc. was purchased by Bayer Healthcare Pharmaceutical Division, Mr. Grossmann was a consultant.

At the close out meeting on June 26, 2013, I discussed with firm management present the exclusion of risk assessment for safety of loose coils inside the peritoneal cavity in Risk Management Plan (b) (4) . This was one of the observations from the previous inspection. Henry V. Bishop, Quality Manager, told me that the FMEA does have perforation (Exhibit #2, pages 1 and 2) and expulsion (Exhibit #2, page 5). All of the observations from the previous inspection had been corrected. I warned firm officials present at the close-out meeting that no even though I was not issuing an FDA 483, that does not mean that there could be, at their firm, conditions which may be objectionable. I warned of penalties for violation of the Food, Drug, and Cosmetic Act.

EXHIBITS COLLECTED

1. Pregnancy Report Data
2. (b) (4) Design FMEA for (b) (4) (14 pages)
3. Organization Chart for Conceptus, Inc. Senior Management Team

ATTACHMENTS

1. FDA 482 (Notice of Inspection)

Timothy C. Grome, Investigator