COMMONWEALTH OF KENTUCKY
PIKE CIRCUIT COURT
DIVISION I
CASE NO. 17-CI-229

FRANKIE NEWSOME,
KIMBERLY HOWELL,
STACEY VARNEY **PLAINTIFFS**

v. **PLAINTIFFS' COMPLAINT**

BAYER CORPORATION
100 Bayer Rd., Building 4
Pittsburgh, PA 15205

SERVE: Corporation Service Company, Registered Agent
421 West Main Street
Frankfort, KY 40601

And

BAYER HEALTHCARE LLC.
100 Bayer Blvd.
Whippany, N.J. 07981

SERVE: Corporation Service Company, Registered Agent
421 West Main Street
Frankfort, KY 40601

And

BAYER ESSURE, INC., (F/K/A CONCEPTUS, INC.)
100 Bayer Road
Pittsburgh, PA 15205

SERVE: Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808

And

SERVE: The Kentucky Secretary of State
Service of Summons
Room 86, State Capitol
Frankfort, KY 40601

EXHIBIT A

Address for Service pursuant to KRS §454.210:

Corporation Service Company
2711 Centerville Road, Suite 400
Wilmington, DE 19808

And

BAYER HEALTHCARE PHARMACEUTICALS INC.
100 Bayer Blvd.
Whippany, NJ 07981

SERVE: Corporation Service Company, Registered Agent
421 West Main Street
Frankfort, KY 40601

And

PIKEVILLE MEDICAL CENTER, INC. **DEFENDANTS**
911 Bypass Road
Pikeville, KY 41501

SERVE: Pamela Todd May
127 Park Street
Pikeville, KY 41501

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COMPLAINT FOR DAMAGES

COME NOW Plaintiffs, by and through their undersigned counsel, and state as their Complaint for Damages against BAYER CORPORATION, BAYER HEALTHCARE LLC., BAYER ESSURE, INC., (f/k/a CONCEPTUS, INC.), and BAYER HEALTHCARE PHARMACEUTICALS, INC., (collectively herein referred to as "Bayer" or "Conceptus" or the "Bayer Defendants"), and Pikeville Medical Center, Inc. ("PMC"), for personal injuries suffered as a result of being implanted with the defective and unreasonably dangerous product Essure®:

I. INTRODUCTION

1. This is an action for the serious and permanent injuries incurred by the Plaintiffs resulting from the promotion, sale, and distribution of an unreasonably dangerous and defective medical device product known as Essure®.

2. Conceptus Inc. ("Conceptus") came up with the idea for the Essure® device in 1998.

3. At that time, Conceptus was in hundreds of millions of dollars of debt.

4. The marketplace for permanent birth control was and is enormous. In 2007, Conceptus estimated that 700,000 American women undergo incisional tubal ligation each year. The market presented a huge business opportunity to Conceptus.

5. The Essure® system consists of two metal coils that are implanted into a woman's fallopian tubes that expand and are intended to elicit tissue growth that causes blockage of the tubes and thus prevents conception.

6. The device was intended to be promoted as a simple solution to permanent birth control needs, and as safer than all other permanent birth control options.

7. By the time the FDA approved Essure® for sale in 2002, it was Conceptus' only commercial product.

8. Conceptus relied entirely on the success of Essure® to solve its massive debt problems and achieve profitability.

9. Essure® was a unique contraceptive device and the first of its kind on the market.

10. As such, Conceptus knew that physicians and patients needed to trust the safety of the device for it to be accepted in the marketplace and compete with other, more established and traditional alternative methods of permanent birth control.

11. Conceptus knew that any apprehensions about the safety of the Essure® device on the part of physicians or patients could devastate sales and lead to the complete failure of the company.

12. To promote the perceived safety of the device and gain market acceptance, Conceptus devised and implemented a scheme to defraud physicians and patients, by means of false and fraudulent pretenses, representations and concealment of material facts.

13. After Essure® came onto the market, thousands of Essure® patients complained of adverse events directly to Conceptus.

14. Conceptus knew that if those complaints made it to the FDA and became public knowledge, it would inevitably result in changes to the Essure® label, its risk/benefit profile, related physician advice, and patients' decisions.

15. In short, Conceptus knew that if the true safety risks and consequences were known to the public, sales of the device would plummet.

16. As a result, Conceptus made a decision to hide these safety risks and consequences from the FDA and the public.

17. Conceptus was obligated under federal law to report the patients' complaints to the FDA.

18. Conceptus withheld the vast majority of those complaints.

19. At the same time, Conceptus conducted enormous and aggressive marketing campaigns that disseminated what they knew to be false and misleading statements pertaining to the convenience, safety and efficacy of the device.

20. Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities to encourage physicians and patients to use the Essure® device.

21. While Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities, it violated its duty owed to the physicians and patients, in concealing and failing to warn the physicians and patients of the known serious increased risks and complications stemming therefrom.

22. Conceptus knew that the withholding of safety information and adverse events, as well as the dissemination of false and misleading statements pertaining to the Essure® device was illegal.

23. In fact, the FDA cited Conceptus several times for withholding safety information.

24. Conceptus knew that manipulating the public's knowledge of safety risks associated with Essure® exposed patients to serious dangers and greatly increased adverse risks.

25. Despite knowing of these dangers and the illegality of their behavior, Conceptus continued to carry out its false and unlawful marketing and promotional scheme.

26. These illegal efforts proved to be highly effective, leading to hundreds of millions of dollars in revenue for Conceptus, and an eventual buyout of the company by Bayer for approximately $1.1 billion in 2013.

27. Bayer continued illegally hiding the true safety risks of Essure®.

28. Those same tactics could not continue working for Bayer.

29. In 2013, the FDA began promoting the use of the MedWatcher app, a system that allowed patients with complaints to report their problems directly to the FDA itself, as opposed to the manufacturer.

30. By that time, thousands of women adversely affected by the Essure® device had formed a support group named "Essure Problems" on Facebook, a digital social network.

31. The group currently consists of over 32,000 members.

32. Conceptus and Bayer had been able to effectively silence their voices and conceal their complaints for years because the companies controlled what information did and did not make it to the FDA.

33. However, through the use of the MedWatcher app, in the fall of 2013 these women began to stand up to Bayer and report their problems directly to the FDA.

34. At that point, Bayer knew Essure® was wreaking havoc on the lives of thousands of women.

35. Bayer could have chosen to acknowledge the true weight of all of this safety information and stopped promoting the device.

36. But with over a billion dollars invested in Essure®, Bayer chose to protect its investment and continue promoting the false impression that the device was safe.

37. Bayer knew that they could no longer hide complaints made through MedWatcher, because those reports were made directly to the FDA.

38. So Bayer began to employ new tactics to conceal and downplay the true safety risks of Essure®.

39. Bayer carefully manipulated its reports to the FDA and presented false and misleading information.

40. Bayer did this in an effort to maintain the impression that the Essure® device had a positive risk/benefit profile and to guard sales.

41. The women affected by Essure® and the "Essure Problems" group, however, would not let Bayer continue to mislead the FDA and more women.

42. They demanded that the FDA take meaningful action to investigate and evaluate the growing scientific knowledge concerning Essure®.

43. At their insistence, in September of 2015 the FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and patients, and plan recommendations for the Essure® device.

44. At the hearing, experts funded by the "Essure Problems" group testified as to the many safety problems they had begun to observe with the device.

45. Shortly after the hearing, researchers from Cornell University published a study in the British Medical Journal with devastating conclusions about the comparative safety profile of Essure®.

46. The study compared thousands of women from New York State who had undergone either a traditional tubal ligation or received the Essure® implant, and concluded that women receiving Essure® were ten times more likely to require a corrective reoperation.

47. Based on the information gathered by the FDA during the advisory process, the FDA realized that "patients are not reliably receiving and/or understanding appropriate information about the device and associated risks prior to making a sterilization decision – for Essure as well as other sterilization methods,"[1] and the FDA finally took aggressive action.

48. In 2016, the FDA required a detailed boxed warning for the Essure® device.

49. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events.

50. Boxed warnings indicate the highest level of risk.

51. The FDA also required that every potential Essure® patient receive and sign a detailed checklist specifically tailored to the risks associated with the device.

52. The boxed warning and patient decision checklist were approved by the FDA on November 15, 2016.[2]

53. In its current form, this patient decision checklist requires a patient's initials and signature six separate times.

54. The checklist specifically warns of device migration and perforation of organs, side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

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

56. Conceptus and Bayer knowingly and purposefully concealed these risks for years.

57. Unfortunately, Plaintiffs herein were not afforded the knowledge and warnings that would have informed and protected them.

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[1] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S046

II. PARTIES

A. PLAINTIFFS.

58. Plaintiffs reside in Pike County, Kentucky and/or were first injured in Pike County, Kentucky, after being implanted with the Essure® device.

B. DEFENDANTS.

59. BAYER CORPORATION is a for-profit corporation incorporated in the state of Indiana with its principal office at 100 Bayer Rd. Building 4, Pittsburgh, PA 15205, and is a wholly-owned subsidiary of Bayer A.G. Defendant, Bayer Corporation, is authorized to do business in the Commonwealth of Kentucky, and its registered agent for service of process is Corporation Service Company, 421 West Main Street, Frankfort, KY 40601. Defendant Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

60. BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the state of Delaware and is a wholly-owned subsidiary of Bayer A.G. Defendant, Bayer Healthcare LLC., has a principal office of 100 Bayer Blvd., Whippany, N.J. 07981. It is authorized to do business in the Commonwealth of Kentucky, and its registered agent for service of process is Corporation Service Company, 421 West Main Street, Frankfort, KY 40601. Defendant Bayer Healthcare LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

61. BAYER ESSURE, INC. (f/k/a CONCEPTUS, INC.) is a for-profit corporation incorporated in the state of Delaware, and is a wholly-owned subsidiary of Bayer A.G. and/or Bayer HealthCare LLC. On or about April 28, 2013, Conceptus, Inc. entered into an Agreement

and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly-owned subsidiary of Bayer HealthCare LLC and/or Bayer A.G., and thereafter renamed "Bayer Essure Inc." For purposes of this Complaint, Conceptus, Inc. and Bayer Essure Inc. are one and the same. Bayer Essure Inc.'s headquarters are located at 331 East Evelyn Avenue, Mountain View, California 94041. Service is proper on the Kentucky Secretary of State pursuant to KRS § 454.210. Defendant, Bayer Essure Inc., is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

62. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. Defendant Bayer Healthcare Pharmaceuticals, Inc., has a principal office of 100 Bayer Blvd., Whippany, N.J. 07981. Defendant, Bayer Healthcare Pharmaceuticals is authorized to do business in the Commonwealth of Kentucky, and has a registered agent for service of process of Corporation Service Company, 421 West Main Street, Frankfort, KY 40601. Defendant Bayer Healthcare Pharmaceuticals, Inc., is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure® device.

63. BAYER A.G. is a German for-profit corporation. Bayer A.G. is authorized to and does business in the Commonwealth of Kentucky through its wholly owned subsidiaries. At all relevant times, Bayer AG and one or more of its groups or divisions has been engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying,

selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Essure® device.

64. Defendants Bayer Corp., Bayer Healthcare LLC, Bayer Essure®, Inc. (f/k/a Conceptus), and Bayer Healthcare Pharmaceuticals, Inc., are hereafter collectively referred to as "Bayer" or the "Bayer Defendants."

65. PIKEVILLE MEDICAL CENTER, INC. (hereinafter "PMC"), is a Kentucky corporation whose principal office is located at 911 Bypass Road, Pikeville, Kentucky 41501. The registered agent for service of process is Pamela Todd May, 127 Park Street, Pikeville, KY 41501.

66. At all times relevant hereto, PMC held itself out to the public as providing medical professional services, particularly in the area of obstetrics and gynecological medicine, and hospital care related to such services.

67. PMC (through its subsidiary and/or affiliated corporations) at all times relevant herein, employed doctors to provide general medical and surgical treatment to Plaintiffs.

68. At all relevant times herein, PMC provided hospital treatment related to the general medical and surgical treatment provided by PMC to Plaintiffs.

69. In providing such medical and surgical treatment to Plaintiffs, these Doctors were the actual and/or ostensible agents, servants and/or employees of PMC.

70. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between the certain Defendants and other Defendants such that any individuality and separateness between them has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will

permit an abuse of the corporate privilege and would sanction fraud and/or would promote injustice.

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

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

73. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

III. JURISDICTION AND VENUE

74. This Court has both general and specific personal jurisdiction over Defendants. The Court has personal jurisdiction pursuant to KRS § 454.210 over the Defendants because, at all relevant times, they have engaged in substantial business activities in the Commonwealth of Kentucky. At all relevant times, the Bayer Defendants transacted, solicited, and conducted business in Kentucky through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Kentucky by marketing the Essure® device to the

women of the state. At all relevant times, Defendant PMC is and was a Kentucky Corporation providing medical services in the Commonwealth of Kentucky. The contacts of the Bayer Defendants and Defendant PMC were and are systematic, continuous and substantial. The Court also has personal jurisdiction over the Bayer Defendants, and Defendant PMC because, at all relevant times, Defendants were either present or domiciled in the state and/or consented to jurisdiction in the state by way of registering to do business herein. Jurisdiction in this court is also proper because the Defendants committed torts in whole or in part against the Plaintiffs in the Commonwealth of Kentucky, and contracted to supply goods in Kentucky. Further, there is no federal subject matter jurisdiction because no federal question is raised, and there is no diversity jurisdiction.

75. There is no federal diversity jurisdiction, because Plaintiffs Newsome, Howell and Varney and Defendant PMC are Kentucky residents.

76. Venue is proper in this Court, pursuant to KRS § 452.450, as the conduct which gave rise to Plaintiffs' actions occurred in the Pike County, Kentucky and they were first injured by the wrongful acts and negligent conduct of Defendants.

77. The Defendants herein are all properly joined in this action pursuant to Ky. CR 20.01 as the Plaintiffs assert jointly, severally, or in the alternative, a right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences, and a question of law or fact is common to all Defendants in the action.

IV. FACTS

A. DESCRIPTION OF ESSURE® AND HOW IT WORKS.

78. Essure® is a Class III medical device manufactured, designed, formulated, tested, packaged, labeled, produced, constructed, assembled, marketed, advertised, promoted,

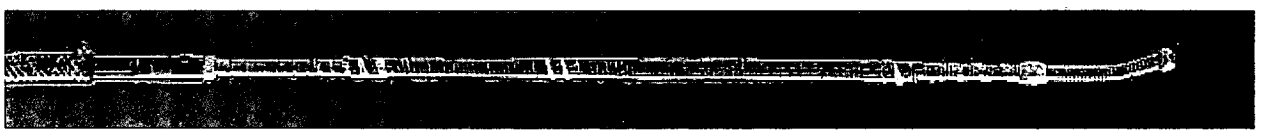
distributed, and sold by Bayer.[3]

79. In April 2002, Conceptus, the original manufacturer of Essure®, submitted its Premarket Approval Application to the United States Food and Drug Administration ("FDA") for the Essure® system. The Essure® system was approved by the FDA on November 4, 2002. At the time of approval, Essure® was manufactured and marketed by Conceptus, Inc. (Bayer acquired Conceptus on June 5, 2013).[4]

80. Essure® is considered a permanent form of female birth control and therefore is not intended to be removed.[5]

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

82. The Essure® micro-inserts are constructed of a stainless steel inner coil, a dynamic outer coil made from a nickel and titanium alloy, called Nitinol, and a layer of polyethylene terephthalate, or polyester fibers, wound between the inner and outer coils.[6]



83. Essure®'s disposable delivery system consists of a single handle containing 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 (camera) equipment

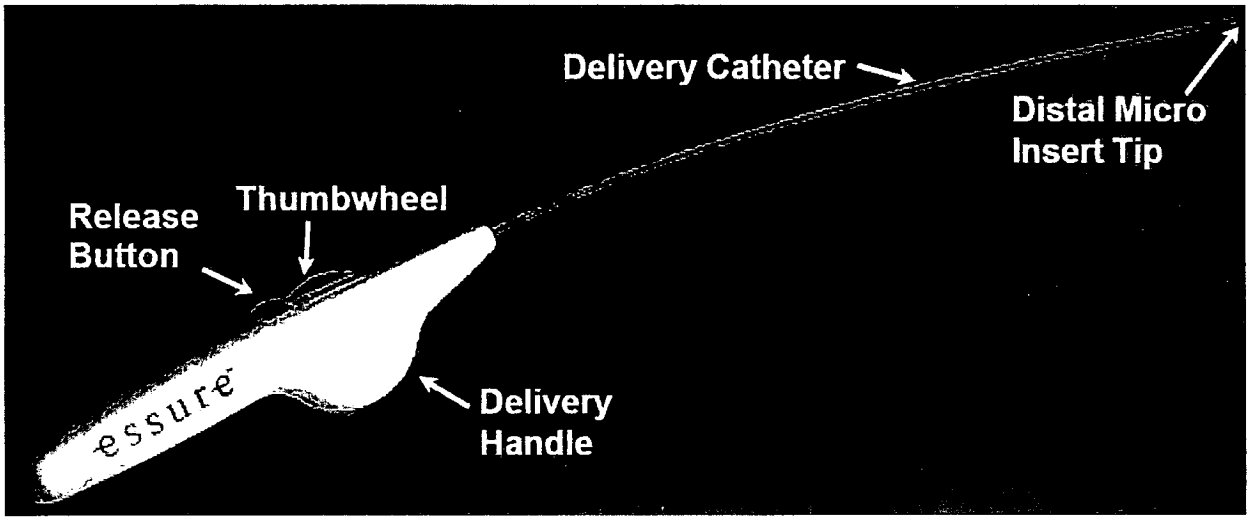
[3] *See* "Essure® Permanent Birth Control: Regulatory History," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm

[4] *Id.*

[5] *See* "Essure® Permanent Birth Control," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm

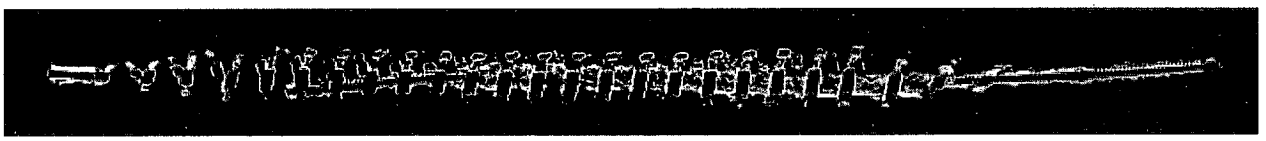
[6] Essure® Micro-Insert shown below in its "Wound-Down Configuration", attached to release catheter.

provided by Bayer.[7]



84. During the Essure® system implantation procedure, a physician inserts the Essure® micro-inserts through the vagina and cervix and into the fallopian tubes via Defendants' disposable delivery system using a hysteroscope for guidance.

85. Once the physician has properly positioned the delivery system in the fallopian tube, the physician releases the micro-insert. When released, the micro-insert automatically expands to the contours of the fallopian tube to anchor into the fallopian tube permanently.[8]



86. After implantation and over a 3-month period, the polyethylene terephthalate (PET) fibers on the micro-inserts are supposed to elicit tissue growth around the coils, which causes bilateral occlusion (blockage) of the fallopian tubes. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs, thus preventing conception.[9] During the 3-

[7] Essure® Delivery System is pictured below.
[8] Essure® Micro-insert shown below in its "Expanded Configuration."
[9] *See* "Essure Permanent Birth Control," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm

month time period, the woman must use another form of birth control while tissue in-growth occurs.

87. At 3-months following the procedure, the patient is to receive a "Confirmation Test" to determine whether the Essure® micro-inserts have created a complete occlusion in each fallopian tube. The Confirmation Test used is a hysterosalpingogram ("HSG Test"), which is performed by slowly adding contrast dye into the uterus until the uterine cornua are distended. Bayer has admitted that the HSG test is "often painful" and "is also known to be highly inaccurate, with false-positive results in as many as 40% of HSG-diagnosed cases of proximal tubal occlusion ("PTO"). Various factors are believed to be responsible for these false indications of tubal occlusion, including tubal spasm (a natural function of the tubes) and a build-up in the tube of natural cellular debris and mucous."

B. MEDICAL DEVICE REGULATORY FRAMEWORK.

88. To understand the full scope of the allegations contained in this Complaint, a brief general background regarding the applicable FDCA provisions is warranted, as well as an application of those laws to the present case.[10]

89. The United States Food and Drug Administration ("FDA") is the federal agency of the United States of America that is charged with safeguarding the health and safety of the public by enforcing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (2012) (the "FDCA").[11]

90. In 1976, Congress enacted the Medical Device Amendments of 1976 ("MDA") to extend the coverage of the FDCA to medical devices. The MDA was passed to protect patients

[10] Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because the Bayer Defendants' conduct violates these provisions. Rather Plaintiffs are alleging that the Bayer Defendants' conduct that violates these federal regulations, as well as the PMA obtained for Essure® also violates parallel state laws.

[11] The ultimate responsibility for the safety of a medical device rests with the manufacturer.

with the idea that medical devices should be subjected to a rigorous approval process for specific indications before medical device manufacturers are allowed to market them. Therefore, the FDA has authority over drugs and medical devices under the FDCA and the MDA.

91. The MDA established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective according to user risk. Class I Medical Devices pose the least risk, whereas Class III Medical Devices pose the greatest risk to the users.[12]

92. Class I Medical Devices are subject to "general controls" such as labeling requirements.[13] Class II Medical Devices are subject not only to "general controls," but also to "special controls" such as "performance standards, post market surveillance, and patient registries."[14] If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and is either marketed as a life supporting device or may cause an unreasonable risk of illness or injury, then it rises to the level of a Class III Medical Device.[15]

93. Class III Medical Devices are the most regulated. The MDA defines a Class III Medical Device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury.[16] Class III Medical Devices pose the greatest risk of death or complications and include most implantable surgical devices.

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[12] 21 U.S.C. § 360c(a)(1) (2012).
[13] 21 U.S.C. § 360c(a)(1)(A) (2012).
[14] 21 U.S.C. § 360c(a)(1)(B) (2012).
[15] 21 U.S.C. § 360c(a)(1)(C) (2012).
[16] *Id.* Bayer's Essure® is a Class III Medical Device.

94. Essure® is a Class III device and received FDA's most stringent review prior to marketing, using the Premarket Approval (PMA) process.[17]

1. Class III Medical Device Pre-Market Approval Requirements.

95. Before a company can market a Class III Medical Device, the company is required to submit a premarket application to the FDA supported by data that provides the FDA with a reasonable assurance that the medical device is safe and effective for its intended use.[18] In order to show safety and effectiveness, the applicant is required to submit evidence to the FDA, typically in the form of clinical trial results.

96. A PMA application must contain certain information, which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue.

97. Once the FDA has approved a medical device through the PMA application process (such as Essure®) the manufacturer/applicant is required to comply with the standards and conditions set forth in the PMA approval letter.[19]

98. A Class III device that fails to meet the PMA requirements after marketing is considered to be adulterated under § 501(f) of the Federal Food, Drug and Cosmetic Act ("FDCA") and cannot continue to be marketed.

99. Essure®'s PMA was accompanied by an attachment setting forth the general "Conditions of Approval." Some of the notable conditions made available to the public via the FDA's website required Defendant to:

A) Conduct two Post-Approval Studies to: (1) gather five-year follow up information on the participants in the two premarket clinical trial patient

[17] *See* "Essure Permanent Birth Control: Regulatory History," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm

[18] 21 U.S.C. § 360e(a)(2), § 360e(d)(1)(B)(iii), §360e(d)(2)(A) (2012).

[19] 21 C.F.R. § 814.80 (2012).

cohorts (Phase 2 trial and Pivotal Trial) and (2) evaluate bilateral placement rate for newly trained physicians.[20]

B) Warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.[21]

C) Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.[22]

D) Submit post-approval reports required under 21 C.F.R. § 814.84 at intervals of 1 year from the date of approval of the original PMA, which shall include: (1) a bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant: (i) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and (ii) reports in the scientific literature concerning the device.[23]

E) Submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" within 10 days after the applicant receives or has knowledge of information concerning, in part: (1) any adverse reaction side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and: (i) has not been addressed by the device's labeling; or (ii) has been addressed by the device's labeling but is occurring with unexpected severity or frequency; (2) any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling.[24]

F) Report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would

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[20] *See* "Essure Permanent Birth Control: Regulatory History," available online at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm

[21] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf (The FDA specifically states that it does not evaluate information related to contract liability warranties).

[22] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf

[23] *Id.*

[24] *Id.*

be likely to cause or contribute to a death or serious injury if the malfunction were to recur.[25]

100. The FDA made clear in the PMA order that "[f]ailure to comply with the conditions of approval invalidated this approval order and commercial distribution of a device that is not in compliance with these conditions is a violation of the act."[26]

2. General Reporting Duties to the FDA are Required After the PMA Process.

101. A medical device manufacturer's obligations do not end with the FDA's Premarket Approval ("PMA") process.

102. Under federal law a medical device manufacturer has a continuing duty to monitor its product after premarket 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.[27]

103. Accurate reporting of adverse events is essential, as it serves to notify the public that a potential problem with the device exists, and can prompt an informed person or organization to develop a solution. The FDA and others, including the public, rely upon accurate and timely reporting of adverse events. Post-market surveillance by the FDA is hampered when mandatory reporting terminology is not clear, accurate, and consistent.

104. Manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

A) may have caused or contributed to death or serious injury; or

[25] *Id.*
[26] *Id.*
[27] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).

B) has malfunctioned in a manner that would likely "cause or contribute to a death or serious injury" if it recurred.[28]

105. "Becomes aware" means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.[29] A manufacturer is considered to have become aware of an event when any of its employees becomes aware of a reportable event that is required to be reported within 30 calendar days.[30] A manufacturer is also considered to have become aware of an event when any of its employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable Medical Device Report ("MDR") event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.[31]

106. "Serious injury" is defined as an injury or illness that: (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.[32]

107. "Malfunction" is defined as a failure of a device to meet its performance specifications or otherwise to perform as intended.[33] Performance specifications include all

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[28] 21 C.F.R. § 803.50(a); *see also* 21 U.S.C. § 360i(a) (further detailing the post approval reporting requirements applicable to device manufacturers).
[29] *See* 21 C.F.R. § 803.3(b) (2012).
[30] *Id.*
[31] *See* 21 C.F.R. § 803.3(b)(2) (2012).
[32] 21 C.F.R. § 803.3 (2012).
[33] *Id.*

claims made in the labeling for the device.[34] The intended performance of a device refers to the intended use for which the device is labeled or marketed.[35]

108. A malfunction should be considered reportable if any one of the following is true:

A) the chance of a death or serious injury resulting from a recurrence of the malfunction is not remote;

B) the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;

C) the malfunction causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences. The essential function of a device refers not only to the device's labeled use, but for any use widely prescribed within the practice of medicine; or,

D) the malfunction involves a long-term device implant that would prevent the implant from performing its function.[36]

109. Reporters do not need to assess the likelihood that a malfunction will recur. The regulation assumes that if a malfunction has occurred once, the malfunction will recur.[37]

110. "*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."[38]

111. "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."[39]

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[34] *Id.*
[35] *Id.*
[36] See "Medical Device Reporting For Manufacturers," available online at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm#al
[37] *Id.*
[38] 21 C.F.R. § 820.198(c) (2012) (Emphasis added).
[39] 21 C.F.R § 820.198(b) (2012).

112. "Any complaint that represents an event which must be reported to FDA under part 803 of the Medical Device Reporting regulations 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) [w]hether the device failed to meet specifications; (2) [w]hether the device was being used for treatment or diagnosis; and (3) [t]he relationship, if any, of the device to the reported incident or adverse event."[40]

113. Manufacturers, such as Defendants, may receive device-related complaints from information from many different sources, including telephone calls or other verbal communication, FAX transmissions, written correspondence, sales representative reports, service representative reports, scientific articles (literature), internal analyses, and legal documents.[41]

114. Additionally, manufacturers of Class III Medical Devices are required to make periodic reports to the FDA regarding approved devices, which must include summaries of:

A) 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; and

B) reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.[42]

115. As presented below, Defendants failed to comply with several of the aforementioned conditions of their PMA Order and federal regulations governing medical device manufacturer reporting requirements.

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[40] 21 C.F.R. § 820.198(d) (2012).

[41] *See* "Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers" available online at: Http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf

[42] 21 C.F.R. § 814.84(b)(2) (2012).

3. A Manufacturer Must Follow Current Good Manufacturing Practices.

116. Under 21 C.F.R. § 820.1(a) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the FDCA.[43] This part establishes basic requirements applicable to manufacturers of finished medical devices.

117. 21 C.F.R. § 820.5 (2012) "Quality Systems", of the FDA regulations states: "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

118. 21 C.F.R. § 820.30(i) (2012): "Design controls" states: "(i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation."

119. 21 C.F.R. § 820.30(g) (2012): Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s) and "shall include testing of production units under actual or simulated use conditions."

120. 21 C.F.R. § 820.22 (2012): "Quality Audit" states, in part: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

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[43] *See* 21 C.F.R. § 820.1(a)(2012).

121. 21 C.F.R. § 820.160(a) (2012): "Distribution" states, in part: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed..." In other words, a manufacturer is only permitted to distribute a medical device that is approved.

122. 21 C.F.R. § 820.170(a) (2012): "Installation" states: "Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device."

123. 21 C.F.R. § 803 (2012), requires that manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting ("MDR") submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use.

124. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states, in part, that Manufacturers shall: "establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

A) 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;

B) investigating the cause of nonconformities relating to product, processes, and the quality system;

C) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

D) verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; [and]

E) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems."[44]

125. "The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence."[45] Implementing corrective and preventive actions "are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures."[46]

126. As presented below, Defendants failed to comply with several of the aforementioned conditions of their PMA Order and federal regulations governing medical device manufacturing processes.

4. PMA Supplements For Labeling Changes.

127. Any changes the manufacturer believes could affect the safety and effectiveness of the device must be submitted via a "PMA Supplement," to the FDA for approval.[47]

128. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include labeling changes if they affect the safety or effectiveness of the device.[48]

129. Most changes to the labeling of a device after premarket approval require prior FDA approval, but a manufacturer may place into effect:

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[44] 21 C.F.R. § 820.100 (2012).
[45] *See* http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm170612.htm
[46] *Id.*
[47] 21 C.F.R. § 814.39(a) (2012).
[48] *Id.*

A) "[l]abeling 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) "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device, and;

C) "[l]abeling changes that delete misleading, false, or unsupported indications."[49]

130. Under those regulations, the manufacturer is required to notify the FDA of "Changes Being Effected" (CBE) to a device's labeling.

5. The FDA Prohibits Misleading Or False Promotion And Marketing.

131. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

132. Generally, to comply with the FDCA and FDA's implementing regulations, and therefore the PMA, such promotional pieces: (a) Cannot be false or misleading in any particular;[50] (b) Must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece.[51]

133. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.

134. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular.[52] Labeling or advertising may be considered misleading if it fails to

[49] *Id.*
[50] 21 U.S.C. §352(a) (2012).
[51] 21 U.S.C. § 321(n) (2012); 21 C.F.R. § 1.21(2012).
[52] 21 U.S.C. § 352(a) (2012).

reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.[53]

135. Defendant's PMA approval letter for Essure® specifically states that the FDA "[d]oes not evaluate information related to contract liability warranties, however [Defendant] 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."[54]

6. Violations of Federal Statutes or FDA Regulations Void the Federal Preemption Defense.

136. There is a presumption against federal preemption of state laws that operate in traditional state domains.[55] "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."[56]

137. "Nothing in § 360k denies [the states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."[57]

138. As the Supreme Court held in *Riegel v. Medtronic, Inc.*, "State requirements are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements."[58]

139. "The idea that Congress would have granted civil immunity to medical device

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[53] *See* 21 U.S.C. § 321(n) (2012).
[54] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf
[55] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).
[56] *Id.* at 475.
[57] *Id.* at 495.
[58] *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008) (internal citations omitted).

manufacturers for their violations of federal law that hurt patients is, to say the least, counterintuitive."[59]

140. "Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they comply with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer's violation of federal law."[60]

141. Claims for failure to warn are not preempted. "Failure to warn claims are neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]'s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device."[61]

142. In *Stengel v. Medtronic, Inc.*, the Supreme Court issued an Order inviting the Solicitor General to submit an Amicus Brief expressing the views of the United States. According to the Solicitor General, only device-specific federal requirements have preemptive force while "by contrast FDA's general manufacturing and labeling regulations do not have preemptive force."[62]

143. The Solicitor General stated that "federal requirement[s] are applicable to the device within the meaning of Section 360k(a)(1) only when they are applicable to the device in question and, in accordance with FDA regulations, only when they are specific counterpart regulations or specific to a particular device."[63]

144. This reasoning led the Solicitor General to the conclusion that "[i]f a state requirement were preempted absent a specific federal requirement that reflects FDA's weighing

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[59] *Bausch v. Stryker Corp.*, 630 F.3d 546, 549-550 (7th Cir. 2010). *See also, Bausch* quoted with approval by the 9th Circuit in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc).
[60] *Id.* at 550 (italicized emphasis original).
[61] *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011).
[62] U.S. Amicus Br. at 9, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013).
[63] *Id.* at 8-9 (internal citations omitted).

of competing considerations on the same subject and specific to the device, the MDA would have the ironic effect of providing less public protection from unsafe and ineffective medical devices than pre-MDA law.[64]

145. In *Stengel*, and similarly in this Complaint, the alleged conduct of the petitioner was governed by general manufacturing and labeling regulations applicable to all medical devices and not the device's pre-market approval.

146. It is the opinion of the Solicitor General that respondents' failure to warn claims escaped express preemption because "such a claim implicates no preemptive device-specific federal requirement."[65]

147. In summary, while manufacturers who comply with federal law may be entitled to certain protections, those who violate federal law are not entitled to preemption of state laws/immunity for their tortious conduct and in fact are liable for their conduct that violates federal law.

C. CONCEPTUS DEPENDED SOLELY ON ESSURE® SALES TO FIX THEIR PROBLEMS WITH MASSIVE DEBT AND ACHIEVE PROFITABILITY.

148. Conceptus accumulated hundreds of millions of dollars in debt throughout its existence, never achieved profitability, and looked to sales of the Essure® product as the sole solution.

149. By the end of 2007, Conceptus had an accumulated deficit of $235.2 million.

150. By the end of 2012, after all of its concerted sales efforts, Conceptus still had an accumulated deficit of $154.9 million.[66]

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[64] *Id.* at 11 (internal citations omitted).
[65] *Id.* at 7 (internal citations omitted).
[66] *See* http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm#toc

151. By that time, Conceptus had been in a cumulative net loss position for twenty years, since its inception.[67]

152. Conceptus stated that it would remain in an accumulated deficit position unless Essure® sales grew large enough to offset its expenses.[68]

153. Beginning in 1998, Conceptus focused solely on the design, development, and clinical testing of Essure®.

154. By 2002, Conceptus' revenue was derived almost entirely from the sale of Essure® to physicians.

155. By 2007, Essure® was Conceptus' only commercial product. Conceptus was entirely dependent on sales of the Essure® device to survive, as these sales accounted for all of the company's revenues.[69]

156. That year, Conceptus stated that if the Essure® device did not achieve acceptance among physicians and patients, the company would fail to sustain profitability.[70]

D. MANIPULATING SAFETY INFORMATION ALLOWED CONCEPTUS TO BECOME A VIABLE COMPANY.

157. In order to profit from Essure® and survive, Conceptus needed to convince physicians and women that the device was safe.

158. Because Essure® was a wholly unique and new form of birth control, Conceptus did not compete with other similar products for share of an existing market.

159. Instead, Conceptus needed to create a new market for its product.

160. Physicians and women needed to accept the safety of Essure® before there could be a demand for it.

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[67] *See* http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm#toc
[68] *Id.*
[69] *See* http://www.sec.gov/Archives/edgar/data/896778/000110465907007326/a07-3143_18k.htm
[70] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

161. Therefore, apprehensions about the device's safety have always been the biggest barrier to its success.

162. In 2007, Conceptus stated that if the Essure® system did not achieve acceptance among physicians and patients, the company would fail to sustain profitability.[71]

163. Conceptus committed all of its resources to persuading physicians and patients to accept the Essure® device as a safe method of birth control.

164. Throughout its entire history, Conceptus marketed Essure® aggressively through the use of public relations and targeted advertising in order to create acceptance of the device among general practitioners, women and the broader medical community.[72]

165. In April of 2003, Conceptus introduced Essure® at the annual conference of the American College of Obstetricians and Gynecologists and offered two presentations as well as a Continuing Medical Education accredited symposium with Essure® as the main topic.[73]

166. In June of 2003, Conceptus sent direct mail to 500,000 women, not physicians, in the Atlanta and Chicago areas.

167. The direct mail campaign encouraged those women to contact Conceptus' call centers, who then referred the women to a physician offering Essure® in her area.[74]

168. Conceptus also ran numerous regional advertisements in a variety of magazines, such as *Parents* and *Self*.[75]

169. Conceptus continuously fought to achieve market acceptance for Essure®.

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[71] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313
[72] *See* http://www.sec.gov/Archives/edgar/data/896778/000089161804000719/f96941e10vk.htm
[73] *Id.*
[74] *Id.*
[75] *Id.*

170. In 2008, Conceptus targeted women directly again in a marketing campaign that incorporated print media, radio and television advertising. The company claimed that the campaign was meant to drive patient awareness and increase physician office utilization.[76]

171. Conceptus also employed a robust sales force whose primary goals were to persuade a growing base of physicians to offer the device.[77]

172. Conceptus repeatedly treated its warning label as a tool to promote market acceptance and manipulated it to achieve those goals.

173. In 2008, Conceptus stated that it intended to make labeling improvements to Essure® in order to increase the adoption of the Essure® procedure. [78]

174. At one point, Conceptus' CEO described certain adequate warning information as merely a barrier to more success in sales.

175. Despite mounting complaints of allergic reactions to Essure®, in 2011, Conceptus drastically altered the warning label and removed sections that encouraged women to confirm their tolerance to nickel by use of a skin test.

176. Conceptus did not change anything about the device itself or its nickel contents.

177. Afterward, the president and CEO of Conceptus stated that the label change would strengthen the company's standing in the permanent birth control market by diminishing Essure®'s biggest competitive disadvantage.

178. Conceptus then reaffirmed its ultimate goal of gaining market acceptance by stating its intentions to aggressively present the label change to the OB/GYN community. The company planned to target those physicians who were promoting other methods of birth control because of potential safety issues with the Essure® device.

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[76] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313
[77] *See* http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm
[78] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

E. CONCEPTUS AND BAYER CONTINUOUSLY SPREAD FALSE AND MISLEADING INFORMATION TO ALTER PERCEPTIONS OF ESSURE®'S SAFETY RISKS.

179. Conceptus and Bayer advertised, promoted and marketed on its websites, in its print and/or video advertisements, brochures and fact sheets the following representations about Essure®:

A) The Essure® patient brochure stated that Essure® was the "only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials." However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Between 1997 and 2005, there were 64 pregnancies reported to Defendants. Additionally, there have been 631 reports of pregnancies according to the FDA as of December 31, 2015. Furthermore, a recent study indicates that women implanted with Essure® have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater. Defendants concealed this information from Plaintiffs and Plaintiffs' physicians, yet promoted Essure® as a more effective form of permanent sterilization than a tubal ligation.

B) The Essure® website, print advertising, and patient brochure describes Essure® as "worry free," and is a "simple procedure performed in your doctor's office" that takes "less than 10 minutes" and "requires no downtime for recovery" and "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Defendants actively concealed and failed to report complaints of perforations and pain, which occurred as a result of the Essure® procedure. Additionally, Essure® is not worry free because there is an increased risk that the Essure® implants will cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical intervention, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, tooth- loss, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications.

C) The Essure® website, print advertising, and patient brochure stated, "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." However, the micro-inserts do not necessarily remain securely in the fallopian tubes and can migrate and

be expelled by the body, as evidenced by the over 850 reports of device migration as of December 31, 2015.[79]

D) The Essure® website, print advertising, and patient brochure stated, "the Essure® inserts are made from the same trusted, silicone free material used in heart stents." However, the micro-inserts are not made from the same material as heart stents which do not elicit tissue growth. The micro-inserts are made of PET fibers, which trigger inflammation and scar tissue growth. PET fibers degrade and leach carcinogens when placed in temperatures over 65 degrees, and the human body stays at about 98 degrees. As such, PET fibers are not designed or manufactured for use in human implantation. However, the PET fibers are made of the same materials as the PVT material in some vaginal meshes, which have a high rate of expulsion.

E) The Essure® website, print advertising, and patient brochure stated, "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure® does not eliminate the risks, discomfort, and recovery time associated with surgical procedures (i.e. tubal ligations) because many women who undergo the Essure® procedure, including Plaintiffs, have never and will never fully recover from the Essure® implant procedure, which has caused them serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, tooth-loss, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications.

F) The Essure® website, print advertising, and patient brochure stated, "Essure® is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy" or words to that effect. Yet, Defendants' SEC Form 10-K filing shows that Defendants never did a comparison to a vasectomy or tubal ligation. Specifically, Defendants stated they "did not conduct a clinical trial to compare the Essure® procedure to laparoscopic tubal ligation."[80]

180. Plaintiffs, PMC and Plaintiffs' physicians relied on these representations by Conceptus and Bayer in recommending and undergoing the Essure® procedure.

[79] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[80] Conceptus, Inc., Annual Report (Form 10-k) (Mar. 15, 2004).

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

A) "[p]hysicians must be signed-off to perform Essure® procedure." However, Defendants failed to adequately train the implanting physician and "signed off" on the implanting physician who did not have the requisite training.

B) "An Essure® trained doctor inserts spring-like coils, called micro-inserts." However, the implanting physician who implanted the device was not adequately trained.

C) "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." However, Defendants failed to adequately train the implanting physician.

D) "[i]n order to be trained in Essure® you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure®." However, Defendants "signed off" on physicians who were not skilled operative hysteroscopists, in order to monopolize and capture the market, including the implanting physician.

E) "[i]n order to be identified as a qualified Essure® physician, a minimum of one Essure® procedure must be performed every 6–8 weeks." However, Defendants "signed off" on "Essure® physicians" who did not perform the procedure every 6–8 weeks.

F) "[t]he PET fibers are what caused the tissue growth," and Essure® "works with your body to create a natural barrier against pregnancy." However, during a PMA meeting with the FDA in 2002, Defendants represented that the trauma caused by the expanding coil hitting the fallopian tubes is what causes the inflammatory response of the tissue.

182. Plaintiffs and Plaintiffs' implanting physician relied on these representations by Conceptus and Bayer in recommending and undergoing the Essure® procedure.

F. CONCEPTUS AND BAYER HAVE ALWAYS KNOWN THAT ESSURE® IS DANGEROUS.

1. Conceptus Was Charged With Early Regulatory Violations.

183. From the beginning of the sale of the Essure® device, Conceptus has repeatedly been cited by regulatory authorities for continuous violations that impacted patient safety.

184. In June and July of 2003, the FDA conducted a Post Market Approval Inspection of Conceptus. The FDA cited Conceptus for failing to adequately analyze all quality data sources to identify existing and potential causes of non-conforming product and other quality problems, and failing to follow procedures for the control of products that do not conform to specifications.

185. In June of 2008, the California Department of Public Health, Medical Device Safety Section ("CDPH"), conducted an inspection of Conceptus' location in Mountain View, California. The CDPH issued a Notice of Violation to Conceptus for failing to obtain a valid license to manufacture medical devices and failing to maintain procedure for inventory transfer.

2. Conceptus Knew About A Myriad Of Manufacturing Problems.

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

A) the stainless steel used in the device became unpassivated, which can cause the device to rust;

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 have existed in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

G) PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;

H) the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body;

I) there was an inadequate solder joint between the inner and outer coils of the micro-insert which can cause the micro-insert to fracture/break apart, and which Bayer admits is or could be a reason for device breakage, and;

J) the central axis was not fully adhered to the spring which can cause the micro- insert to fracture/break apart, and which Bayer admits is or could be a reason for device breakage.

3. Conceptus Concealed Thousands of Migration and Perforation Reports From the FDA.

187. Conceptus knew of thousands of instances where the Essure® device had migrated in a woman or perforated a woman's organs, failed to report all of them, and then fought the FDA on its reporting obligations once the agency discovered the problem.

188. In the years before 2011, Conceptus had accumulated thousands of reports from women that their devices had migrated throughout their bodies or punctured one of their organs.

189. To protect the marketability of the device, Conceptus chose not to report the vast majority of them.

190. Then, in December of 2010 the FDA conducted a "for cause" inspection of Conceptus and its reporting procedures.

191. At the conclusion of the inspection, the FDA inspector cited Conceptus for four conditions which he found objectionable and/or violations of the FDCA and federal regulations.

192. Three of the four objectionable conditions pertained to Medical Device Reporting deficiencies and/or violations and included:

A) Conceptus' failure to submit Medical Device Reporting ("MDR") determinations to the FDA within 30 days for reports of a serious injury involving the Essure® device including 2 (two) reports of bowel perforation, and 1 (one) report of pain and the Essure® device breaking into pieces immediately following implant;

B) Conceptus' failure to submit MDR's to the FDA within 30 days for reports of a serious injury involving the Essure® device including, but not limited to 5 (five) reports of the Essure® coils perforating the fallopian tubes and penetrating the peritoneal cavity; and

C) Conceptus' failure to include a failure mode for perforation itself and for the Essure® micro-inserts migrating into the peritoneal cavity in their latest Risk Analysis Design FMEA for Essure®, despite having documented at least 508 complaints of perforation between January 1, 2009 and December 8, 2010, and at least 177 complaints of perforation with the micro-insert was found in the peritoneal cavity between January 1, 2009 and January 4, 2011.

193. Specifically, the FDA inspector discovered that Conceptus was not reporting complaints of Essure® coils being seen inside the patients' abdominal cavity and not opening a corrective and preventive action ("CAPA") when they became aware of these complaints.

194. The FDA discovered that Conceptus submitted MDRs and reported complaints of the coils migrating into the peritoneal or abdominal cavity only if the patient was complaining of pain and a second procedure was required to remove the device.

195. Conceptus concealed such complaints if the coil was subsequently removed during a laparoscopic tubal ligation surgery that was performed due to a failure of occlusion of the fallopian tubes.

196. The FDA inspector demanded that Conceptus report these incidents because a migrated coil was inherently likely to lead to an injury. Conceptus' own complaint files contained hundreds of instances where this condition led to a serious complication.

197. Conceptus did not agree with FDA's position that physicians and women had a right to know about all dangerous events associated with the device.

198. Instead, Conceptus officials attempted to persuade the FDA inspector that they should not be forced to report such adverse events and make them publicly available.

199. Conceptus officials argued that a coil falling out of the fallopian tube was not technically a "malfunction" of the device, and therefore it did not need to be reported.

200. The FDA inspector explained that because the coil was designed to remain inside the fallopian tube, a coil that migrates out of the fallopian tube represents a situation where the Essure® device is not functioning as it was designed and intended.

201. There was no medical reason to withhold this information from the public. Conceptus concealed these reports specifically to mislead physicians and women about the safety of the Essure® device.

202. The size and scope of Conceptus' failure to report adverse events up until that time was enormous.

203. Just between January 1, 2008 and December 6, 2010, Conceptus received at least 16,581 complaints relating to Essure®.

204. Of these 16,581 complaints, 16,399 were never reported to the FDA.

205. Conceptus had compiled a spreadsheet of 2,752 complaints about Essure® received from July 20, 2010 through December 10, 2010. Not a single one of these that indicated perforation of a patient's organs was reported to the FDA.

206. In fact, during that time period Conceptus reported only 182 complaints total to the FDA.[81]

207. At the close of the inspection on January 6, 2011, the FDA inspector made it abundantly clear to Conceptus officials that an abdominally located coil was the precursor to becoming symptomatic in all cases in which an intra-abdominal coil had to be removed surgically.

208. Nonetheless, Conceptus continued to conceal complaints if a patient had a coil in her peritoneal cavity but was asymptomatic.

209. Conceptus revealed in this inspection that it had no intention of keeping physicians and women fully informed.

210. Conceptus' sole purpose was to maintain the marketability of its device by concealing as much adverse safety information related to its device as it could.

211. Conceptus' fraudulent scheme to conceal reports of device migration and perforation was undertaken in conscious disregard of the health and safety of all Essure® patients, and in violation of federal law, the PMA, and parallel state law.

212. Thousands of vulnerable and unsuspecting patients, including the Plaintiffs herein, have been seriously injured as a result of Conceptus' wrongful, illegal and immoral actions.

4. Conceptus Demonstrated A Continuing Pattern of Concealing Safety Complaints.

213. In 2013, several years after being cited by the FDA for withholding safety information, the FDA discovered again that Conceptus had been concealing thousands of complaints from the agency and the public.

[81] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm

214. Between May and June of 2013, the FDA conducted another inspection of Conceptus' Mountain View, CA facility. This inspection included an evaluation of Conceptus' complaint handling and adverse event reporting practices.

215. The FDA's review revealed 16,047 complaints Conceptus had received regarding Essure® between January 2011 and the date of the inspection.

216. Of these 16,047 complaints, Conceptus withheld 15,712 from the FDA, ensuring that they would not be made public.[82]

217. Out of those 16,047, the FDA inspector reviewed 18 random complaints that contained the key words "peritoneal" or "abdominal" with "pain" or "pregnancy" and discovered that none of the complaints stating that one or more of the coils were imaged outside the fallopian tubes were reported to the FDA if the patient had not reported pain at last contact.

218. Conceptus did not provide an explanation as to why the patient had stopped reporting pain, such as possible removal of the device.

219. Conceptus withheld thousands of complaints of side effects from the FDA for years because it needed to protect the perception that its device was safe.

220. If Essure® was ever perceived as unsafe, or not as safe as alternative birth control methods, then the device would not have achieved acceptance in the marketplace and the company would fail.

[82] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm

5. Trends in FDA Reports Prove That Conceptus and Bayer Withheld An Enormous Amount of Safety Information.

221. Alarming trends in the FDA's database exist because Conceptus and Bayer chose not to report adverse events to the FDA as required by federal law.

222. The FDA did not receive accurate numbers of safety reports concerning Essure® until Conceptus and Bayer no longer controlled the information.

223. The FDA learned of an overwhelming number of Essure® adverse events only after women were no longer forced to report their problems directly to Conceptus or Bayer.

224. Between Essure®'s inception in 2002 and through to 2015, the FDA received approximately 9,900 medical device reports (MDRs) related to safety problems with the device.[83]

225. Of those 9,900 MDRs, only 943 were made between 2002 and October 25, 2013. The FDA received the remaining 8,950 reports between October 26, 2013 and December 31, 2015.[84]

226. Therefore, approximately 90% of all Essure® related adverse events reported through the year 2015 were reported after late October of 2013.[85]

227. The rate at which women suffered adverse events associated with the Essure® device did not change. The device itself did not change. Only the reporting mechanisms changed.

228. Up until late 2013, women adversely affected by Essure® had no convenient method of reporting their problems directly to the FDA. These women were thus forced to

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[83] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[84] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[85] *Id.*

report their problems solely to Conceptus or Bayer.

229. Around that time, the FDA introduced a new method of reporting adverse events named "MedWatcher."

230. MedWatcher is an app that allows individuals to submit their reports of serious medical device problems directly to the FDA through the convenient use of their smart phone or tablet, thus disposing of the need to contact a device manufacturer first.[86]

231. Authors studying Essure® adverse event reporting recently concluded that the ability for women to report Essure® related complaints via the MedWatcher app resulted in a massive increase in Essure® related MDRs reported to the FDA since October 26, 2013.[87]

232. The study, entitled *Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US*, examined voluntary patient adverse event reporting directly to the FDA using the FDA's new MedWatcher app.[88]

233. The study began by encouraging women in an Essure® support group who had been adversely affected by the device to file a report using MedWatcher.[89]

234. The Essure® support group was a Facebook group named "Essure Problems" consisting of women who underwent the Essure® procedure and began experiencing severe pain and problems related to the device. Currently, the group has over 32,000 members.[90]

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[86] *See* http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm385880.htm
[87] *Id.*
[88] *See* "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html
[89] *See id.*
[90] *See* https://www.facebook.com/groups/Essureproblems/

235. In October 2013, a representative from the MedWatcher app development team joined the "Essure Problems" group to provide technical support to patients filing adverse event reports via the MedWatcher app.

236. This change in reporting mechanisms directly caused the explosion of adverse event reports that became public after October of 2013.

237. According to "Essure Problems" group administrators, many women with Essure® reported these same complaints directly to Conceptus for many years prior to October of 2013.

238. Those women were never contacted for follow-up investigations and Conceptus and Bayer chose not to report the vast majority of those complaints to the FDA.

239. As a result, while Conceptus maintained growing complaint files detailing thousands of problems experienced with the device, the FDA and the public only became aware of a fraction of them.

240. Conceptus and Bayer successfully concealed thousands of reports of adverse events associated with Essure® from the FDA and the public because they controlled the information for years.

6. Bayer Misled the FDA About Rates of Essure® Breaking.

241. Despite knowing about hundreds of instances of the Essure® device breaking, Bayer has repeatedly reported to the FDA that only single cases exist.

242. Between May 29, 2014 and January 20, 2016, Bayer received at least 462 complaints that a patient's Essure® coils had broken apart.

243. When forwarding the first few complaints, Bayer notified the FDA that "single cases have been reported of Essure® breakage."

244. However, as reports of breakage continued to mount, Bayer continued to submit to the FDA that only single cases of breakage had been reported.

245. After 100 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

246. After 200 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

247. After 462 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

248. In fact every single report of device fracture or breakage included a statement by Bayer to the FDA stating that "single cases have been reported of Essure® breakage."

249. Bayer did this because it knew that the FDA would not discover the trend in the data on its own.

250. Bayer knows that multiple FDA analysts read each individual MDR that it submits, and they do not necessarily communicate with each other or compare data.

251. Therefore, when multiple FDA analysts read separate reports that each state "single cases have been reported of Essure® breakage," it causes each individual analyst to falsely believe that instances of device breakage are extremely rare.

252. Bayer's MDRs regarding device breakage were inaccurate, misleading, and not in compliance with MDR reporting requirements.

253. Bayer did this to withhold knowledge from the public and to prevent the FDA from requiring it to make changes to its label concerning device breakage, a condition with potentially life-threatening consequences.

7. Now The Medical Community Is Discovering What Conceptus And Bayer Knew For Years: Essure® Is Dangerous.

a. Women with Essure® Are Ten Times More Likely to Undergo Subsequent Surgical Re-Operation than Women Who Undergo a Tubal Ligation

254. The Essure® device leads to far more complications than alternative permanent birth control methods. It is significantly less safe than the traditional alternative method of undergoing a tubal ligation.

255. On October 13, 2015, the British Medical Journal ("BMJ") published a study entitled *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study,* in which Dr. Art Sedrakyan of Weill Cornell Medicine in New York and his colleagues analyzed data from women who had received either the Essure® implant or undergone a traditional tubal ligation between 2005 and 2013 in New York State.[91]

256. The data included 8,048 women who underwent the Essure® procedure and 44,278 women who had undergone a tubal ligation.

257. This study used data collected from the New York State Department of Health Statewide Planning and Research Cooperative System, which is a database that collects patient and treatment information for every hospital discharge, outpatient service, ambulatory surgery, and emergency department records in New York State.[92]

258. This study is the first large comparative cohort study ever to have been conducted to compare the efficacy and safety of the implant based hysteroscopic procedure with the

[91] *See* "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study" available online at: http://www.bmj.com/content/351/bmj.h5162
[92] *Id.*

traditional laparoscopic procedure.[93] It is the largest collection of data related to Essure® that was not controlled by Conceptus or Bayer.

259. The study found that women who used Essure® as a means for permanent sterilization were ten times more likely to undergo re-operation due to device related complications and injuries compared to women who underwent tubal ligation.[94]

260. The study reported that although Essure® is advertised as a surgery-free alternative to the minimally invasive laparoscopic surgery, women who had the Essure® implant often required a subsequent major surgery due to complications resulting from Essure®, and at far greater rates than the traditional option.[95]

261. The authors also analyzed the Essure® MAUDE data and indicated that most of the adverse events reported by patients with Essure® were for injuries that would require and did require a subsequent surgical operation.[96] Such injuries included pelvic pain, hemorrhage, and device migration or incompatibility.

262. Reports of chronic pain, hemorrhage, and device migration, which necessitate surgical intervention, are indeed serious injuries and are therefore reportable events.[97]

263. Conceptus and Bayer did not submit any MDR reportable events derived from this study to the FDA.

264. Bayer still falsely claims to this day that Essure® is safer than undergoing tubal ligation.

b. Essure® Is Not As Effective As Alternative Methods

265. Women with Essure® are more likely to get pregnant than women who undergo a

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[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] 21 C.F.R. § 803.3 (2012).

tubal ligation.

266. In March of 2014, the online medical journal Conception published a study entitled *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*, which compared the expected probability of pregnancy after hysteroscopic sterilization (Essure®) with laparoscopic sterilization based on available data using decision analysis.[98]

267. The study analysis took into account uncertainties in successful placement of coils, return for follow-up confirmation testing and successful blockage of tubes. Using real-life circumstances, the authors concluded that at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization.[99]

268. The study found that the expected pregnancy rates per 1000 women at 1 year are 57, 7 and 3 for hysteroscopic sterilization, laparoscopic silicone rubber band application and laparoscopic bipolar coagulation, respectively. At 10 years, the cumulative pregnancy rates per 1000 women are 96, 24 and 30, respectively.[100]

269. This means that the probability of getting pregnant at 1 year and over 10 years is higher in women who receive Essure® as compared to laparoscopic sterilization.[101]

270. Essure® sterilization failure rates after typical use in the community by a variety of physicians on a variety of patients are significantly higher than the failure rates reported to the FDA by the manufacturer in its own highly controlled study.

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[98] *See* "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/ journals/contra/CON-8309-FINAL.pdf

[99] *Id.*

[100] *Id.*

[101] *Id.*

271. However, Bayer still falsely claims to this day that Essure® is more effective than undergoing tubal ligation.

c. Leading Practitioners Have Criticized Conceptus for Its Lack of Transparency

272. Experts in the field of gynecology disapprove of Conceptus' and Bayer's failure to provide information to the public.

273. On September 23, 2015, the New England Journal of Medicine published an article entitled *Revisiting Essure – Toward Safe and Effective Sterilization.* Authored by several prominent gynecologists, the article expressed concerns about the inadequacy of Essure®'s premarketing and postmarketing studies.[102]

274. More specifically, the authors identified problems relative to incomplete follow-up with patients and biased results.

275. Ultimately, the authors concluded that many of the Essure® adverse events and safety concerns, along with problems with the device's effectiveness, might have been detected sooner or avoided altogether if there had been higher-quality premarketing and postmarketing evaluations and more timely and transparent dissemination of study results by the manufacturers.[103]

276. Coinciding with other developing understandings, the article notes that evidence suggests that Essure® is neither as effective nor as safe as the premarketing-approval evaluation indicated.[104]

8. <u>The Revelation Of Safety Information In The Public Leads To The Inevitable: FDA Mandates Major Changes To Essure® Sales.</u>

277. As thousands of reports about Essure®'s true safety risks became public recently,

[102] *See* "Revisiting Essure – Toward Safe and Effective Stjerilization" available online at: http://www.nejm.org/doi/full/10.1056/NEJMp1510514
[103] *Id.*
[104] *Id.*

the FDA forced drastic changes to the product's warning label and took aggressive measures to ensure that patients are fully informed of the risks.

278. Patients and physicians have reported to the FDA upwards of 9,000 adverse events related to Essure® since October 2013. This significant increase prompted the FDA to convene a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to examine safety concerns about Essure® raised by patients and cited in MDRs.

279. The meeting was held on September 24, 2015 and FDA heard available scientific data pertaining to Essure®'s safety and effectiveness, expert scientific and clinical opinions on the risks and benefits of Essure®, and concerns and experiences of women implanted with the device.

280. On February 29, 2016 the FDA announced that it would 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.[105]

281. 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.[106]

282. The new warning and checklist were finally approved on November 15, 2016, and will change the risk/benefit profile of Essure® for all potential patients. They will reveal the alternatives as far better choices for many women. It will lead to far less patients choosing to use the Essure® system.

283. This result is why Conceptus and Bayer withheld safety information from the FDA and the public for years.

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

[106] *Id.*

284. Conceptus and Bayer knew that if the true risks of Essure® were known to the FDA, then they would inevitably be communicated to physicians and women.

285. Conceptus and Bayer knew that if physicians and women understood the true risks of Essure®, then sales of the device would be devastated.

286. Conceptus and Bayer withheld thousands of complaints of adverse events from the FDA for years to protect and promote the false perception that the Essure® device was safe.

287. If Essure® was ever perceived as unsafe, or not as safe as alternative birth control methods, then the device would not have achieved market acceptance and the company would fail.

288. To protect sales and revenue, Conceptus and Bayer purposefully ignored their mandatory federal reporting requirements and actively hid safety information from the public for as long as they could.

a. FDA Orders Bayer to Give Warnings Indicating the Highest Level of Risk

289. In February of 2016 the FDA determined that a boxed warning needed to be a part of the Essure® warning label.

290. The FDA reserves boxed warnings for only the most serious adverse events, and they indicate the highest level of risk.

291. On March 4, 2016, the FDA noted that it would receive public input for the following suggested 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.[107]

292. On October 31, 2016, the FDA issued the following final guidance, "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization," which stated that "a boxed warning should be part of the labeling for a permanent, hysteroscopically-placed tubal implant for sterilization…" The FDA states that this warning should:

- Note the types of significant and/or common adverse events that may be associated with the device and its insertion, use, and/or removal procedure, including those noted in clinical trials, as well as those reported in other device use experience.
- Include a statement noting that these risks should be conveyed to the patient during the decision-making process.[108]

293. The October 2016 Boxed Warning Example issued by the FDA was implemented in November 2016, and states as follows:

> **WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.**[109]

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

295. Conceptus and Bayer hid from patients safety information about the most serious adverse events and the highest levels of risk.

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

[108] *See* "Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization," at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf

[109] *Id.* at pg. 9; *see also* http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf; *and see* http://labeling.bayerhealthcare.com/html/products/pi/essure_ifu.pdf

296. If Conceptus and Bayer had not violated federal reporting violations, the public would have known about these safety risks years earlier. Thousands of women who decided to have the Essure® device implanted would have received the knowledge that they deserved, and thousands of injuries could have been prevented.

297. Conceptus and Bayer could have prevented this problem by updating their warnings to patients.

298. The Essure® warning label has never been adequate.

299. Conceptus and Bayer did all in their power to keep serious side effects and warnings off of the Essure® label for years.

300. Over the course of many years, despite knowing of hundreds of instances where the Essure® device had migrated from its proper position, Conceptus did not warn of this potential problem.

301. After being caught by the FDA in 2011 for not reporting migration events, the company still refused to warn about this problem on its label.

302. It was not until 2013 that Conceptus even acknowledged migration events on the Essure® label.

303. At that time, Conceptus changed the warning label to state only that "There are reports of the Essure® insert migrating."

304. This warning gravely downplayed the true incidence of risk that a woman's Essure® coils might migrate.

305. Conceptus should have been adequately informing women about migrations.

306. This issue illustrates Conceptus' policy of deliberately refusing to provide adequate warnings to physicians and patients.

307. For years Conceptus and Bayer have downplayed on the Essure® warning label the true risks of migration, as well as perforation, persistent pain, allergy or hypersensitivity reactions, autoimmune-like reactions, the likelihood of reoperation, and other serious side effects.

308. The FDA has now forced what could and should have been done years ago.

b. FDA Takes Drastic Measures to Ensure Patients Are Fully Informed

309. Because Conceptus and Bayer denied thousands of women the information that they deserved, every potential Essure® patient is now required to receive and sign a detailed checklist specifically tailored to the risks associated with the device.

310. The Patient Decision Checklist requires a patient's initials and signature six separate times.

311. The checklist specifically warns of device migration and perforation of organs, side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

312. The checklist also specifically warns that some women may develop allergic reactions following implantation of Essure®, which could cause symptoms such as rashes or itching.

313. Most importantly, the checklist describes the review of its form as a critical step in deciding whether to have the Essure® device implanted, and suggests that a woman should carefully consider the risks before making the decision.

314. The checklist has a major impact on the risk/benefit profile of the device.

G. CONCEPTUS' AND BAYER'S PARTICIPATION IN THE COVERING UP OF AND FAILURE TO ADEQUATELY WARN OF SERIOUS ADVERSE EVENTS AND INCREASED RISKS AND COMPLICATIONS ASSOCIATED WITH ESSURE® CAUSED PLAINTIFFS' INJURIES.

315. A manufacturer has the duty to provide adequate and timely warnings regarding increased risks and dangers associated with the foreseeable uses of its product.

316. Conceptus and Bayer grossly failed to satisfy their duties mandated by federal law, the Essure® PMA, and state common law duties.

317. Conceptus and Bayer did not provide adequate and timely warnings or instructions regarding the true risks of Essure®.

318. Conceptus and Bayer disseminated misleading and false information concerning the true risks of Essure®.

319. Conceptus and Bayer purposefully concealed the serious increased risks and complications associated with Essure®.

320. Conceptus and Bayer failed to take the required actions when they learned that Essure® was causing thousands of problems in patients.

321. Bayer cannot and should not be permitted to absolve itself from liability by pointing to the FDCA or the MDA, claiming preemption, when it was Conceptus and Bayer who chose to deliberately conceal their knowledge of the increased risks, complications, and the serious and dangerous adverse side effects associated with Essure®.

322. Bayer cannot and should not be permitted to absolve itself from liability when it was Conceptus and Bayer who, in violation of federal law and the PMA, concealed and failed to report the true number of adverse events being reported by women with Essure®.

323. A medical device manufacturer only receives the benefits afforded by federal law, i.e. the FDCA and MDA, when it abides by federal law.

324. Federal law requires that a manufacturer report all known adverse events associated with a medical device to the FDA.

325. Not only did Conceptus and Bayer not provide the Plaintiffs' physicians nor Plaintiffs with the necessary information in order to make an informed decision in the best interests of Plaintiffs' health, but they purposefully deceived Plaintiffs' physicians and the Plaintiffs as to the safety and efficacy of Essure®.

326. Conceptus and Bayer did not discharge their duty, required by federal law, the Essure® PMA, and state common law duties to adequately and fully warn and inform Plaintiffs' physicians and Plaintiffs of the known dangers and increased risks associated with the use of Essure®.

327. Plaintiffs' physicians and Plaintiffs reasonably relied, and did rely, on Conceptus and Bayer's misrepresentations and concealments.

328. Moreover, Plaintiffs would not have consented to undergo the Essure® procedure had they been fully informed of its increased dangers, risks, and adverse consequences.

329. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment and misrepresentations concerning material health and safety risks associated with Essure®, Plaintiffs were injured and suffered and will continue to suffer injuries, damages, and economic loss.

330. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment and misrepresentations concerning material health and safety risks associated with Essure®, Plaintiffs have been injured and incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the quality and enjoyment of life as a result.

V. EQUITABLE TOLLING/FRAUDULENT CONCEALMENT

331. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

332. Conceptus and Bayer's failure to report, document, or follow up on the known adverse event complaints, and concealment of adverse events, known defects, serious increased risks, dangers, and complications, constitutes fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiffs herein. Plaintiffs herein has therefore satisfied applicable statutes of limitations and statutes of repose.

333. Bayer is 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, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure®, failed to satisfy FDA and PMA requirements, failed to satisfy FDA and PMA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and the Plaintiffs.

334. Instead, Conceptus and Bayer continued/continues to represent that Essure® was/is safer, more effective and the best alternative for permanent female sterilization all the while they knew that this was absolutely false and not true, even after the recent Cornell study was published and patient complaints accumulated in the thousands.

335. Conceptus and Bayer did the above acts which were and are illegal under federal law, the PMA and parallel state law, to effectively market Essure® and encourage physicians, including Plaintiffs' physicians, to recommend and perform the Essure® procedure.

336. Conceptus and Bayer did the above acts which were and are illegal under federal law, the PMA and parallel state law, to encourage patients, including Plaintiffs, to undergo the Essure® procedure rather than choose an alternative procedure, such as a traditional tubal ligation.

337. At all relevant times, Conceptus and Bayer were under a continuing duty under federal law, the PMA and parallel state laws to disclose the true character, quality, and nature of the increased risks, adverse events, and dangers associated with Essure®.

338. As a result of Conceptus and Bayer's concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

339. Conceptus and Bayer 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 systematic failure to disclose and/or cover-up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

340. Conceptus and Bayer's acts and omissions, before, during and/or after the acts causing Plaintiffs injuries, prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injuries or cause thereof until recently.

341. Conceptus and Bayer's conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of the Plaintiffs.

VI. GENERAL ALLEGATIONS

342. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

343. At all relevant times, Essure® was researched, developed, manufactured, marketed, promoted, advertised, sold and distributed by Conceptus and Bayer.

344. Conceptus and Bayer negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold and distributed Essure® as a safe and effective device to be used for permanent female sterilization.

345. Conceptus and Bayer knew, and/or had reason to know, that Essure® was defective, unreasonably dangerous and not safe because of the thousands of adverse events that both companies knew about.

Representations

346. Conceptus and Bayer negligently, carelessly, recklessly, and/or intentionally promoted Essure® to physicians and patients, including the Plaintiffs and Plaintiffs' physicians.

347. Conceptus and Bayer downplayed to physicians and patients, including Plaintiffs and Plaintiffs' physicians, the dangerous side effects of Essure®.

348. Conceptus and Bayer misrepresented the safety of Essure® to physicians and patients, including Plaintiffs and Plaintiffs' physicians.

349. Conceptus and Bayer willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiffs and Plaintiffs' physicians, of the increased risks and significant dangers resulting from being implanted with the Essure® device.

350. Conceptus and Bayer knew and/or had reason to know, that their representations and suggestions to physicians that Essure® was safe and more effective than alternative permanent sterilization methods were materially false and misleading such that physicians and patients, including Plaintiffs and Plaintiffs' physicians, would rely on such representations.

351. Conceptus and Bayer knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to physicians, including Plaintiffs and Plaintiffs' physicians, as part of their surreptitious campaign to promote Essure®.

352. Any warnings Conceptus and Bayer may have issued concerning the risks and dangers of Essure® were inadequate and insufficient in light of their contradictory prior, contemporaneous and continuing illegal promotional efforts of Essure® to hide or downplay the true risks and serious dangers of the device.

353. The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without knowledge and complicity of personnel at the highest levels of Conceptus and Bayer, including the corporate officers and directors.

354. Conceptus and Bayer knew and/or had reason to know of the likelihood of serious injuries caused by the promotion, sale, and distribution of Essure®, but they concealed this information and did not warn the FDA, Plaintiffs or Plaintiffs' physicians, preventing Plaintiffs and Plaintiffs' physicians from making informed choices in selecting alternative sterilization procedures prior to Plaintiffs' Essure® implantation procedure and preventing Plaintiffs and Plaintiffs' physicians from timely discovering Plaintiffs' injuries.

Causation

355. Plaintiffs would not have consented to undergo the Essure® procedure had Plaintiffs known of or been fully and adequately informed by Conceptus and Bayer of the true increased risks, hazards, and serious dangers of Essure®.

356. Plaintiffs and Plaintiffs' physicians reasonably relied on Defendants' representations and omissions regarding the safety and efficacy of Essure®.

357. Plaintiffs and Plaintiffs' physicians did not know of the specific increased risks and serious dangers, and/or were misled by Conceptus and Bayer, who knew or should have known of the true risks and dangers, but consciously chose not to inform Plaintiffs or their physicians of those risks and to actively misrepresent those risks and dangers to the Plaintiffs and Plaintiffs' physicians. Conceptus' and Bayer's promotion and marketing of Essure® caused Plaintiffs' physicians to decide to recommend and implant Essure® in Plaintiffs. Plaintiffs' physicians would not have recommended and performed the Essure® procedure in the absence of Conceptus and Bayer's false and misleading promotion.

Damages

358. Plaintiffs have suffered serious personal injuries as a direct and proximate result of Conceptus and Bayer's illegal misconduct.

359. As a direct and proximate result of Conceptus' and Bayer's illegal conduct, Plaintiffs have suffered and will continue to suffer from severe injuries and damages, including but not limited to autoimmune-like symptoms, organ perforation, and severe chronic pain which required surgical intervention to remove the Essure® coils and/or will require surgical intervention to remove the Essure® coils in the future.

360. As a result of Conceptus' and Bayer's failure to warn of the risks, dangers, and adverse events associated with Essure® as manufactured, promoted, sold and supplied by both companies, and as a result of the negligence, callousness, and other wrongdoing and misconduct of Conceptus and Bayer as described herein:

A) Plaintiffs have been injured and suffered and will continue to suffer injuries to their body and mind, the exact nature of which are not completely known to date;

B) Plaintiffs have sustained and will continue to sustain economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

C) Plaintiffs have incurred and will be required to incur additional medical expenses in the future to care for themselves as a result of the injuries and damages Plaintiffs have suffered;

D) Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

361. Plaintiffs had no reason until recently to suspect that their injuries were caused by Essure®. Thus, Plaintiffs did not know and could not have known and through the exercise of reasonable diligence, that the Essure® device caused their injuries.

362. Plaintiffs herein brings their causes of action within the applicable statute of limitation. Specifically, Plaintiff brings their actions within the prescribed time limits following their injuries and their knowledge of the wrongful cause and by whom the wrong was committed. Prior to such time, Plaintiffs did not know nor had reason to know of their injuries and/or the wrongful cause thereof.

363. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

VII. SPECIFIC PLAINTIFFS' ALLEGATIONS

A. FRANKIE NEWSOME.

1. Initial Essure® Procedure:

364. On or around May 2, 2012, Plaintiff Newsome underwent the Essure® procedure at PMC in Pikeville, Kentucky. At that time, she was 24 years old.

365. Dr. Rebecca Hobbs (f/k/a Dr. Rebecca McCowan) implanted the Essure® device in Plaintiff Newsome. Dr. Hobbs advocated the use of the Essure® device over other methods of birth control, which were more appropriate forms of birth control for a woman only 24 years old.

366. Dr. Hobbs maintained that Essure® was a superior form of permanent birth control. She stated to Plaintiff Newsome that, with Essure®, there was virtually no chance of becoming pregnant, similar to or better than a tubal ligation. However, with Essure® (unlike a tubal ligation), there was no need for surgery; there would be no surgical scar and virtually no side effects. Dr. Hobbs asserted that Essure® was as safe or safer than tubal ligation and just as effective, with less than or the same side-effects.

2. Post Essure® Procedure Condition and Treatment:

367. Plaintiff Newsome's post-procedure period has been marked by hair loss, severe dyspareunia and severe pelvic pain in the right lower quadrant. However, it was as late as the Summer of 2016 (after a discussion with another woman implanted with Bayer's device) that Plaintiff Newsome understood that she was just not unlucky, but that these were were side-effects of typical of Essure® and that thousands of women, like her, were suffering from the device.

368. Immediately after the implantation of the device, such heavy vaginal bleeding occurred that Plaintiff Newsome was admitted to the emergency room, complaining of using 6 sanitary pads an hour and intermittent dizziness. At that time, and thereafter, Dr. Hobbs and other doctors at PMC assured her that this severe bleeding was not associated with Essure®. Since that time, Plaintiff Newsome has experienced heavy vaginal bleeding, and pelvic pain, as well as difficult and painful sexual relations with her husband.

369. On or around October 15, 2012, Plaintiff Newsome underwent a hysterosalpingogram ("HSG") at PMC which showed mal-positioning of the right Essure® device with spillage of contrast noted in the right adnexal region.

370. On or around October 22, 2012, Plaintiff Newsome had an office visit with Dr. Hobbs (f/k/a Dr. McCowan) to discuss options. Her records state: "Items reviewed/discussed during today's visit: Salpingectomy vs. Repeat Essure on Right tube discussed…"

371. On or around April 8, 2013, Plaintiff Newsome presented for a pre-op appointment at PMC. Her records state: "Pt here to schedule salpingectomy. Pt had [Essure] procedure done and Right side didn't take."

372. On or about April 22, 2013, Plaintiff Newsome underwent a laparoscopic bilateral salpingectomy. The surgical pathology report shows that "[t]he first fallopian tube has a coiled wire in the lumen." No such finding was noted for the second fallopian tube.

373. Following her April 22, 2013 surgery, Plaintiff Newsome was not informed that only one Essure® coil was noted in the pathology findings and that the other coil had not been removed.

374. Plaintiff Newsome continued to experience the symptoms described above, including the prolonged and abnormal bleeding first experienced after the implantation Essure® coils.

375. Plaintiff Newsome also has experienced ongoing fatigue and nausea.

376. On or about November 11, 2013, Plaintiff Newsome had an appointment with Dr. Hobbs where she described heavy, prolonged bleeding. The records show that ablation was discussed. At that visit, Dr. Hobbs did not inform Plaintiff Newsome that only one Essure® coil was located during her April 22, 2013 surgery, and that the other was likely still in her body.

377. On or about November 22, 2013, Plaintiff Newsome presented to PMC for an office visit with Dr. Hobbs, where she discussed continued abdominal pain and bleeding. She underwent a transvaginal ultrasound, which showed a simple ovarian cyst.

378. On January 29, 2014, Plaintiff Newsome underwent Novasure endometrial ablation.

379. Following, Plaintiff Newsome complained of pelvic pain, cramping and stabbing pain in her abdomen. She underwent a transvaginal ultrasound on May 16, 2014.

380. Plaintiff Newsome continues to suffer from cramping, abdominal pain and dyspareunia. She also continues to experience significant hair loss.

381. Plaintiff Newsome had her annual gynecological exam with Dr. Natalie Adams at PMC on or about October 11, 2016, where an exploratory laparoscopic procedure was discussed due to Plaintiff's ongoing pain. According to the records, Plaintiff complained of groin pain that radiated up into her back and worsened with intercourse and defecation.

382. The medical records from Plaintiff Newsome's October 11, 2016 office visit state that the pathology from Plaintiff Newsome's April 22, 2013 bilateral salpingectomy confirmed a coil in the first fallopian tube, but did not confirm it in the second fallopian tube. The records also state that Dr. Adams discussed with Plaintiff Newsome that the general etiology of her pain is uncertain, and gave various possibilities for her pain, including: adhesions from previous surgery, endometriosis, or non-gynecological etiology such as gastrointestinal issues, urologic issues, and chronic pain.

383. Nevertheless, Dr. Adams failed to mention that the Essure® coil still retained in her body was likely the cause of her symptoms.

B. KIMBERLY HOWELL.

384. Plaintiff Howell is thirty (30) years old and resides in Teaberry, Floyd County, Kentucky.

1. <u>Initial Essure® Procedure:</u>

385. On or around April 17, 2013, Plaintiff Howell underwent the Essure® procedure at PMC in Pikeville, Kentucky. At that time, she was 26 years old.

386. Dr. Rebecca Hobbs (f/k/a Dr. Rebecca McCowan) implanted the Essure® device in Plaintiff Howell. Dr. Hobbs advocated the use of the Essure® device over other methods of birth control, which were more appropriate forms of birth control for a woman only 26 years old.

387. Dr. Hobbs maintained that Essure® was a superior form of permanent birth control. She stated to Plaintiff Howell that, with Essure®, there was virtually no chance of becoming pregnant, similar to or better than a tubal ligation. However, with Essure® (unlike a tubal ligation), there was no need for surgery; there would be no surgical scar and virtually no side effects.

2. Post Essure® Procedure Condition and Treatment:

388. Plaintiff Howell's post-procedure period has been marked by autoimmune-type symptoms, dysmenorrhea, menorrhagia, dyspareunia and an unexpected pregnancy. However, it was as late as the Summer of 2016 (after Plaintiff Howell heard a radio ad regarding Bayer's device and saw a Facebook ad) that she realized that she was not just "unlucky," but that these were typical side effects of Essure® and that thousands of women, like her, were suffering because of the Essure® device.

389. Before Essure®, whether on or off birth control, Plaintiff Howell had never experienced the combination of symptoms described above.

390. On or around July 16, 2013, Plaintiff Howell underwent a hysterosalpingogram ("HSG") at PMC, which demonstrated satisfactory placement of the Essure® devices with no spillage of contrast.

391. On or around November 11, 2013, Plaintiff Howell discovered she was pregnant.

392. Plaintiff Howell vaginally delivered her son on or around June 30, 2014.

393. On or around December 12, 2014, Plaintiff Howell had an office visit with Dr. Aaron Crum at PMC, where she complained of dysmenorrhea, menorrhagia, and dyspareunia. Dr. Crum prescribed Plaintiff Howell an oral contraceptive at that time, in light of the fact that Essure® had not been effective in avoiding her most recent pregnancy. At that time, Dr. Crum did not associate any of her symptoms with the fact that Plaintiff Howell still has the Essure® device in her.

394. However, Plaintiff Howell continued to complain of headaches, stiffness and joint pain; however, Dr. Tara Newsome (another physician at PMC) told her that these symptoms were due to her being a mother of three small children.

395. On or around July 2, 2015, Plaintiff Howell underwent a bilateral salpingectomy. The operative report states that the surgeon was unable to locate either of Essure® coils in Plaintiff Howell's fallopian tubes.

396. Plaintiff Howell continues to suffer from the pain and injury described above, caused by the implantation of the Essure® device. She still suffers from rashes, joint pain, heavy menstrual bleeding and painful intercourse. In all probability, one or all the Essure® coils are still in Plaintiff Howell, causing her symptoms.

C. STACEY VARNEY.

397. Plaintiff Varney is thirty-six (36) years old and resides in Raccoon, Pike County, Kentucky.

1. <u>Initial Essure® Procedure:</u>

398. On or around January 13, 2012, Plaintiff Varney underwent the Essure® procedure at PMC's Clinic at Harold, Kentucky for Women's Health ("the Harold Clinic"). Dr.

Angela Maggard implanted the Essure® device at the Harold Clinic.

399. At that time, Plaintiff Varney had two children. James (boy) was 3 and Lyndsey (girl) was 6.

400. Plaintiff Varney had tried other methods of birth control, but they were not effective for her; therefore, she initially approached Dr. Maggard at the Harold Clinic and requested a tubal ligation.

401. Dr. Maggard convinced Plaintiff Varney to use the Essure® device. Dr. Maggard presented the Essure® device as a faster way to get back to work, with less healing time. At that time, Plaintiff Varney was a housekeeper for PMC and she was the sole source of income for her family. She was told that 3 days would be all that was necessary for recovery on Essure® versus a full week off work with a tubal ligation. She was further reassured by Dr. Maggard that Bayer's device was equal to or more effective at preventing pregnancy than a tubal ligation, that there were no significant side effects and that surgery (and the risks and scars that come with it) would not be necessary. In sum, Dr. Maggard maintained that Essure® was a superior form of permanent birth control when compared to tubal ligation.

402. On the day of the implantation of Essure® (although Plaintiff Varney had not expected to be put to sleep or have to undergo anesthesia), she was instructed by Dr. Maggard to go to the pharmacy to fill and take several prescriptions in preparation for the procedure. These prescriptions essentially rendered Plaintiff Varney unconscious, throughout the procedure at the Harold Clinic.

403. During the procedure, the bleeding was so profuse that Dr. Maggard was forced to perform an endometrial ablation of Plaintiff Varney's uterus.

404. During the procedure, Plaintiff Varney's husband waited for her at the Clinic, and

afterwards helped her get dressed, back into her street clothes, because the medication prescribed by Dr. Maggard made it impossible for Plaintiff to perform even the simplest of tasks.

405. Plaintiff had Essure® put in on Friday and went back to work for PMC as a housekeeper on the following Monday. She's since left PMC's employment and now works for AT&T as wire technician, installing DSL.

2. Post Essure® Procedure Condition and Treatment:

406. Plaintiff Varney's post-procedure period has been marked by pelvic pain and severe bleeding. After having the procedure, it took 6 months for her to stop bleeding huge clots of blood. However, this abnormal bleeding and pelvic pain continued until June of 2016 when Plaintiff was forced to have a hysterectomy. Moreover, Plaintiff Varney during this period developed a condition known as "Mondor's Disease."

407. Shortly after her implant, on or around February 16, 2012, Plaintiff Varney called Dr. Maggard with complaints of heavy vaginal bleeding, where she stated she was passing "huge clots." Dr. Maggard prescribed Prometrium for the bleeding.

408. Plaintiff Varney presented to PMC for a follow-up visit on April 12, 2012 with continued complaints abnormal bleeding. Plaintiff Varney was prescribed Enjuvia and her hysterosalpingogram ("HSG") was scheduled.

409. Plaintiff Varney had a HSG on or about April 24, 2012, which demonstrated no evidence of spillage of contrast into the pelvic cavity from either fallopian tube, thus confirming tubal occlusion.

410. Because of her continued bleeding and pelvic pain, Plaintiff Varney underwent a CT of her abdomen and pelvis on or around October 10, 2012. The CT demonstrated no evidence of acute intra-abdominal or pelvic abnormalities.

411. On or around January 21, 2014, Plaintiff Varney underwent Transvaginal Ultra Sonography because of complaints of pelvic pain and irregular menstrual bleeding. Dr. Maggard then performed an endometrial biopsy. The pathology report showed findings of focal stromal breakdown consistent with bleeding.

412. Despite repeated examinations, Dr. Maggard could not determine the cause of the bleeding. At no time did Dr. Maggard suggest that Essure® or the procedure implanting the device were the possible causes of her problems.

413. Also during this time period, Plaintiff Varney developed Mondor's disease. Mondor's disease is a rare condition caused by inflammation of a vein just under the skin of the breast or chest wall. It's also known as thrombophlebitis. It can affect any of the veins in the breast, but most commonly affects those on the outer side of the breast or under the nipple. Dr. Maggard referred Plaintiff to another doctor working at PMC, Dr. Oon Leedhanachoke, who maintained that the disease was being caused by Plaintiff Varney's deodorant.

414. Plaintiff Varney then sought a second opinion from physicians outside her own county and city. She turned to doctors in Prestonsburg, Floyd County, Kentucky, and sought help from Dr. Sammie S. Gibson. Dr. Gibson did additional research regarding Essure® and asked Plaintiff whether she had an allergy or any reaction to the metal nickel, because Essure® contained nickel. Plaintiff stated that she does have an allergic reaction to costume jewelry and questioned whether such jewelry contained nickel.

415. Plaintiff was completely unware that Essure® contained nickel.

416. On or around June 13, 2016, Dr. Sammie S. Gibson, assisted by Dr. Brett Akers, performed a total vaginal hysterectomy with Essure® removal, in addition to, placement of a pubovaginal sling and suprapubic catheter with cystoscopy. The operative report states: "[t]he

uterus was examined and noted to have the [Essure®] coils in the corneal areas. The sidewalls were examined and noted to be slightly oozy."

417. Since her hysterectomy and the removal of the device, Plaintiff Varney's symptoms and her Mondor's Disease have completely resolved.

418. But for Essure®, Plaintiff would not have suffered from the pain, suffering and disease for over 4 ½ years, described above, and would not have been required to undergo a hysterectomy at a young age.

VIII. AGENCY, ALTER-EGO, JOINT VENTURE, AND CONSPIRACY

438. At all times herein mentioned, the Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of the Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

439. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased, and these Defendants are the alter-egos of the other certain Defendants and exerted control over those Defendants. Bayer AG controlled its wholly owned subsidiaries to such a degree and in such a manner as to render them more business units and to make them merely an agency, instrumentality, adjunct, or its alter ego. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege, sanction a fraud, and/or promote injustice.

440. Each of the Bayer Defendants herein expressly or impliedly agreed to work with and assist each other Defendant and unnamed parties, toward the common purpose of promoting, recommending, and selling Essure® and toward the common interest of pecuniary gain.

441. Each of the Bayer Defendants herein performed the acts and omissions described herein in concert with the other Bayer Defendants herein and/or pursuant to a common design with the other Defendants herein.

442. Each of the Bayer Defendants herein knew the acts and omissions of the other Bayer Defendants herein constituted a breach of duty, and yet, each Bayer Defendant provided each other Bayer Defendant substantial assistance and/or encouragement.

443. Each of the Bayer Defendants herein provided substantial assistance to the other Bayer Defendants herein in accomplishing the intentional and tortious conduct described herein, and each Bayer Defendants' conduct, even when separately considered, constitutes a breach of duties owed to the Plaintiffs.

444. At all times herein mentioned, each of the Bayer Defendants were engaged in the business of and/or were a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling Essure® device for use by the Plaintiffs and the Plaintiffs' physicians. As such, each of the Bayer Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for the Plaintiffs' damages.

445. The conduct of the Defendants herein caused the Plaintiffs' harm as described herein. The Plaintiffs' harm is not in any way attributable to any fault of the Plaintiffs.

Uncertainty may exist regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' harm. The Defendants possess superior knowledge and information regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' injuries.

446. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

447. Due to the above, each Cause of Action named below is asserted against each Defendant herein, jointly and severally, even if each and every Defendant herein is not specifically identified as to each and every count.

IX. PLAINTIFFS ARE ENTITLED TO PUNITIVE DAMAGES

448. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

449. As a result of Conceptus and Bayer's oppression, fraudulent concealment, wantonness, malice, and reckless disregard for Plaintiffs' safety, Plaintiffs are entitled to punitive or exemplary damages to the fullest extent necessary as plead in detail below.

X. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
Stengel[110] - Failure to Warn
Restat. 2d of Torts § 388[111]
Restat. 3d of Torts: Products Liability § 2[112]
Restat. 3d of Torts: Products Liability § 6(d) [113]

450. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

A. CONCEPTUS AND BAYER HAD A DUTY TO REPORT ADVERSE

[110] *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013).
[111] Adopted by *Lloyd v. Lloyd*, 479 S.W.2d 623, 625 (Ky. 1972); *see also Larkin v. Pfizer*, 153 S.W.3d 758 (Ky. 2004).
[112] *See Larkin v. Pfizer*, 153 S.W.3d 758 (Ky. 2004).
[113] Adopted in *Larkin v. Pfizer*, 153 S.W.3d 758 (Ky. 2004).

EVENTS TO THE FDA UNDER FEDERAL LAW.

451. Conceptus and Bayer at all times herein were medical device manufacturers and subject to the Medical Device Reporting (MDR) regulations under 21 C.F.R. § 803.

452. As discussed above, Conceptus and Bayer, through their employees and agents, had a federal duty to "report deaths and serious injuries that a device [such as Essure®] has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports" of these Adverse Events ("AEs") related to Essure® to the FDA. *See* 21 C.F.R. § 803.1.

453. "These reports help [the FDA] 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." *Id.*

454. As set out in detail above, Conceptus and Bayer failed to timely and accurately report to the FDA these adverse events reasonably associated with the use of their medical device, Essure®. The Defendants' failure to report was in violation of their duties under the PMA, FDCA and various federal regulations (e.g. 21 C.F.R. § 803.1-.58, 21 C.F.R. § 814.82).

1. Conceptus and Bayer Had a Federal Duty to Report AEs Under the "Conditions for Approval" of Essure®'s PMA.

455. Class III devices, such as Essure®, are required to go through the PMA process to provide reasonable assurance of their safety and effectiveness.

456. The federal government has established requirements applicable to Essure® in part because of the PMA process established specific requirements applicable to the device, including Conceptus' and Bayer's duties under the "Conditions for Approval" to Essure®'s PMA to issue a CBE (as explained in Paragraphs above) or to seek a PMA supplement to change Essure®'s labeling "when unanticipated adverse effects, increases in the incidence of anticipated adverse

effects, or device failures necessitate a labeling, manufacturing, or device modification,"[114] described in ¶99(C) above. These Conditions for Approval require manufacturers, like Conceptus and Bayer, to take the steps to change their labeling under such circumstances in order to assure that the devices "are not adulterated or misbranded and are safe and effective for their intended use."[115]

457. Further, the FDA may impose post-approval requirements, including a "[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use."[116]

458. The FDA did impose these post-approval requirements in the Essure® PMA, which stated that the in order for the FDA to be continually assured of the safety and effectiveness of the device, an "Adverse Reaction Report" or "Device Defect Report" should be filed within 10 days of Bayer and Conceptus receiving knowledge or information of, in part, "[a]ny adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and: a. has not been addressed by the device's labeling; or b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency."

459. Instead, and in violation of 21 C.F.R. § 820.198, 21 C.F.R. § 803.3 and the Essure® PMA "Conditions of Approval," Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure® device was malfunctioning or otherwise not responding to its Design Objective Intent,

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[114] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm134504.htm.

[115] These requirements are identical to that required of a drug manufacturer in the same or similar circumstances. *See also* 21 C.F.R. § 814.80, which requires that a device "not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."

[116] 21 C.F.R. § 814.82

which was to remain permanently in Plaintiffs' fallopian tubes, and (2) Conceptus and Bayer continued to place Essure® into the stream of interstate commerce when they knew, or should have known, that the Essure® device was malfunctioning or otherwise not responding to its Design Objective Intent.

2. Conceptus and Bayer Had a Duty to Report Adverse Events Under 21 C.F.R. § 803.50, § 814.82.

460. As described above, a medical device manufacturer's obligations do not end with FDA's Premarket Approval ("PMA") process. Under federal law a medical device manufacturer has a continuing duty to monitor their product after premarket 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.

461. As detailed above, this includes information the manufacturer receives or otherwise becomes aware of, from any source, that reasonably suggests that a device may have caused or contributed to death or serious injury; or has malfunctioned in a manner that would likely "cause or contribute to a death or serious injury" if it recurred.[117]

462. As discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury.

463. As detailed above, the FDA discovered the overwhelming number of Essure® adverse events only after women were no longer forced to report their problems directly to Conceptus or Bayer (or indirectly through healthcare providers), and had the option to use the "MedWatcher App" and report directly to the FDA.

[117] 21 C.F.R. § 803.50(a); *see also* 21 U.S.C. § 360i(a) (further detailing the post approval reporting requirements applicable to device manufacturers).

464. The FDA received 8,950 of the approximately 9,900 MDRs regarding Essure® between October 26, 2013 and December 31, 2015.

465. The most frequent MDRs regarding patient problems were as follows: "pain/abdominal pain (6989), heavier menses/menstrual irregularities (3210), headache (2990), fatigue (2159), and weight fluctuations (2088). Most of the reports received listed multiple patient problems in each report." "The most frequent device problems reported were patient-device incompatibility (2016) (for example, possible nickel allergy), migration of the device or device component (854), device operating differently than expected (490), device breakage (429), device difficult to remove (280), malposition of the device (199), and device difficult to insert (187). Multiple device problems can also be listed in each report."[118]

466. Defendants' failure to report adverse events is further evidenced by the 2011 FDA Form 483.[119]

467. Conceptus and Bayer failed to adequately disclose to the FDA under its regulations Adverse Events which clearly impacted the safety, effectiveness, and foreseeable risk, and revealed increased risks and dangers of Essure® of which these manufacturers were informed after Essure®'s PMA approval.

3. Conceptus and Bayer Had a Federal Duty to Report New Clinical Investigations and/or Scientific Studies under 21 C.F.R. § 814.84(b)(2).

468. As discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles

[118] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[119] http://3qg8x72qeng62erdph228vql.wpengine.netdna-cdn.com/wp-content/uploads/Conceptus-2011-483.pdf

describing twelve (12) cases of Essure® abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

4. Conceptus and Bayer Had Continuing Duties Under 21 C.F.R. §§ 820.198, 820.300, 820.700 & 820.100 to Discover, Investigate and Respond to Adverse Events.

469. Federal law also requires certain procedures be put into place to discover and address adverse events and their causes. Conceptus and Bayer violated these requirements as follows:

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

B) **21 C.F.R. § 820.198**: Conceptus and Bayer had duties to receive, review, investigate, evaluate, record and report adverse events. "[R]ecords of investigation under this paragraph shall include a determination of: (a) [w]hether the device failed to meet specifications; (b) [w]hether the device was being used for treatment or diagnosis; and (c) [t]he relationship, if any, of the device to the reported incident or adverse event." Conceptus and Bayer failed to comply with these quality control standards, and failed to establish and maintain procedures for implementing CAPAs in response to, *inter alia*, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure® device; and failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure® device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes;

C) **21 C.F.R. § 820.30:** Conceptus and Bayer failed to 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, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage; and,

D) **21 C.F.R. § 820.70**: Conceptus and Bayer failed to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure® device.

5. Conceptus and Bayer Had a Federal Duty to Modify Essure®'s Labeling under 21 C.F.R. § 803.39(a).

470. Any changes the manufacturer believes could affect the safety and effectiveness of the device must be submitted via a "PMA Supplement," to the FDA for approval under 21 C.F.R. § 803.39(a).

471. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, labeling changes if they effect the safety and effectiveness of the device.[120]

472. Conceptus and Bayer had a duty to submit a PMA supplement once it knew or should have known that the label approved by the FDA under the PMA approval had become inadequate, due to the multiple post-approval reports of serious adverse events associated with the use of Essure®.

473. Due to its failure to submit a PMA supplement, the labeling originally approved by the FDA for Essure® became inadequate before the Plaintiffs' surgery and thus failed to protect the public health by failing to adequately disclose the harms, risks and benefits of Essure®.

[120] 21 C.F.R. § 814.39(a).

6. Conceptus and Bayer Chose Not to Submit a "CBE" Supplement[121] Under 21 C.F.R. § 803.39(d).

474. Although most changes to the labeling of a device after premarket approval require FDA approval of a supplemental application, under the CBE regulation a manufacturer may place into effect any change that enhances the safety of the device or the safety in the use of the device prior to the receipt of a written FDA order approving the PMA supplement, including:

> "[l]abeling 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[122]

475. Under those regulations, the manufacturer is required to notify the FDA of "Changes Being Effected" to a device's labeling.

476. Under the FDA's CBE supplement procedure, Conceptus and Bayer could have unilaterally (without prior FDA approval) added a stronger, accurate warning to Essure® once they learned of the adverse events associated with the device.

477. Conceptus and Bayer had a duty to amend and strengthen its labeling for Essure® once it knew or should have known that the label approved by the FDA under the PMA approval had become inadequate, due to the multiple post-PMA approval reports of serious adverse events associated with the use of Essure®, which Bayer failed to properly report to the FDA and failed to adequately investigate. A CBE supplement would have been one way for Bayer to satisfy this federal duty.

478. Thus, under the PMA approval, and under 21 C.F.R. § 803.39(a), Bayer was required to modify and strengthen the Essure® labeling and was permitted to do so without prior FDA approval.

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[121] In this Complaint, "CBE" refers to "Changes Being Effected" pursuant to 21 C.F.R. § 814.39 (2012).
[122] 21 C.F.R. § 814.39(d) (2012).

479. The FDA, in its website, readily advises and recognizes that such a change can be made without preapproval, and that the change is not inconsistent with any device specific regulations. [123]

480. There is no evidence that the FDA would have rejected a CBE label change, and in fact the subsequent "Black Box Warning" and patient check-list from the FDA indicates that the FDA would have accepted any label which strengthened the safety warnings had the FDA known of all the adverse events that these Defendants had a duty to report.

481. Due to the Defendants' failure to strengthen its warning under a CBE or through a PMA supplement, the labeling approved by the FDA in the Essure® PMA became inadequate and did not disclose the harms, risks and dangers of Essure® which were known or should have been known through adequate investigation of adverse events by Bayer and Conceptus.

B. CONCEPTUS AND BAYER HAD A DUTY TO REPORT ADVERSE EVENTS TO THE FDA UNDER KENTUCKY LAW AND A DUTY TO MODIFY THE LABELING BASED ON KENTUCKY LAW TO ADEQUATELY WARN PHYSICIANS AND THEIR PATIENTS.

482. Under Kentucky state law, these Defendants had a parallel and identical duty to report and warn the FDA and other third parties of dangers associated with medical devices marketed for uses intended by them.[124]

483. These state law requirements provided only another reason for these Defendants to conform to their duties under federal law, FDA Regulations and PMA Conditions of Approval, detailed above.

484. Such parallel duties were essentially identical because both required these Defendants to take the same action in order to assure the safe and effective use of their medical

[123] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm

[124] *See Larkin v. Pfizer*, 153 S.W.3d 758 (Ky. 2004) (There is a common law duty to warn in Kentucky), citing *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516 (Ky. 1968).

devices. Both required not only that serious adverse events be reported to third parties, but also that these Defendants investigate such events and determine the root cause of such events. Under Kentucky law, Conceptus and Bayer had a duty to warn pursuant to the Restatement 2d of Torts § 388 (1965).[125] Comment n provides that,

> a supplier's duty to warn is discharged by providing information about the product's dangerous propensities *to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product* or those who may be exposed to its hazardous effects. Restatement (2d) of Torts § 388 cmt. n.[126]

485. Conceptus and Bayer had a duty to warn under Restatement 3d of Torts: Products Liability § 2 (1998), which states, in part, that a product is defective when, at the time of sale or distribution, it is defective because of inadequate instructions or warnings. A product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm [such as those reflected in adverse event report] posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe." Comment (i) explains that "[d]epending on the circumstances, Subsection (c) may require that instructions and warnings be given not only to purchasers, users, and consumers, ***but also to others who a reasonable seller should know will be in a position to reduce or avoid the risk of harm.***" (Emphasis added.)

486. Under Kentucky state law, the FDA (regarding Adverse Events relating to Essure®) is and was another person, "who a reasonable seller should know will be in a position to reduce or avoid the risk of harm."

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[125] Adopted by *Lloyd v. Lloyd*, 479 S.W.2d 623, 625 (Ky. 1972); *see also Larkin v. Pfizer*, 153 S.W.3d 758 (Ky. 2004).

[126] Emphasis added. *See also McLaughlin v. Bayer Corp.*, 2016 U.S. Dist. LEXIS 37516,*85 (E.D. Pa. Mar. 22, 2016).

487. Conceptus and Bayer had a duty to warn under Restatement 3d of Torts: Products Liability § 6(d).[127] Restat. 3d. § 6(d) provides that:

> [A] medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing or other health-care providers who are in position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

488. The "learned intermediary rule," which is generally an exception to a manufacturer's duty to warn, cannot apply where a device manufacturer fails at its legal obligation to provide adequate warning to the health-care provider.[128] "If the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient-consumer."[129]

489. Conceptus' and Bayer's failure to report Adverse Events to the FDA resulted in the PMA-approved labeling and warnings for Essure® being inadequate, due to the additional "after-acquired" information regarding the harms, risks and benefits contained in the Adverse Events associated with Essure® that were not reported to the FDA, not available to the FDA at the time of the PMA approval and/or not adequately investigated by Conceptus and Bayer.

C. CONCEPTUS' AND BAYER'S DUTY TO WARN UNDER KENTUCKY LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

490. "State requirements are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law.[130] Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of

[127] Adopted in *Larkin v. Pfizer*, 153 S.W.3d 758 (Ky. 2004).
[128] *Larkin* at 764, 770.
[129] *Id.* (internal citations omitted).
[130] 21 U.S.C. § 360k(a)(1).

FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements."[131]

491. As described above, claims for failure to warn are not preempted. "Failure to warn claims are neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]'s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device."[132]

492. Plaintiffs are not suing because Bayer's and Conceptus' conduct violated federal law. Instead, Plaintiffs are suing based on the premise that Bayer's and Conceptus' conduct violates parallel regulations and requirements under Kentucky law.

493. Kentucky law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted. "Although Plaintiffs cannot [under Kentucky law] bring a negligence *per se* claim based on violations of the FDA regulations and FDCA provisions, Kentucky courts have held that federal laws can support the existence of a duty of care in a negligence action."[133] In essence, Kentucky law incorporates FDA standards of care as a part of the duty of care in state law negligence actions; therefore, state law duties in this instance are identical to requirements of federal law, FDA Regulations, PMA requirements and the PMA Conditions of Approval.

494. Conceptus and Bayer had a continuing duty under the various regulations discussed above and per the terms of the PMA approval by the FDA to monitor its product after receiving FDA approval and to discover and report to the FDA any complaints about the

[131] *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008).
[132] *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011).
[133] *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 2013 U.S. Dist. LEXIS 32228, 2013 WL 898152 (W.D. Ky. 2013).

product's performance and any adverse health consequences and other such serious events of which they became aware.

495. Conceptus and Bayer failed to perform these duties under federal law to warn the FDA, and thus failed to perform its duty under Kentucky law, as these Defendants had a parallel duty to report and warn the FDA and other third parties of dangers associated with medical devices marketed for uses intended by them.

496. Under the above Restatements, which have been adopted by Kentucky, the FDA is a "third person" in a position to reduce the foreseeable risks and harms suffered by Plaintiffs in their use of Essure®; thus, these Defendants had identical federal and state law duties to inform the FDA of the adverse events they knew or had reason to know about regarding Essure®, so consumers, such as Plaintiffs, and their physicians were properly informed of the dangerous conditions of the Essure® device and the facts which made it likely to be dangerous, so as to provide adequate warning of foreseeable risks of harm.

497. Alternatively, under Restat. 3d. § 2 and 6(d), Conceptus and Bayer had a duty to warn of foreseeable harms regarding the Essure® device by taking steps to modify the labeling to include harms, risks and benefits of the Essure® device that were not known or apparent at the time the FDA gave its PMA approval to the Essure® labeling, but which later became apparent through multiple reports of Adverse Events, which Bayer and Conceptus failed to timely report to the FDA and failed to adequately investigate. This state law duty to modify the labeling is identical to the federal duty under Essure®'s PMA "Conditions of Approval, "which required Bayer and Conceptus to "[s]ubmit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling,

manufacturing, or device modification." Had Bayer and Conceptus conformed to these duties, Plaintiffs and their physicians would have been adequately warned.

498. Bayer and Conceptus could have submitted a CBE under 21 C.F.R. § 803.39(d) to seek such a modification or could have submitted a PMA supplement so seeking. Bayer and Conceptus failed to do either and thus violated its federal and state law parallel duties to modify the labeling and include the information to which it had access, through the adverse events (AEs) which it failed to report. Bayer's and Conceptus' state law duties to modify the labeling are simply additional reasons for them to perform their federal duties, explained above.

499. Kentucky law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to warn of the known dangers of Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND THE BAYER DEFENDANTS' BREACH OF THEIR STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.

500. As discussed in detail above, Conceptus and Bayer failed to review, investigate, evaluate, record and report adverse events, and/or timely report adverse events, including but not limited to: complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries required Plaintiffs to undergo surgical intervention to prevent further injury.[134]

501. As discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus

[134] *See* 21 C.F.R. § 803.50; 21 C.F.R. § 814.80; and 21 U.S.C. § 360i(a).

and Bayer knew or reasonably should have known, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure® abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.[135]

502. As discussed in detail above, Conceptus and Bayer failed to: (1) analyze or identify existing potential causes of non-conforming products and other quality problems; (2) follow procedures used to control products which did not conform to specifications; (3) take any and all Corrective and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues; and/or (4) conduct adequate risk analysis.

503. Had Conceptus and Bayer reported adverse events that it knew or had reason to know to the FDA, the FDA would have been in a position to reduce the risk of harm to the ultimate consumers of Essure® and would have moved to strengthen the warnings in the Essure® labeling much earlier than February, 2016.

504. Had Conceptus and Bayer analyzed and identified causes of non-conforming products and quality problems, conducted adequate risk analysis, and implemented CAPA as required, the FDA would have been on notice of harms of Essure® much earlier and would have been in a position to reduce the harm to consumers.[136] Instead, the non-compliance with quality control and CAPA is another example of the trend by Bayer and Conceptus to provide inadequate follow-up and reporting regarding adverse events associated with Essure®.

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[135] *See* 21 C.F.R. § 814.84(b)(2).

[136] "Postmarket surveillance is designed to better identify uncommon but potentially serious adverse events related to the use of the device in the general public." Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database, available at: http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext

1. Had Bayer and Conceptus Reported Adverse Events Earlier, the FDA Would Have Moved To Strengthen the Essure® Labeling Much Earlier, Prior to Plaintiffs' Implantations.

505. As described above, the information that led the FDA to take steps to strengthen the labeling was available much earlier to these Defendants and this information would have led the FDA to strengthen the labeling much earlier, before implantation of the device into Plaintiffs. However, Bayer and Conceptus failed to report adverse events to the FDA and thus Plaintiffs and their implanting physicians were not informed of the true risks and benefits of the Essure® device prior to Plaintiffs' surgeries.

506. Had Bayer and Conceptus timely reported adverse events to the FDA that they either knew about or should have known, FDA would have provided warning of foreseeable risks of harm to Plaintiffs' implanting physicians, who would have been in a position to inform Plaintiffs of these risks.

507. Had Plaintiffs been informed of these risks, they would have declined to have the device implanted and they would not have suffered injuries.

2. Had Bayer and Conceptus Investigated and Reported Adverse Events Earlier, the Information in Those AEs Would Have Been Available to the Medical Community as a Whole.

508. Under state and federal law, Conceptus and Bayer are charged with knowing the risks and benefits of their medical device products. Nevertheless, these Defendants did not reveal their knowledge or investigate the causes of these adverse events. Instead, women implanted with the Essure® device reported adverse events directly to the FDA through the "MedWatcher app."[137]

[137] *See* "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html

509. As stated above, approximately 90% of all Essure® related adverse events were reported from October of 2013 to December of 2015 by patients through MedWatcher.

510. The FDA publishes adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with all reports received prior to the update. The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. For example, in October of 2015, Dr. Dhruva, *et al.* published a study in the New England Journal of Medicine entitled *Revisiting Essure – Toward Safe and Effective Sterilization*, which assessed the safety and effectiveness of Essure®.[138] This study was based in part on a search and analysis of the MAUDE database. The study concluded that the increase in reported Essure® related adverse event complaints since mid-2013 led the FDA to update Essure®'s patient label in 2014 to include information about risks of chronic pelvic pain and device migration into the lower abdomen and pelvis, and led to the FDA's decision to reconvene its Obstetrics and Gynecology Devices Panel to reassess Essure®'s safety and effectiveness on September 24, 2015.

511. Similarly, a study published in November 2013 in The Journal of Minimally Invasive Gynecology entitled *Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database*, utilized the FDA's MAUDE database.[139] The study objective stated that the MAUDE database is useful for clinicians using an FDA approved medical device to identify the occurrence of adverse events and complications.

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[138] *See* "Revisiting Essure — Toward Safe and Effective Sterilization," available at: http://www.nejm.org/doi/pdf/10.1056/NEJMp1510514.

[139] *See* "Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database," available at: http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext

512. If Conceptus and Bayer had timely and accurately investigated such adverse events and reported them to the FDA, these reports would have been publically available and would have effectively warned Plaintiffs' physicians both directly, such as through the MAUDE database, and through the discussion of adverse events that would have occurred in the published literature and in the medical community, much earlier.

513. Because of Conceptus and Bayer's failures, Plaintiffs' surgeons relied on inadequate, false and misleading information concerning the benefits and harms when deciding to use the Essure® device in Plaintiffs' surgeries.

3. Had Bayer and Conceptus Modified the Essure® Labeling as Required under State and Federal Law, Information Regarding the True Risks, Harms and Benefits of Essure® would have been Available Much Earlier.

514. Defendants were aware that the intended uses of Essure® were likely to cause adverse events that were neither as safe nor as effective as available alternative products and medical treatments. These harms, risks and benefits (revealed by adverse events reported to Bayer only after the original PMA approval of the labeling) were not contained in the original labeling and therefore were not adequately reported in that labeling.

515. Bayer and Conceptus failed to comply with the Essure® PMA "Conditions of Approval," and 21 C.F.R. § 814.39 which required them to "[s]ubmit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

516. Bayer and Conceptus could have complied with its requirements under the Conditions of Approval (and/or the FDA Regulations) by either submitting a CBE under 21 C.F.R. §803.39(d), or by filing a supplemental PMA to modify the warnings to reflect the true harms, risks and benefits of the device.

517. Had an appropriate warning regarding the risks associated with the use of Essure® been provided, Plaintiffs' physicians would not have used the device and Plaintiffs would not have consented to its use.

4. Had Bayer and Conceptus Conformed to their Identical State and Federal Duties, Plaintiffs' Specific Injuries Would Not Have Occurred.

518. As a direct and proximate cause of one or more of the above-listed dangerous conditions, defects and negligence, Plaintiffs sustained serious injuries of a personal and pecuniary nature from the date of their Essure® surgeries to the present.

519. Plaintiffs suffered from injuries including, but not limited to, pain subsequent surgeries, heavy bleeding, hair loss, rashes, dyspareunia, joint pain, and allergic reactions following their Essure® implantations.

520. Because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction, there is reasonable evidence of a causal association between Plaintiffs' injuries and these Defendants' failures to comply with federal and state duties; such evidence includes but is not limited to the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, the numerous Essure® studies consisting of thousands of women reporting that patients who undergo the Essure® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

521. The 2002 Essure® label described cramps as a typical temporary effect, and only described a micro-insert outside of the fallopian tube as an "incorrect position" found in the

clinical studies, among three other issues including perforation, expulsion and placement too far or not far enough in the tube, in 4% of women at a routine 3-month follow up.[140]

522. It was not until October of 2013 that Conceptus changed the patient information booklet to include risks of chronic pain and device migration.[141] However, the modified label stated: "There are reports of the Essure® insert migrating." This modification of the labeling provided only a vague reference, and would have been much stronger and more informative, as required by the FDA in 2016, had the true information regarding adverse events been reported and investigated by these Defendants.

523. Had Bayer and Conceptus complied with the PMA and timely reported adverse events, applied for a PMA supplement, or unilaterally changed the label through a CBE, Plaintiffs and their physicians would have been warned of the true adverse events and incidence of adverse events prior to Plaintiffs' surgeries, and would not have elected to use Essure® for Plaintiffs' permanent sterilization needs.

524. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

[140] http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014D.pdf
[141] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S040

E. TO THE EXTENT THE ESSURE® WARNING WAS ADEQUATE, IT WAS NULLIFIED BY DEFENDANTS' CONDUCT.

525. The Essure® warning was nullified due to the reckless or intentional minimizing and/or downplaying of the risks of serious side effects, the misrepresentations, concealments and omissions, and/or the failure to report known adverse events by Conceptus and Bayer as described generally above.

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

527. Conceptus and Bayer's misrepresentations and false and misleading promotion of Essure® nullified otherwise adequate warnings under Kentucky law.[142]

F. ESSURE® IS AN "ADULTERATED" AND "MISBRANDED" DEVICE AND IS THEREFORE EXTRA-REGULATORY.

528. A Class III device that fails to meet the PMA requirements after marketing is considered to be adulterated under § 351(f) of the Federal Food, Drug and Cosmetic Act ("FDCA").

529. Under 21 U.S.C. § 352 and KRS § 217.065, a device is "misbranded" if its labeling is false or misleading in any particular.[143]

530. As detailed above, the Essure® device was manufactured, labeled, distributed, and/or advertised in a manner that is inconsistent with the Conditions for Approval specified in

[142] *See Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93 (Ky. 2008); *see also* KRS § 217.105 ("[a]n advertisement of a …device…shall be deemed to be false if it is false or misleading in any particular").
[143] *See also* KRS § 446.070, allowing recovery of damages for violation of a Kentucky statute.

the PMA.[144]

531. Specifically, these Defendants failed to submit a PMA supplement for unanticipated adverse effects and increases in the incidence of anticipated adverse effects or device failures.[145]

532. As detailed above, Conceptus and Bayer concealed reports of adverse events, in violation of federal law, the PMA, and parallel state law.

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

534. Accurate and timely reporting of adverse events helps to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

535. Bayer and Conceptus failed to comply with the PMA, thus making the Essure® device "adulterated" and extra-regulatory.

536. Conceptus and Bayer promoted for sale misbranded and adulterated products because the Essure® label is false and misleading as Essure® is not a safer and more effective method of permanent sterilization than alternative methods, as evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure® studies consisting of thousands of women reporting that patients who undergo the Essure®

[144] 21 C.F.R. § 814.80.
[145] *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf

procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus' and Bayer's complaint files.

537. Plaintiffs are not suing to enforce federal law based on the adulterated status of the Essure® device, but are instead suing on the parallel state claims detailed above, which allow a state cause of action for damages due to Bayer's and Conceptus' failure to warn the FDA, Plaintiffs, and Plaintiffs' physicians of the misbranded condition of the device.

538. Had Plaintiffs and their physicians known that Essure® was adulterated due to Conceptus' and Bayer's failure to comply with the PMA, Plaintiffs would not have chosen to have Essure® implanted in their fallopian tubes.

539. Plaintiffs suffered from adverse events known to Bayer and Conceptus well before Plaintiffs' implant surgeries. Bayer and Conceptus chose to conceal adverse events in violation of the PMA, rendering Essure® adulterated.

540. Therefore, Plaintiffs' injuries are causally and factually related to the adulterated status of Essure® due to Bayer and Conceptus' failure to report adverse events in violation of the PMA.

SECOND CAUSE OF ACTION
Fraudulent Misrepresentation / Fraud in the Inducement
Restat. 3d of Torts: Products Liability §9.

541. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

542. Plaintiffs brings a claim against Conceptus and Bayer under Kentucky law for fraudulent misrepresentation / fraud in the inducement regarding the Essure® device.

A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE FRAUDULENT MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

543. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

544. Under the FDCA and FDA's implementing regulations, labeling and promotional advertisements, claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

545. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations. Notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of the following ways:

A) Conceptus and Bayer had duties to not make false or misleading statements regarding Essure® under 21 U.S.C. §§ 331(a), 351 & 352(a),(q)&(r); 21 U.S.C. §§ 360(q)&(r); and 21 C.F.R. § 814.80.

B) Conceptus and Bayer had duties to investigate and address adverse events under the following regulations: 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. § 820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.100; 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198; 21 C.F.R. § 820.30; 21 C.F.R. § 803.3; 21 C.F.R. § 820.70 and 21 C.F.R. § 820.170(a).

C) Conceptus and Bayer had duties to submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association under 21 C.F.R. § 814.39, 21 C.F.R. § 803.56.

D) Conceptus and Bayer had duties to report adverse events under 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a).

E) Conceptus and Bayer had duties to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known about under 21 C.F.R. §

814.84(b)(2).

546. The above regulations imposed duties on Conceptus and Bayer to accurately, timely, and honestly represent to the FDA, the public, Plaintiffs and Plaintiffs' physicians, the safety and effectiveness of Essure®.

B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE FRAUDULENT MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

547. In Kentucky, a party claiming harm resulting from fraudulent misrepresentation / fraud in the inducement must establish six elements of fraud by clear and convincing evidence as follows: a) material representation b) which is false c) known to be false or made recklessly d) made with inducement to be acted upon e) acted in reliance thereon and f) causing injury.

548. Further, under the Restatement 3d of Torts: Products Liability § 9:

> One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation.[146]

C. CONCEPTUS AND BAYER'S DUTY TO NOT MAKE FRAUDULENT MISREPRESENTATIONS UNDER KENTUCKY LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

549. Under both Kentucky state and federal law, Conceptus and Bayer were under parallel duties not to make fraudulent misrepresentations of material facts regarding the benefits and harms of the medical devices sold by them. The state law and federal duties are identical because both prohibit these Defendants from making misrepresentations in the sale of their

[146] *See Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747-48 (Ky. 2011) (adopting the Restatement (Third) of Torts § 9); and *see Morris Aviation, LLC v. Diamond Aircraft Indus.*, 536 F. App'x 558, 567-68 (6th Cir. 2013) (The Sixth Circuit in *Morris* recognized that the Kentucky Supreme Court adopted Restatement (Third) of Torts § 9).

medical devices; [147] thus, the state law cause of action alleged herein is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

550. Conceptus and Bayer were required to comply with the duties listed in Section B. above, and were required to be truthful, accurate, and timely in performing the duties under federal law, as detailed above.

551. Kentucky law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

552. Kentucky law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to not make false and misleading statements regarding Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.

553. Conceptus and Bayer breached their duties under federal and state laws, as follows:

A) Fraudulently misrepresented the health and safety hazards, symptoms, diseases and/or health problems associated with use of Essure® for the purposes intended by these Defendants;

B) Fraudulently misrepresented their illegal, improper and unethical schemes to promote and market Essure® as "simple" and "worry-free"; and

[147] *See*, e.g., 21 U.S.C. § 352(q) and 21 U.S.C. § 321(n), KRS § 217.065, c.f. Kentucky common law. *See also, United States v. Shabbir*, 64 F. Supp. 2d 479, 481 (D. Md. 1999), which explains:

> The FDCA regulates, inter alia, the introduction of certain articles into the United States. *See* 21 U.S.C. § 301 et seq. Section 331 prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated and misbranded." 21 U.S.C. § 331(a). n1 "[A] drug or device shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular. . . ." 21 U.S.C. § 352. "Labeling" is expansively defined, and includes "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321 (m).

C) Fraudulently misrepresented information about the known comparative risks and benefits of the use of Essure® and the relative benefits and availability of alternate products, treatments and/or therapies.

554. As described above in this Complaint, to promote the perceived safety of the device and gain market acceptance, Conceptus devised and implemented a scheme to defraud physicians and patients, by means of false and fraudulent pretenses, so physicians and their patients would believe Essure® to be a safe and effective product, and thus increase the demand and profitability.

1. Conceptus and Bayer Intentionally Misrepresented the Health and Safety Information Associated with Essure®.

555. In connection with the Essure® product, Conceptus and Bayer fraudulently and intentionally misrepresented material and important health and safety product risk information to Plaintiffs and Plaintiffs' physicians, all as alleged in this Complaint.

556. For example, Conceptus and Bayer used the Essure® label to increase revenue,[148] and in doing so made false and misleading statements about the safety and efficacy of Essure® to Plaintiffs and Plaintiffs' physicians, as it concealed important health and safety information from the FDA and failed to follow proper quality control measures, regulations, and/or implement CAPAs; thus rendering the label false.

557. The Essure® label at the time of Plaintiffs' implants represented that Essure® was a safer and more effective method of permanent sterilization than alternative methods. This is false and misleading, as evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the Essure® studies consisting of thousands of women and reporting that patients who undergo the Essure® procedure are more likely to experience injuries

[148] In 2008, Conceptus stated for the 2007 fiscal year that it intended to make labeling improvements to Essure® to increase the adoption of the Essure® procedure. *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

and complications which require or will require surgical intervention or re-operation, as well as by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

558. Bayer and Conceptus presented false and misleading information after being caught by the FDA in 2011 for not reporting migration events. It was not until October of 2013 that Conceptus changed the warning label to state only that "There are reports of the Essure insert migrating." This warning gravely downplayed the true incidence of risk that a woman's Essure® coils might migrate.

559. Conceptus and Bayer represented to the FDA, the public, Plaintiffs and Plaintiffs' implanting physicians that Essure® was less invasive and less costly than tubal ligation, required no incision or general anesthesia, no abdominal entry for implantation, and could be implanted in an office setting. These Defendants also represented that Essure® was beneficial to patients because there were no risks associated with hormones, which are used in hormone-based contraception, and no recurring management of contraception.[149]

560. These representations were false and misleading, and were intentionally and fraudulently made to generate sales.

561. Conceptus stated that they were a "one product company and if our product fails to gain market acceptance, our business will suffer… [w]e are dependent on the Essure® system."[150]

562. Conceptus believed that the recommendations and endorsements of physicians would be essential for market acceptance of Essure®, and that physicians would not endorse the

[149] *See* "Revisiting Essure — Toward Safe and Effective Sterilization," available at: http://www.nejm.org/doi/pdf/10.1056/NEJMp1510514; and *see* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

[150] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

product unless it was an attractive alternative to other forms of contraception and more cost-effective.[151]

563. Evidence that these representations were intentionally false and misleading can be seen in the adverse event reporting that occurred subsequent to the launch of the MedWatcher app.

564. A retrospective study published in November 2013 in The Journal of Minimally Invasive Gynecology entitled *Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database,*[152] analyzed and investigated reports associated with the Essure® hysteroscopic sterilization system from November of 2002 to February of 2012 using the MAUDE database. The study found that 457 adverse events were reported during this period, which included 217 reports of pain, 121 events of delivery catheter malfunction, 61 reports of post-sterilization pregnancy, of which 29 were ectopic pregnancies, 90 events of perforation, 44 reports of abnormal bleeding and 33 events of microinsert malposition. There were 270 cases (which is 59.1% of all reported adverse events) where the adverse events resulted in an additional surgical procedure, of which 44 were hysterectomies.

565. Another study, *Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure® Device in the US,*[153] examined voluntary patient adverse event reporting directly to the FDA using the FDA's new MedWatcher app. The study began by

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[151] *See* http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313

[152] *See* "Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database," available at: http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext

[153] *See* "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html

encouraging women in an Essure® support group who had been adversely affected by the device to file a report using MedWatcher.

566. The study analyzed data collected from May 11, 2013 to December 7, 2014, which included 1349 women who reported adverse events through MedWatcher. The study found that 1047 women (77.6%) reported serious events such as hospitalization, disability and permanent damage after implantation.

567. When the MedWatcher app launched in the fall of 2013, and women started to report adverse events from Essure® directly to the FDA, Bayer chose to continue promoting the device as safe.

568. Between May 29, 2014 and January 20, 2016, Bayer received 462 complaints that a patient's Essure® coils had broken apart. Bayer submitted the reports of breakage in an intentionally misleading manner. When forwarding the first few complaints, Bayer notified the FDA that "single cases have been reported of Essure breakage." However, as reports of breakage continued to mount, Bayer continued to submit to the FDA that only single cases of breakage had been reported. Bayer's MDRs regarding device breakage were inaccurate, misleading, and not in compliance with MDR reporting requirements.

569. On October 8, 2015, Dr. Dhruva, *et al.* published a study in the New England Journal of Medicine entitled *Revisiting Essure – Toward Safe and Effective Sterilization*, which assessed the safety and effectiveness of Essure®. This study was based in part on a search and analysis of the MAUDE database. The study concluded that the increase in reported Essure® related adverse event complaints since mid-2013 led the FDA to update Essure®'s patient label in 2014 to include information about risks of chronic pelvic pain and device migration into the lower abdomen and pelvis, and led to the FDA's decision to reconvene its Obstetrics and

Gynecology Devices Panel to reassess Essure®'s safety and effectiveness on September 24, 2015.

570. The number of patient-reported adverse events following the launch of the MedWatcher app evidence a strong contradiction to the safety and efficacy of Essure® as reported by Conceptus and Bayer.

571. As thousands of reports about Essure®'s true safety risks became public recently, the FDA mandated changes to the product's warning label and took measures to ensure that patients are fully informed of the risks by requiring patients to fill out the "Patient Decision Checklist."

572. As medical device manufacturers, Conceptus and Bayer had a duty to not present false and misleading information about the Essure® device to the public, including Plaintiffs and Plaintiffs' physicians regarding the increased risks and dangers they knew, learned, or should have known about associated with Essure®.

573. Had Conceptus and Bayer complied with their duties to the FDA as described under the FDCA and detailed above in this Complaint, the necessary and resultant actions by the FDA and/or appropriate government agencies would have precluded the use of the product by Plaintiffs and Plaintiffs' physicians.

2. Conceptus and Bayer Made Intentional Misrepresentations Regarding the Safety and Efficacy of Essure® Through Marketing.

574. Conceptus conducted enormous and aggressive marketing campaigns that disseminated what they knew to be false and misleading statements pertaining to the convenience, safety and efficacy of the device.

575. Conceptus and Bayer created and distributed false and misleading advertising for Essure®, which is a "Restricted Device," because Essure® is not a safer and more effective

method of permanent sterilization than alternative methods; evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the Essure® studies consisting of thousands of women reporting that patients who undergo the Essure® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

576. For example, the Essure® website, print advertising, and patient brochure stated, "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." However, the micro-inserts can migrate, as evidenced by the over 850 reports of device migration as of December 31, 2015,[154] which would have deterred Plaintiffs and their physicians from using Essure® in Plaintiffs.

577. As a further example, the Essure® website, print advertising, and patient brochure stated, "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." This is false and misleading, as many women, including Plaintiffs, have experienced lifelong complications from the device and have required surgical removal of the device, which typically requires removal of organs such as the fallopian tubes and uterus. All three Plaintiffs unfortunately required subsequent surgeries as a result of adverse events regarding their Essure® devices. Further, the British Medical Journal ("BMJ") published a study entitled *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*,[155] in which Dr. Art Sedrakyan of Weill Cornell

[154] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[155] *See* "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study" available online at: http://www.bmj.com/content/351/bmj.h5162

Medicine in New York and his colleagues analyzed data from women who had received either the Essure® implant or had undergone a traditional tubal ligation between 2005 and 2013 in New York State. The study found that women who used Essure® as a means for permanent sterilization are ten times more likely to undergo re-operation within one year of the initial procedure due to device related complications and injuries compared to women who undergo tubal ligation. Further, "[g]eneral anesthesia was less frequently used when performing hysteroscopic sterilization compared with laparoscopic sterilization but it was still used in about half of the patients. This finding is remarkable in light of the marketing and proposed benefits of avoiding general anesthesia associated with the Essure® device."

578. The Essure® patient brochure stated that Essure® was the "only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials." However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Between 1997 and 2005, there were 64 pregnancies reported to Defendants. Additionally, there have been 631 reports of pregnancies according to the FDA as of December 31, 2015. Furthermore, a recent study indicates that women implanted with Essure® have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization.

579. The Essure® website, print advertising, and patient brochure describes Essure® as "worry free," and as a "simple procedure performed in your doctor's office" that takes "less than 10 minutes" and "requires no downtime for recovery" and "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure® is not worry free because there is an increased risk that the Essure® implants will cause women serious, life-altering complications including but not limited to debilitating pain,

heavy bleeding necessitating medication and/or additional surgical intervention, allergic reactions, autoimmune-like symptoms, dyspareunia, hysterectomy, and other complications.

580. The Essure® website, print advertising, and patient brochure stated, "the Essure® inserts are made from the same trusted, silicone free material used in heart stents." However, the micro-inserts are not made from the same material as heart stents. In contrast, the micro-inserts in Essure® are made of PET fibers, which trigger inflammation and scar tissue growth. PET fibers degrade and leach carcinogens when placed in temperatures over 65 degrees, and the human body stays at about 98 degrees. As such, PET fibers are not designed or manufactured for use in human implantation. However, the PET fibers are made of the same materials as the PVT material in some vaginal meshes, which have a high rate of expulsion.

581. The Essure® website, print advertising, and patient brochure stated, "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures." However, Essure® does not eliminate the risks, discomfort, and recovery time associated with surgical procedures (i.e. tubal ligations) because many women who undergo the Essure® procedure, including Plaintiffs, have never and will never fully recover from the Essure® implant procedure, which has caused them serious complications, including but not limited to debilitating pain, additional surgical procedures, allergic reactions, autoimmune-like symptoms, and other complications.

582. The Essure® website, print advertising, and patient brochure stated, "Essure® is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy" or words to that effect. Yet, Defendants' SEC Form 10-K filing shows that Defendants never did a comparison to a vasectomy or tubal ligation. Specifically,

minimum of one Essure® procedure must be performed every 6–8 weeks". However, Defendants "signed off" on "Essure® physicians" who did not perform the procedure every 6–8 weeks.

F) "[t]he PET fibers are what caused the tissue growth," and Essure® "works with your body to create a natural barrier against pregnancy." However, during a PMA meeting with the FDA in 2002, Defendants represented that the trauma caused by the expanding coil hitting the fallopian tubes is what causes the inflammatory response of the tissue.

3. Conceptus and Bayer Intentionally Misrepresented the Comparative Risks and Benefits of Essure® to Alternative Methods of Permanent Sterilization.

585. Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities to encourage physicians and patients to use the Essure® device.

586. Conceptus represented that Essure® had the following "key advantages" over laparoscopic tubal ligation: transcervical placement (non-incisional, compared to an abdominal incision or puncture), local, IV sedation (compared to general anesthesia), 45 minutes of average post-op recovery (compared to 4-5 hours of average post-op recovery), procedure performance in an outpatient/hospital, surgical center or doctor's office (compared to procedure performance in an inpatient/hospital or surgical center), and a 1-2 day average wait time to return to regular activities (compared to 4-6 days).

587. However, the BMJ study, *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*,[157] found that women who used Essure® as a means for permanent sterilization are ten (10) times more likely to undergo re-operation within one (1) year of the initial procedure due to device related complications and injuries compared to women who undergo tubal ligation. "A more than 10-fold higher occurrence of reoperation during the first year following Essure® based surgery is a

[157] *See* "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study" available online at: http://www.bmj.com/content/351/bmj.h5162

serious safety concern." As indicated in this study, "additional surgeries were performed to alleviate complications such as device migration or incompatibility after surgery."

588. The BMJ article also reported "[t]he hysteroscopic procedure with Essure® device does not require general anesthesia, and its safety has been considered to be similar or superior to that of laparoscopic sterilization." However, this study found that "[g]eneral anesthesia was less frequently used when performing hysteroscopic sterilization compared with laparoscopic sterilization but it was still used in about half of the patients."

589. Additionally, the authors analyzed the Essure® MAUDE data and indicated that most of the adverse events reported by patients with Essure® were for injuries that would require and did require a subsequent surgical operation. Such injuries included pelvic pain, hemorrhage, and device migration or incompatibility.

590. Conceptus and Bayer did not submit any MDR reportable events derived from this study and reported in the BMJ to the FDA.

591. In March of 2014, the online medical journal Conception published a study entitled *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*, which compared the expected probability of pregnancy after hysteroscopic sterilization with laparoscopic sterilization based on available data using decision analysis.[158] The authors concluded that at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization.

592. Bayer still falsely claims that Essure® is more effective than undergoing tubal ligation.

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[158] *See* "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/journals/contra/CON-8309-FINAL.pdf

4. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Fraudulent Misrepresentations, Plaintiffs Sustained Substantial Injuries.

593. Conceptus engaged in the above activities despite knowing that manipulating the public's knowledge of safety risks associated with Essure® exposed patients to serious dangers and greatly increased adverse risks.

594. Conceptus and Bayer intentionally and consciously misrepresented the benefits and harms associated with Essure®.

595. These Defendants knew that doctors such as Plaintiffs' implanting physicians would rely on such misrepresentations, thus subjecting their patients, like Plaintiffs, to an unreasonable risk of physical harm. Such misrepresentations corrupted resources available to surgeons, like Plaintiffs' implanting surgeons, regarding the safety and effectiveness of Essure®.

596. Conceptus and Bayer's motive in failing to advise surgeons, the public, Plaintiffs, and the FDA of these increased risks was for financial gain and fear that, if they provided proper and adequate information, Essure® would lose sales and market share.

597. Conceptus and Bayer chose not to provide the Plaintiffs' physicians nor Plaintiffs with the necessary information in order to make an informed decision in the best interests of Plaintiffs' health, and they purposefully deceived Plaintiffs' physicians and the Plaintiffs as to the safety and efficacy of Essure®.

598. Conceptus and Bayer provided inaccurate, false, or misleading information which was material to Plaintiffs' implanting physicians' treatment decisions, which misled Plaintiffs' physicians and Plaintiffs who were relying on their physicians' professional judgment.

599. Conceptus and Bayer knew that use of Essure® was unreasonably dangerous and could lead to serious side effects as listed herein. Conceptus and Bayer failed to take any

measures whatsoever to alert surgeons or the public regarding increased risks and dangers and instead continued to promote the Essure® device as safe.

600. When Conceptus and Bayer engaged in this deceptive campaign and made the above representations, they knew those representations to be false. These representations were made by Conceptus and Bayer with the intent of defrauding and deceiving the public, including Plaintiffs, Plaintiffs' physicians, and the medical community.

601. At the time the aforesaid representations were made by Conceptus and Bayer, Plaintiffs and their medical providers were unaware of the falsity of said representations and reasonably relied upon Conceptus' and Bayer's assertions, promulgated through aggressive sales tactics as set forth herein, that the Essure® device was safe when in fact it was not.

602. As detailed above, Bayer continues false claims that Essure® is safer and more effective than undergoing tubal ligation.

603. Conceptus and Bayer intended to induce Plaintiffs and their physicians to rely on their misrepresentations to use Essure® over the alternative methods of permanent sterilization.

604. In reliance upon Conceptus and Bayer's representations, Plaintiffs and Plaintiffs' physicians used Essure®.

605. Plaintiffs and Plaintiffs' physicians were justified in their reliance on Conceptus' and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure® implant procedure, which ultimately caused Plaintiffs' serious physical injuries.

606. As a direct and proximate result of said misrepresentations, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the

enjoyment of life.

607. Had Plaintiffs' implanting physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, Plaintiffs' physicians would not have recommended Essure® to Plaintiffs and Plaintiffs would not have chosen to have Essure® implanted in their fallopian tubes.

608. Had the FDA known of the actual dangers of and inefficacy of the use of Essure®, they would have initiated a recall of the product, dear doctor letter, or safety signal and/or warned the public of the danger.

609. Conceptus' and Bayer's conduct, as alleged above, was malicious, fraudulent, and oppressive toward Plaintiffs in particular and the public generally, and Conceptus and Bayer conducted themselves in a willful and wanton manner by actively violating federal regulations.

610. Conceptus and Bayer are guilty of malice, oppression, and fraud, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in sum according to proof at trial.[159]

THIRD CAUSE OF ACTION
Fraudulent Concealment
Fraudulent Omissions: Restat. 2d of Torts §551

611. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

612. Plaintiffs bring claims against Conceptus and Bayer under Kentucky law for fraudulent concealment / fraudulent omissions regarding the Essure® device.

A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING

[159] KRS § 411.184 permits an award of punitive damages for "fraud," which is defined as "an intentional misrepresentation, deceit, or concealment of material fact known to the defendant and made with the intention of causing injury to the plaintiff." "The mere fact that the act is intentional and a tort does not justify punitive damages absent this additional element of implied malice, meaning conscious wrongdoing." *Fowler v. Mantooth*, 683 S.W.2d 250, 252 (Ky. 1984) (internal citations omitted).

FEDERAL DUTIES TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

613. Under the FDCA and FDA's implementing regulations, labeling and promotional advertisement claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

614. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

615. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations. Notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of, the following ways:

A) Conceptus and Bayer had duties to not make false or misleading statements regarding Essure® under 21 U.S.C. §§ 331(a), 351 & 352(a), (q)&(r); 21 U.S.C. §§ 360(q)&(r); and 21 C.F.R. § 814.80.

B) Conceptus and Bayer had duties to investigate and address adverse events under the following regulations: 21 C.F.R. § 820.3(z)(x); 21 C.F.R. § 820.22; 21 C.F.R. § 820.5; 21 C.F.R. §820.1(a); 21 C.F.R. § 820.22; 21 C.F.R. § 820.100; 21 C.F.R. § 820.160(a); 21 C.F.R. § 820.198; 21 C.F.R. § 820.30; 21 C.F.R. § 803.3; 21 C.F.R. § 820.70 and 21 C.F.R. § 820.170(a).

C) Conceptus and Bayer had duties to submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association under 21 C.F.R. § 814.39, 21 C.F.R. § 803.56.

D) Conceptus and Bayer had duties to report adverse events under 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a).

E) Conceptus and Bayer had duties to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known about under 21 C.F.R. § 814.84(b)(2).

616. The above regulations imposed duties on Conceptus and Bayer to accurately, timely, and honestly represent to the FDA, the public, Plaintiffs and Plaintiffs' physicians, the safety and effectiveness of Essure®.

B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

617. In Kentucky, "[a] fraud by omission claim is grounded in a duty to disclose … To prevail, a plaintiff must prove: (1) the defendant had a duty to disclose the material fact at issue; (2) the defendant failed to disclose the fact; (3) the defendant's failure to disclose the material fact induced the plaintiff to act; and (4) the plaintiff suffered actual damages as a consequence."[160]

C. CONCEPTUS' AND BAYER' S DUTY TO NOT TO MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE® UNDER KENTUCKY LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

618. Under both Kentucky state and federal law, Conceptus and Bayer were under parallel duties not to make fraudulent concealments and/or omissions of material facts regarding the benefits and harms of the medical devices sold by them, and were under parallel duties to disclose material facts regarding the benefits and harms of medical devices sold by them, specifically the Essure® device, to the FDA, Plaintiffs' physicians, and Plaintiffs, as detailed

[160] *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747-48 (Ky. 2011) (Also stating that Kentucky recognizes a duty to disclose in four circumstances: 1. A duty arising from a confidential or fiduciary relationship; 2. A duty provided by statute; 3. When a defendant has partially disclosed material facts to the plaintiff but created the impression of full disclosure; and 4. Where one party to a contract has superior knowledge and is relied upon to disclose same (internal citations omitted)). The Kentucky elements of a claim for fraudulent omission are similar to those stated in the Restatement 2d of Torts § 557A, and follow the Restatement 2d of Torts § 551, as cited in *Giddings*. *See also, Smith v. General Motors Corp.*, 979 S.W.2d 127, 129 (Ky. Ct. App. 1998) (discussing actionable case of fraud based on suppression of a fact).

above in this Complaint.

619. The state law and federal duties are identical because both prohibit these Defendants from making fraudulent concealments and/or omissions in the sale of their medical devices; [161] thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

620. Conceptus and Bayer were required to comply with the duties listed in Section B. above, and were required to be truthful, accurate, and timely in performing the duties under federal law, as detailed above.

621. Conceptus and Bayer had a continuing duty under the various regulations discussed above and per the terms of the PMA approval by the FDA to monitor its products after receiving FDA approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences and other such serious events of which they became aware. The duties to discover and report necessarily include the duties to not actively conceal and omit material health information of which it knew or should have known had it followed the federal regulations.

622. Conceptus and Bayer failed to perform these duties under federal law, and thus failed to perform its duties under Kentucky law, as these Defendants had parallel duties to not conceal and omit material health information regarding the safety of the Essure® device to the FDA and other third parties.

623. Kentucky law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

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[161] *See*, FN 144, *supra*.

624. Kentucky law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to disclose material facts regarding the safety and efficacy of Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.

625. Conceptus and Bayer breached its duties under federal and state laws by fraudulently omitting, concealing and misrepresenting the health and safety information about increased risks, dangers, hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the Essure® device, as well as the relative benefits and availability of alternative procedures, to physicians including Plaintiffs' physicians.

1. Conceptus and Bayer Intentionally Concealed and/or Omitted Material Health and Safety Information Associated with Essure®.

626. In connection with the Essure® product, Conceptus and Bayer intentionally concealed and/or omitted material and important health and safety product risk information to Plaintiffs and Plaintiffs' physicians, all as alleged in this Complaint.

627. To protect sales and revenue, Conceptus and Bayer purposefully ignored their mandatory federal reporting requirements and actively hid safety information from the public.

628. As detailed above, Conceptus knew of thousands of instances wherein the Essure® device had migrated in a woman or perforated a woman's organs and failed to report all of them.

629. The FDA inspector cited Conceptus in 2003 for failing to adequately analyze all quality data sources to identify existing and potential causes of non-conforming products and other quality problems, and for failing to follow procedures for the control of products that do not conform to specifications.

630. In June of 2008, the California Department of Public Health, Medical Device Safety Section ("CDPH") issued a Notice of Violation to Conceptus for failing to obtain a valid license to manufacture medical devices and failing to maintain procedure for inventory transfer.

631. In December of 2010 the FDA inspector cited Conceptus for not reporting complaints of Essure® coils being seen inside the patients' abdominal cavity and not opening a CAPA when they became aware of these complaints. Conceptus was submitting MDRs and reporting complaints of the coils migrating into the peritoneal or abdominal cavity only if the patient was complaining of pain and a second procedure was required to remove the device.

632. Conceptus concealed such complaints if the coil was subsequently removed during a laparoscopic tubal ligation surgery that was performed due to a failure of occlusion of the fallopian tubes.

633. Conceptus concealed these adverse events, complaints and reports, and failed to follow adequate quality control procedures, investigate and analyze complaints, and open CAPAs, specifically to mislead physicians and women about the safety of the Essure® device.

634. As detailed above, between January 1, 2008 and December 6, 2010, Conceptus received at least 16,581 complaints relating to Essure®. Of these 16,581 complaints, 16,399 were never reported to the FDA.

635. Between May and June of 2013, the FDA conducted an inspection of Conceptus' Mountain View, CA facility which revealed 16,047 complaints Conceptus had received regarding Essure® between January 2011 and the date of the inspection. Of these 16,047 complaints, Conceptus withheld 15,712 from the FDA and the public.[162]

[162] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm

636. Further, and as detailed above, between Essure®'s inception in 2002 and through to 2015, the FDA received approximately 9,900 MDRs related to safety problems with the device.[163] Of those 9,900 MDRs, only 943 were made between 2002 and October 25, 2013. The FDA received the remaining 8,950 reports between October 26, 2013 and December 31, 2015.[164]

637. The influx in MDR's is a result of the launch of the MedWatcher app, which allowed women to report their adverse events directly to the FDA.[165]

638. Prior to the MedWatcher app, women reported their adverse events directly to Conceptus, who actively concealed them from the FDA and the public, and/or omitted information from reporting.

639. Conceptus and Bayer failed to adequately disclose to the FDA adverse events of which these manufacturers were informed after Essure®'s PMA approval.

640. As detailed above, this significant increase prompted the FDA to convene a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015 to examine safety concerns about Essure® raised by patients and cited in MDRs, and on February 29, 2016 to announce that it will require a major change to the Essure® warning label and also require all women considering Essure® placement to fill out a Patient Decision Checklist" to ensure that they are fully informed of the true risks, and on November 15, 2016 to approve changes for physician instructions for use, and a patient information booklet including a boxed warning and patient decision checklist.[166]

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[163] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[164] *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm

[165] *See* "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html

[166] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm; *and see* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S046

641. Due to Conceptus and Bayer's failure to report adverse events when they had a duty to speak, the labeling originally approved by the FDA for Essure® became false before the Plaintiffs' surgeries and thus failed to protect the public health by failing to adequately disclose the harms, risks and benefits of Essure®.

642. Had Conceptus and Bayer timely and accurately reported adverse events, and implemented quality control procedures and CAPAs to investigate and analyze complaints associated with Essure®, instead of actively concealing and/or omitting material safety information in their required reporting to the FDA, the "Black Box Warning" and "Patient Decision Checklist" would have come out earlier and effectively warned Plaintiffs and their physicians.

2. Conceptus and Bayer Fraudulently Concealed and/or Omitted the Risks of Essure® as Compared to Alternative Methods of Permanent Sterilization.

643. Conceptus and Bayer represented that Essure® had the following "key advantages" over laparoscopic tubal ligation: transcervical placement, local IV sedation, 45 minutes of average post-op recovery, procedure performance in an outpatient/hospital, surgical center or doctor's office, and a 1-2 day average wait time to return to regular activities.

644. Conceptus concealed from the public that most of the adverse events reported by patients with Essure® were for injuries that would require and did require a subsequent surgical operation.

645. When the BMJ study, *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*,[167] found that women who used Essure® as a means for permanent sterilization are ten times more likely to undergo re-operation

[167] *See* "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study" available online at: http://www.bmj.com/content/351/bmj.h5162

within one year of the initial procedure due to device related complications and injuries compared to women who undergo tubal ligation, Conceptus and Bayer did not submit any MDR reportable events derived from this study to the FDA.

646. In March of 2014 the authors of *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*[168] concluded that at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization. Bayer and Conceptus continued the pattern of concealment by omitting this information from their promotion of Essure® as a more effective option than tubal ligation.

647. Conceptus and Bayer marketed Essure® as the "only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials," and concealed and/or omitted information regarding the four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. A recent study indicates that women implanted with Essure® have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater.

648. Instead of disclosing these risks, Conceptus and Bayer intentionally concealed and/or omitted this information from their patient brochures and promotional information.

3. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Fraudulent Concealments and/or Omissions, Plaintiffs Sustained Substantial Injuries.

649. Conceptus and Bayer knew, or should have known, that they were concealing, suppressing, and misrepresenting true information about the known increased risks and benefits

[168] *See* "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/journals/contra/CON-8309-FINAL.pdf

of the use of Essure® and the relative benefits and availability of alternate procedures.

650. Conceptus and Bayer knew that Plaintiffs and Plaintiffs' physicians would regard the matters that they concealed, suppressed, and misrepresented to be important in determining the course of treatment for the Plaintiffs, including Plaintiffs' and Plaintiffs' physicians' decisions to use Essure® as a method of permanent sterilization.

651. Conceptus and Bayer intended to cause Plaintiffs and Plaintiffs' physicians to rely on their concealment of material safety information, suppression, and misrepresentations about the increased risks and dangers related to Essure® as a method of permanent sterilization.

652. Plaintiffs and Plaintiffs' physicians were justified in relying, and did rely, on Conceptus' and Bayer's concealment of information and misrepresentations about the increased safety risks and dangers related to Essure® in deciding to recommend and choose the Essure® procedure for permanent sterilization.

653. As a direct and proximate result of Conceptus' and Bayer's fraudulent concealment, suppression, and misrepresentations of material increased health and safety risks and dangers relating to Essure®, and Conceptus' and Bayer's promotion and marketing practices, Plaintiffs suffered injuries and economic loss, and Plaintiffs will continue to suffer injuries, damages and economic loss.

654. As the direct, proximate, and legal cause and result of Conceptus' and Bayer's false and deceptive marketing and promotion practices related to Essure®, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the enjoyment of life.

655. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

656. Conceptus' and Bayer's conduct, as alleged above, was malicious, oppressive, intentional, reckless and/or outrageous, and constituted willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

FOURTH CAUSE OF ACTION
Negligent Misrepresentation
Restat. 2d of Torts, § 311.
Restat. 3d of Torts: Products Liability § 9.

657. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

658. Plaintiffs bring a claim against Conceptus and Bayer under Kentucky law for negligent misrepresentation regarding the Essure® device.

A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

659. Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, section A, above.

660. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

661. Under the FDCA and FDA's implementing regulations, labeling and promotional advertisements about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

662. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations, notwithstanding this duty, Conceptus and Bayer

violated federal law, the FDCA, the MDA, and the regulations.

B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

663. Kentucky follows the Restatement 3d of Torts: Products Liability § 9 to determine liability of a commercial product seller or distributor for harm resulting from negligent misrepresentation:

> One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation.[169]

664. Restatement 3d of Torts: Products Liability § 9, comment (a),[170] references Restat. 2d of Torts § 311 for the elements of negligent misrepresentation, which are as follows:

> (1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results (a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken.
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> (2) Such negligence may consist of failure to exercise reasonable care (a) in ascertaining the accuracy of the information, or (b) in the manner in which it is communicated.

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[169] *See Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747-48 (Ky. 2011) (adopting the Restatement (Third) of Torts § 9); and *see Morris Aviation, LLC v. Diamond Aircraft Indus.*, 536 F. App'x 558, 567-68 (6th Cir. 2013) (The Sixth Circuit in *Morris* recognized that the Kentucky Supreme Court adopted Restatement (Third) of Torts § 9).

[170] "Liability for fraudulent or negligent misrepresentation. The rules in the Restatement, Second, of Torts, governing liability for fraudulent and negligent misrepresentation, are contained in §§ 310 and 311. Case law has followed these Sections. Although these Sections do not explicitly apply to commercial product sellers, they admit of such application. Given the availability to Plaintiff of the rule under § 402B of the Restatement, Second, of Torts, subjecting product sellers to strict liability even in the absence of fraud or negligence, (see Comment b), there can be no doubt that product sellers are subject to liability for fraudulent or negligent misrepresentation. By hypothesis, given the rule stated in § 402B, a plaintiff who proves that the misrepresentation that caused harm was made fraudulently or negligently should have a remedy." Restatement 3d of Torts: Products Liability § 9, comment (a).

C. CONCEPTUS AND BAYER' S DUTY TO NOT TO MAKE NEGLIGENT MISREPRESENTATIONS UNDER KENTUCKY LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

665. Under both Kentucky state and federal law, Conceptus and Bayer were under parallel duties not to make negligent or other misrepresentations of material facts regarding the benefits and harms of the medical devices sold by them. The state law and federal duties are identical because both prohibit these Defendants from making misrepresentations in the sale of their medical devices; [171] thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

666. Conceptus and Bayer were required to comply with the duties listed in Section B. above, and were required to be truthful, accurate, and timely in performing the duties under federal law, as detailed above.

667. Kentucky law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

668. Kentucky law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to not make false and misleading statements regarding Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF THEIR STATE LAW DUTIES AND IDENTICAL FEDERAL REQUIREMENTS.

669. Plaintiffs incorporate by reference the allegations stated in the Second Cause of Action, section D, above.

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[171] *See* FN 144, *supra.*

670. Conceptus and Bayer breached their duties under federal and state laws, as follows:

A) Negligently misrepresented the health and safety hazards, symptoms, diseases and/or health problems associated with use of Essure® for the purposes intended by these Defendants;

B) Negligently misrepresented their illegal, improper and unethical schemes to promote and market Essure® as "simple" and "worry-free"; and

C) Negligently misrepresented information about the known comparative risks and benefits of the use of Essure® and the relative benefits and availability of alternate products, treatments and/or therapies.

1. Conceptus and Bayer Negligently Misrepresented the Health and Safety Information Associated with Essure®.

671. Plaintiffs incorporate by reference the allegations stated in the Second Cause of Action, section D(1), above.

672. In connection with the Essure® product, Conceptus and Bayer failed to exercise reasonable care in ascertaining the accuracy of important health and safety information and/or the manner in which it is communicated to Plaintiffs and Plaintiffs' physicians, all as alleged in this Complaint.

673. As medical device manufacturers, Conceptus and Bayer had a duty to use reasonable care ascertaining the accuracy of material health and safety information about the Essure® device, and in the presentation and communication of such information to the public, Plaintiffs and Plaintiffs' physicians.

674. Had Conceptus and Bayer complied with their duties to the FDA as described under the FDCA and detailed above in this Complaint, which are parallel to their state law duties, the necessary and resultant actions by the FDA and/or appropriate government agencies would have precluded the use of the product by Plaintiffs and Plaintiffs' physicians.

2. Conceptus and Bayer Made Negligent Misrepresentations Regarding the Safety and Efficacy of Essure® Through Marketing.

675. Plaintiffs incorporate by reference the allegations stated in the Second Cause of Action, section D(2), above.

676. Conceptus conducted enormous and aggressive marketing campaigns that disseminated false and misleading statements pertaining to the convenience, safety and efficacy of the device.

3. Conceptus and Bayer Negligently Misrepresented the Comparative Risks and Benefits of Essure® to Alternative Methods of Permanent Sterilization.

677. Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, section D(3), above.

678. Conceptus misrepresented that Essure® had "key advantages" over laparoscopic tubal ligation, as alleged in the Second Cause of Action, Section D(3).

4. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Negligent Misrepresentations, Plaintiffs Sustained Substantial Injuries.

679. Conceptus engaged in the above activities which influenced the public's knowledge of safety risks associated with Essure® and exposed patients to serious dangers and greatly increased adverse risks.

680. Conceptus and Bayer negligently misrepresented to the FDA, the public, Plaintiffs and Plaintiffs' physicians the benefits and harms associated with Essure®.

681. Such misrepresentations corrupted resources available to surgeons, like Plaintiffs' implanting surgeons, regarding the safety and effectiveness of Essure®.

682. Plaintiffs' implanting physicians relied on such misrepresentations, thus subjecting their patients, including Plaintiffs, to an unreasonable risk of physical harm.

683. Due to Conceptus' and Bayer's negligence, Plaintiffs' physicians and Plaintiffs did not have the necessary information in order to make an informed decision in the best interests of Plaintiffs' health.

684. Conceptus and Bayer provided inaccurate, false, or misleading information which was material to Plaintiffs' implanting physicians' treatment decisions, which misled Plaintiffs' physicians and Plaintiffs who were relying on their physicians' professional judgment.

685. When Conceptus and Bayer made the above representations, they did so without any regard for the accuracy of the information presented, or the manner in which the information was communicated.

686. Had the FDA known of the actual dangers of and inefficacy of the use of Essure®, they would have initiated a recall of the product, dear doctor letter, safety signal and/or warned the public of the danger.

687. At the time the aforesaid representations were made by Conceptus and Bayer, Plaintiffs and their medical providers were unaware of the falsity of said representations and reasonably relied upon Conceptus' and Bayer's assertions, that the Essure® device was safe when in fact it was not.

688. In reliance upon Conceptus' and Bayer's representations, Plaintiffs and Plaintiffs' physicians used Essure®.

689. Plaintiffs and Plaintiffs' physicians were justified in their reliance on Conceptus' and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure® implant procedure, which ultimately caused Plaintiffs' physical injuries.

690. As a direct and proximate result of said misrepresentations, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses,

lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

691. Had Plaintiffs' implanting physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, as well as Bayer's and Conceptus' failure to investigate and analyze adverse events and/or implement CAPAs, Plaintiffs' physicians would not have recommended Essure® to Plaintiffs, and Plaintiffs would not have chosen to have Essure® implanted in their fallopian tubes.

FIFTH CAUSE OF ACTION
Negligent Training

692. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

693. Plaintiffs bring claims against Conceptus and Bayer under Kentucky law for Negligent Training regarding the Essure® device.

694. In order to capture the market, Conceptus and Bayer independently undertook a duty of training physicians, including Plaintiffs' implanting physicians, on (1) the safe and proper use of the Essure® procedure; (2) how to properly use its own mechanism of delivery; and (3) the specialized hysteroscopic equipment manufactured by a third party.

695. The PMA approval sets forth Conceptus' and Bayer's duty to train physicians, and a manufacturer/applicant is required to comply with the standards and conditions set forth in the PMA approval letter.[172]

696. Conceptus and Bayer had a parallel duty under Kentucky law to exercise reasonable care in their training of physicians to avoid foreseeable injury.[173]

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[172] 21 C.F.R. § 814.80 (2012).

[173] *C.D. Herme, Inc. v. R.C. Tway Co.*, 294 S.W.2d 534, 537 (Ky. 1956). Further, in Kentucky, a party claiming harm resulting from negligence must generally establish: 1. A duty of care owed to Plaintiff by the Defendant; 2.

697. Under both Kentucky state and federal law, Conceptus and Bayer were under parallel duties to use reasonable care in the training of physicians on the safe and proper use of the Essure® device. The state law and federal duties are identical; thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

698. Kentucky law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

699. Kentucky law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to use reasonable care in the training of physicians on the proper use of Essure®, which parallel federal regulations and requirements.

700. Conceptus and Bayer breached their duties under the PMA and federal law to train physicians on the safe and proper use of Essure®.

701. Conceptus and Bayer breached their duties under Kentucky law, as follows:

A) Conceptus and Bayer were negligent in choosing not to take reasonable steps in developing an adequate training program for the Essure® procedure, educating employees to properly train physician users on the safe and proper methods of the Essure® procedure, and supervising employees while training physician users on the safe and proper methods of the Essure® procedure.

B) Conceptus and Bayer were negligent in not safely and properly training Plaintiffs' implanting physicians on how to safely and properly perform the Essure® procedure.

702. Conceptus and Bayer (1) undertook a duty to train physicians on the safe and proper use of the Essure® procedure; (2) failed to adequately train the physicians on how to use

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Conduct of the Defendant which breaches the standard by which the duty is measured; 3. Injury which results in actual loss or damage to the Plaintiff's person or property; and 4. Causation between the inadequate conduct of the Defendant and the injury to the Plaintiff.

its delivery system and the hysteroscopic equipment manufactured by a third party; (3) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (4) it was foreseeable that Conceptus and Bayer's negligent training program would cause harm to Plaintiffs.

703. Conceptus and Bayer engaged in the above activities which exposed patients, including Plaintiffs, to serious dangers and greatly increased adverse risks.

704. Conceptus and Bayer failed to properly train Plaintiffs' implanting physicians on proper management of post-implant complications.

705. Conceptus and Bayer failed to properly train Plaintiffs' implanting physicians on how to safely and effectively remove the Essure® coils once the implant procedure was completed.

706. Conceptus and Bayer failed to properly train Plaintiffs' implanting physicians on how to use its delivery system and the hysteroscopic equipment.

707. Despite Conceptus' and Bayer's failure to train Plaintiffs' implanting physicians, these Defendants "signed-off" on Plaintiffs' implanting physicians and provided specialized hysteroscopic equipment to them to perform Essure® procedures.

708. Due to Conceptus' and Bayer's negligence, Plaintiffs' physicians and Plaintiffs did not have the necessary information in order to make an informed decision in the best interests of Plaintiffs' health.

709. Had Conceptus and Bayer implemented a training program on the safe and proper methods of implanting Essure® prior to Plaintiffs' surgeries, their physicians would have adequately performed their implants.

710. As a proximate and legal result of these Defendants' failure to properly discharge a duty it undertook to train physicians, Plaintiffs' implanting physicians did not adequately perform Plaintiffs' implants.

711. Instead, Plaintiffs' implants were improperly performed, causing the coils to migrate and/or perforate Plaintiffs' organs. Plaintiffs suffered severe pain and bleeding without proper management of these post-implant complications; and Plaintiffs required subsequent surgeries as a result of their implanting physicians' improper performance of the Essure® procedure.

712. As a proximate and legal result of these Defendants' failure to properly discharge a duty it undertook to train physicians, they breached their duty of care to Plaintiffs under Kentucky law and caused Plaintiffs injuries, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

SIXTH CAUSE OF ACTION
Sadler Negligent Failure to do *Postmarket* Testing

713. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

714. Under both state and federal law, these Defendants were under parallel duties to conform to the PMA approval process. This process is designed to prevent a manufacturer from introducing into the stream of commence a medical device that has ***not*** been tested in adequately designed clinical trials and which has ***not*** otherwise passed a rigorous scientific review to determine that such a device is safe and effective for the use intended by the manufacturer.

715. In this regard, the manufacturers' duties of due care under Kentucky state law and its federal duties pursuant to FDA rules and regulations are identical. Both prohibit these

Defendants from marketing untested devices, which are unreasonably dangerous; thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under federal law.

716. Defendants marketed the Essure® device to and for the benefit of Plaintiffs.

717. Defendants owed Plaintiffs, and their physicians, duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing scientific knowledge at the time the product was sold.

718. This is also a parallel violation of the duty of due care under the Kentucky negligence rule of reasonable care, which requires a manufacturer to take ordinary and reasonable care before marketing such devices by submitting them to adequately designed clinical testing for safety and effectiveness. Such testing is reasonably necessary and ordinarily prudent in order to prevent the distribution of unreasonably dangerous products into the market place.[174]

719. At the time of Plaintiffs' implants, Conceptus and Bayer failed to perform adequately designed post-market clinical testing of Essure® as required under its PMA and supplements, federal regulations and parallel state law.

720. A new post-marketing study was required as a condition of the Essure® 2007 premarketing approval supplement.[175]

721. Nevertheless, Conceptus and Bayer intended to and did promote and market Essure® as a safe and effective device, and did distribute this unreasonably dangerous device to Plaintiffs and Plaintiffs' implanting physicians without completing the required postmarket study.

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[174] 21 U.S.C. §§ 351 and 352; Kentucky Common Law, KRS §§ 217.065 and 217.175.
[175] *See* "Revisiting Essure – Toward Safe and Effective Sterilization" available online at: http://www.nejm.org/doi/full/10.1056/NEJMp1510514

722. "This study was never registered at ClinicalTrials.gov, despite the 2007 FDA Amendments Act requirement, and was stopped early at the manufacturer's request after 578 [of the 800 required] underwent attempted implantation. Its findings are minimally informative, since no follow-up data were collected and nearly all study results reported on the FDA website are redacted."[176]

723. One purpose of this aborted study was to determine adverse effects potentially related to the device, however it is clear from the limited data available on the FDA website that no follow-up visits occurred based on the adverse event findings and "N/A" listed next to "Followup Visits and Length of Followup."[177]

724. The Essure® device marketed and distributed by Conceptus and Bayer was misbranded because their FDA-approved labeling was inadequate to convey the true safety and effectiveness information as marketed by these Defendants.

725. The distribution of these misbranded devices is a violation of federal law because of the failure to conform to procedures required by the PMA Supplement approval.

726. Plaintiffs were harmed by Conceptus and Bayer's marketing and distribution of a misbranded device.

727. Conceptus and Bayer could have discovered the defective condition of Essure®, but failed to conduct and complete adequate postmarket tests and inspections that would have disclosed the defects.

728. Conceptus and Bayer failed to exercise reasonable care in adequately testing and completing such testing of the Essure® device subject to the 2007 PMA supplement.

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[176] *Id.*

[177] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?c_id=112&t_id=367828

729. Conceptus and Bayer knew, or should have known, that due to their failure to use reasonable care, Plaintiffs and their physicians would use and did use Essure® to the detriment of Plaintiffs' health, safety and well-being.

730. As the direct, producing, proximate and legal result of these Defendants' negligence, Plaintiffs have suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

731. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

SEVENTH CAUSE OF ACTION
Breach of Express Warranty
Ky. Rev. Stat. § 355.2-301, *et. seq.*

732. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

733. Conceptus and Bayer utilized journal articles, advertising media, and sales representatives to promote, encourage, and urge the use and purchase of the Essure® device, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that Essure® would conform to the representations.

734. More specifically, Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, section D (1-3), above.

735. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

736. Essure® did not conform to the representations made by Conceptus and Bayer, as the Essure® device was not safe and effective and was not safe and effective for use by individuals such as Plaintiffs.

737. At all relevant times, Plaintiffs used Essure® for the purpose and in the manner intended by Conceptus and Bayer.

738. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized Essure®'s hidden increased risks and its unreasonable dangers.

739. Defendants' breaches constitute violations of state common laws, including but not limited to, the following statutory provisions: Ky. Rev. Stat. § 355.2-301, *et. seq.*[178]

740. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

741. Conceptus and Bayer intended to induce Plaintiffs and their physicians to rely on their misrepresentations to use Essure® over the alternative methods of permanent sterilization.

742. In reliance upon Conceptus' and Bayer's representations, Plaintiffs and Plaintiffs' physicians used Essure®.

743. Plaintiffs and Plaintiffs' physicians were justified in their reliance on Conceptus' and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure® implant procedure, which ultimately caused Plaintiffs' serious physical injury.

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[178] (1) Express warranties by the seller are created as follows: (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model. Ky. Rev. Stat. § 355.2-313.

744. As a direct and proximate result of said misrepresentations, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

745. Had Plaintiffs' implanting physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, Plaintiffs' physicians would not have recommended Essure® to Plaintiffs, and Plaintiffs would not have chosen to have Essure® implanted in their fallopian tubes.

EIGHTH CAUSE OF ACTION
Kentucky Products Liability Action
KRS § 411.300 *et. seq.*
Restat. 2d of Torts, § 402A

746. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

A. PLAINTIFFS HAVE A CAUSE OF ACTION UNDER THE KENTUCKY PRODUCTS LIABILITY STATUTES, KRS § 411.300 *ET. SEQ.* AND RESTAT. 2D OF TORTS, § 402A.

747. Ky. Rev. Stat. Ann. §§ 411.300 et seq. governs claims or actions brought for personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, certifying, warning, instructing, marketing, advertising, packaging, or labeling of any product.

748. As used in Ky. Rev. Stat. Ann. §§ 411.300 *et seq.*, the term "products liability action" means "any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying,

warning, instructing, marketing, advertising, packaging or labeling of any product."

749. Ky. Rev. Stat. Ann. §§ 411.300 et seq. and Kentucky Common Law, which adopts Section § 402 of the Restatement (Second) of Torts,[179] permits a claim or portion of a claim in which the plaintiff seeks relief in the form of damages on a theory that the defendant is strictly liable for such damages because: (1) Conceptus and Bayer, wherever situated in the chain of commerce, transferred a product in the course of their business; and (2) The product was used in a manner reasonably anticipated; and (3) Either or both of the following: (a) The product was then in a defective condition and unreasonably dangerous when put to a reasonably anticipated use, and the Plaintiffs were damaged as a direct result of such defective condition that existed when the product was sold; or (b) The product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and the Plaintiffs were damaged as a direct result of the product being sold without an adequate warning.

750. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder, and parallel state law.

751. Kentucky law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

752. The state law and federal duties are identical; thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

[179] *See Dealers Transport Co. v. Battery Distribution Co.*, 402 S.W.2d 441 (Ky. Ct. App. 1965). *See also Kroger Co. v. Bowman*, 411 S.W.2d 339 (Ky. 1967).

753. Kentucky law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties, which parallel federal regulations and requirements.

1. Conceptus and Bayer failed to comply with the following federal requirements regarding Essure®.

754. Conceptus and Bayer at all times herein were medical device manufacturers and subject to duties under the PMA, FDCA and various federal regulations.

755. Conceptus and Bayer designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure®, including the Essure® devices that were implanted into Plaintiffs.

756. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations.

757. Conceptus and Bayer had duties to not make false or misleading statements regarding Essure® under 21 U.S.C. §§ 331(a), 351 & 352(a),(q)&(r); 21 U.S.C. §§ 360(q)&(r); and 21 C.F.R. § 814.80. Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action, Fourth Cause of Action, and Seventh Cause of Action, which are incorporated by reference herein.

758. Conceptus and Bayer had duties to investigate and address adverse events under the following regulations: 21 C.F.R. § 820.3(z)(x); 21 C.F.R. § 820.22; 21 C.F.R. § 820.5; 21 C.F.R. §820.1(a); 21 C.F.R. § 820.22; 21 C.F.R. § 820.100; 21 C.F.R. § 820.160(a); 21 C.F.R. § 820.198; 21 C.F.R. § 820.30; 21 C.F.R. § 803.3; 21 C.F.R. § 820.70 and 21 C.F.R. § 820.170(a). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action, Fourth Cause of

Action, and Seventh Cause of Action, which are incorporated by reference herein.

759. Conceptus and Bayer had duties to submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association under 21 C.F.R. § 814.39, 21 C.F.R. § 803.56. Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

760. Conceptus and Bayer had duties to report adverse events under 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, 21 C.F.R. § 814.84(b)(2) and 21 U.S.C. § 360i(a). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

761. Conceptus and Bayer had duties to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known about under 21 C.F.R. § 814.84(b)(2). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

762. Conceptus and Bayer had duties to comply with quality control standards under 21 C.F.R. § 820.3(z)(x); 21 C.F.R. § 820.22; 21 C.F.R. § 820.5; 21 C.F.R. §820.1(a); 21 C.F.R. § 820.22; 21 C.F.R. § 820.160(a); 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First

Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action which are incorporated by reference herein.

763. Conceptus and Bayer had duties to establish and maintain procedures for implementing CAPAs under 21 C.F.R. § 820.100. Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

2. Conceptus and Bayer failed to comply with FDA approval of Essure®, resulting in a "manufacturing defect" of the device.

764. Conceptus and Bayer also violated federal law in the manufacture of Essure® in that they:

A) used non-conforming material;

B) failed to use pre-sterile and post-sterile cages;

C) manufactured Essure® at an unlicensed facility;

D) manufactured Essure® for three years without a license to do so;

E) failed to analyze or identify existing potential causes of non-conforming product and other quality problems;

F) failed to track the non-conforming product;

G) failed to follow procedures used to control products which did not conform to specifications;

H) failed to have complete Design Failure Analyses; and

I) failed to document CAPA activities for a supplier correction action;

765. The original design for a Class III medical device is the product that is approved by the FDA. This FDA approval includes not only the physical components of the product, but the labeling and intended use of the product as well.

766. Under federal regulations, a product that does not comply with the FDA

approval is considered "adulterated" and/or "misbranded." Under state law, a product that does not comply with the FDA approval is considered a "manufacturing defect." Therefore, any product sold that is not incompliance with the FDA approval is both misbranded and/or adulterated under federal law and a manufacturing defect under State law. Therefore, the same underlying defect and/or actions of the manufacturer that have given rise to a federal violation are also a parallel state violation.

767. Violating the conditions of approval for the FDA approval is another way of saying that the manufacturer violated the original design of the product and therefore creates a viable manufacturing defect claim.

768. There are multiple manufacturing defects in the Essure® device that were implanted into Plaintiffs which caused Plaintiffs' device to migrate and/or break/fracture apart and/or caused Plaintiffs to experience heavy menstrual cycle bleeding and long-term chronic pain amongst other side effects, all which became known to Conceptus and Bayer, including but not limited to:

A) The stainless steel used in the device became unpassivated, which can cause the device to rust;

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 have existed in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;

G) PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;

H) the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body;

I) there was an inadequate solder joint between the inner and outer coils of the micro-insert which can cause the micro-insert to fracture/break apart, and which Conceptus and Bayer admit is or could be a reason for device breakage, and;

J) the central axis was not fully adhered to the spring which can cause the micro- insert to fracture/break apart, and which Conceptus and Bayer admit is or could be a reason for device breakage.

769. The Essure® device implanted in Plaintiffs was not reasonably safe for its intended uses and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Conceptus and Bayer's design and manufacturing specifications in such a manner as to pose unreasonable increased risks of serious bodily harm to Plaintiffs.

770. The Essure® devices manufactured and sold by Conceptus and Bayer and implanted into Plaintiffs were defective in manufacture because they did not comply with Conceptus' and Bayer's own design specifications, used non-conforming material, and deviated from otherwise identical units from the same product line, manufactured with the same specifications.

771. At all times mentioned herein, Conceptus and Bayer placed Essure® on the market and supplied the Essure® device used during Plaintiffs' permanent sterilization procedures.

772. Conceptus and Bayer have a duty to manufacture the Essure® device

consistent with the specifications, requirements, federal regulations, PMA, and/or conditions of approval.

773. At the time the Essure® devices left control of Conceptus and Bayer when they were implanted into Plaintiffs, they were unreasonably dangerous due to non-compliance by both companies with the FDCA, and the regulations promulgated pursuant to it.

B. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES AND IDENTICAL FEDERAL REQUIREMENTS.

774. Conceptus and Bayer breached their identical state and federal duties, as alleged in all prior Counts of this Complaint, and incorporated by reference herein.

775. Since Conceptus and Bayer failed to meet their duties under the above mentioned federal and parallel state laws, Plaintiffs and Plaintiffs' treating physicians did not know and had no reason to know that Essure® was causing Plaintiffs' injuries.

776. As such, Plaintiffs and Plaintiffs' treating physicians could not properly and/or timely diagnose the cause of Plaintiffs' injuries, which caused and/or contributed to Plaintiffs having to endure prolonged and unnecessary pain and suffering.

777. As a direct and proximate result of Defendants' violations of one or more of the above mentioned federal statutory and regulatory standards of care, Essure® was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3.

778. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

NINTH CAUSE OF ACTION
Violation of Kentucky Consumer Protection Law
KRS §§ 367.170 *et seq.*

779. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

780. Conceptus and Bayer had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Essure® product.

781. Conceptus and Bayer engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for Essure® that would not have been paid had Conceptus and Bayer not engaged in unfair and deceptive conduct.

782. Conceptus and Bayer engaged in unfair methods of competition or deceptive acts or practice that were proscribed by law, including the following:

A) Representing that goods or services have characteristic ingredients, uses, benefits or quantities that they do not have;

B) Advertising goods or services with the intent not to sell them as advertised; and

C) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

783. Conceptus and Bayer are the supplier, manufacturer, advertiser, and seller, who is subject to liability under Ky. Rev. Stat. Ann. §§ 367.170 *et seq.* for unfair, deceptive, false, and misleading consumer sales practices.

784. Conceptus' and Bayer's deceptive and fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair, misleading, deceptive or false acts or practices in the conduct of trade or commerce in violation of Ky. Rev. Stat. Ann. §§ 367.170 *et seq.*

785. Conceptus and Bayer violated the state statutes that were enacted to protect consumers against unfair, deceptive, false and misleading trade practices and false advertising, by knowingly and falsely representing that the Essure® product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

786. Conceptus and Bayer had actual knowledge of the defective and unreasonably dangerous condition of Essure® and failed to take any action to cure such defective and dangerous conditions.

787. Plaintiffs were injured by the cumulative and indivisible nature of Conceptus' and Bayer's conduct. The cumulative effect of Conceptus' and Bayer's conduct directed at patients, physicians and consumers was to create demand for and sell Essure®. Each aspect of Conceptus' and Bayer's conduct combined to artificially create sales of Essure®.

788. Plaintiffs purchased and used the Essure® device for personal use and suffered ascertainable losses as a result of Conceptus' and Bayer's actions in violation of Ky. Rev. Stat. Ann. §§ 367.170 *et seq.*

789. Had Conceptus and Bayer not engaged in the deceptive conduct described herein, Plaintiffs' physicians could not have used Essure® and Plaintiffs would not have purchased and/or paid for Essure® and would not have incurred related medical costs and injury.

790. Plaintiffs' physician relied upon Conceptus' and Bayer's misrepresentations and material omissions in determining whether to use Essure®.

791. Bayer's conduct and acts of unfair competition are ongoing and present a continuing threat of harm to the general public.

792. By reason of unlawful acts engaged in by Conceptus and Bayer, and as a direct

and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

793. As a direct and proximate result of Conceptus' and Bayer's violations of the state consumer protection laws cited herein, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

TENTH CAUSE OF ACTION
Product Liability for Reseller of Medical Products
Against PMC

794. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

795. PMC purchased for distribution and sale to all Plaintiffs the Essure® devices.

796. Essure® as sold by PMC was unreasonably dangerous and defective, and failed to perform as safely as an ordinary consumer would expect because its risks outweighed its benefits for the use intended when it was sold to the aforementioned Plaintiffs.

797. PMC knew or should have known at the time of distribution or sale of the Essure® devices that they were defective.

798. Under KRS § 411.340, a hospital is a "middleman" under Kentucky law and thus shielded from products liability unless an exception applies. For the "middleman" defense to apply: (1) the product resold by the middleman must be in its original manufactured condition or package, or in the same condition such product was in when received by said wholesaler, distributor or retailer; (2) the wholesaler, distributor or retailer must not have breached an express warranty, or known or should have known at the time of distribution or sale of such product that the product was in a defective condition, unreasonably dangerous to the user or consumer; and (3) the damages must have arisen solely from distribution or sale of the product.

799. PMC is not entitled to the "middleman" defense because it knew or should have known that the medical device delivered and intended to be used in Plaintiffs' surgeries were in a defective condition, unreasonably dangerous to the user or consumer.

800. Plaintiffs used Essure® in a manner intended and reasonably foreseeable by PMC.

801. Plaintiffs were not aware of the aforementioned defects at any time prior to the injuries caused by Essure®.

802. As a legal and proximate result of the aforementioned defects of Essure®, Plaintiffs have sustained the injuries and damages set forth herein.

803. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

ELEVENTH CAUSE OF ACTION
Medical Negligence
Against PMC

804. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

A. PLAINTIFFS' CLAIMS FOR MEDICAL NEGLIGENCE.

805. By and through its agents, servants and/or employees, ostensible agents, servants and/or employees, PMC undertook a duty to provide appropriate medical care and treatment to Plaintiffs and allowed Essure® to be used in its medical facilities.

806. PMC had a duty to render that degree of medical care that an ordinarily prudent hospital would render in the same or similar circumstances.

807. Prior to their Essure® procedures, PMC, through its agents and employees, failed to inform Plaintiffs that the Essure® device was not an appropriate form of birth control for them. Instead, PMC advocated Essure® over other more appropriate forms of birth control. By failing

to fully inform Plaintiffs of this, PMC deviated from acceptable medical practice by not fully and appropriately informing Plaintiffs of their options.

808. Under KRS § 304.40-320, all "health care providers" have a duty to ensure that a patient gives his or her informed consent for a procedure. PMC breached this duty by failing to appropriately inform Plaintiffs of their options for birth control.

809. In addition, on April 22, 2013, and July 2, 2015, Plaintiffs Newsome and Howell had bilateral salpingectomies. One purpose of these procedures was the removal of the Essure® devices. However, the pathology reports did not show that their devices had been removed.

810. Plaintiffs Newsome and Howell were not informed that their devices had not been completely removed.

811. PMC, in failing to take measures to completely remove the Essure® devices and in failing to inform Plaintiffs Newsome and Howell that they had not been removed, deviated from an acceptable standard of medical care.

812. PMC's failure to conform to the standard of ordinarily prudent health care providers in the same or similar circumstances was a substantial factor in causing Plaintiff Newsome's and Howell's injuries, detailed in this Complaint.

813. Plaintiffs would not have consented to the use of Essure® had they been fully informed of the risks by PMC and its agents.

814. As a proximate result of the negligence and carelessness of the employees, associates, partners, agents, affiliates, contract employees, and/or officers of PMC, Plaintiffs were caused to suffer serious physical and mental pain and anguish, past and future medical and hospital expenses, past and future wage loss, loss of enjoyment of life, increased risk of future harm, and future impairment of Plaintiffs' ability to work and earn money, all in excess of the

jurisdictional limits of this Court.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against all Bayer Defendants and PMC, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages to for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial.

Respectfully submitted,

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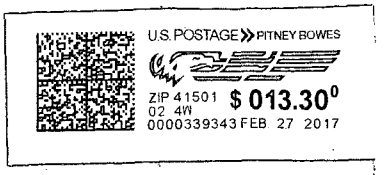
Date: February 24, 2017



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KENTUCKY COURT OF JUSTICE

17-CI-00229

NEWSOME, FRANKIE , ET AL VS. BAYER CORPORATION, , ET AL

PIKE CIRCUIT COURT

Filed on **02/24/2017** as **CONTRACT** with **HON. EDDY COLEMAN**

****** NOT AN OFFICIAL COURT RECORD ******

Parties **17-CI-00229**

BAYER CORPORATION, as **DEFENDANT / RESPONDENT**

Address

100 BAYER RD
BUILDING 4
PITTSBURGH PA 15205

Summons

CIVIL SUMMONS issued on **02/24/2017** served on **03/03/2017** by way of **CERTIFIED MAIL**
SERVE CSC LINDA SMITH

BAYER ESSURE, INC.,, as **DEFENDANT / RESPONDENT**

Address

FKA CONCEPTIUS,INC
100 BAYER ROAD
PITTSBURGH PA 15205

Summons

CIVIL SUMMONS issued on **02/24/2017** served on **03/09/2017** by way of **CERTIFIED MAIL**
SERVE CSC THROUGH SOS SERVED 3-2-17

BAYER HEALTHCARE LLC, as **DEFENDANT / RESPONDENT**

Address

100 BAYER BLVD.
WHIPPANY NJ 07981

Summons

CIVIL SUMMONS issued on **02/24/2017** served on **03/03/2017** by way of **CERTIFIED MAIL**
LINDA SMITH SERVE CSC

BAYER HEALTHCARE PHARMACEUTICALS INC, as **DEFENDANT / RESPONDENT**

Address

100 BAYER BLVD
WHIPPANY NJ 07981

Summons

CIVIL SUMMONS issued on **02/24/2017** served on **03/03/2017** by way of **CERTIFIED MAIL**
LINDA A SMITH SERVE CSC

HWELL, KIMBERLY as **PLAINTIFF / PETITIONER**

NEWSOME, FRANKIE as **PLAINTIFF / PETITIONER**

PIKEVILLE MEDICAL CENTER, INC., as **DEFENDANT / RESPONDENT**

Address

911 BYPASS ROAD
PIKEVILLE KY 41501

Summons

CIVIL SUMMONS issued on **02/27/2017** served on **02/27/2017** by way of **RETURNED TO ATTORNEY/PETITIONER**
CIVIL SUMMONS issued on **02/24/2017** served on **03/03/2017** by way of **CERTIFIED MAIL**
SERVE PAMELA TODD MAY

VARNEY, STACEY as **PLAINTIFF / PETITIONER**

JOHNSON, GARY C., as **ATTORNEY FOR PLAINTIFF**

Address

P O BOX 231
PIKEVILLE KY 41501

Documents	17-CI-00229
ANSWER filed on **03/17/2017** *TO PLAINTIFFS COMPLAINT ON BEHALF OF DEFENDANT PIKEVILLE MEDICAL CENTER INC*	
CERTIFICATE OF MAILING filed on **02/27/2017** *BAYER HEALTHCARE CSC*	
CERTIFICATE OF MAILING filed on **02/27/2017** *BAYER CORP CSC*	
CERTIFICATE OF MAILING filed on **02/27/2017** *PIKE MED PAM MAY*	
CERTIFICATE OF MAILING filed on **02/27/2017** *SOS BAYER ESSURE INC.*	
CERTIFICATE OF MAILING filed on **02/27/2017** *BAYER HEALTHCARE CSC*	
COMPLAINT / PETITION filed on **02/24/2017**	

Images	17-CI-00229
There are no images found for this case.	

****** End of Case Number : 17-CI-00229 ******

Alison Lundergan Grimes
Secretary of State

Commonwealth of Kentucky
Office of the Secretary of State

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Pike County
PO Box 1002
Pikeville, KY 41502-1002

FROM: SUMMONS DIVISION
SECRETARY OF STATE

RE: CASE NO: 17-CI-229

DEFENDANT: **BAYER ESSURE, INC.**
F/K/A CONCEPTUS, INC.

DATE: March 13, 2017

USPS Certified Mail ID: 71922677001002349103

The Office of the Secretary of State was served with a summons and accompanying documents for the captioned defendant on

March 2, 2017

This office served the defendant by sending a copy of the summons and accompanying documents via certified mail, return receipt requested, on

March 2, 2017

The US Postal Service has provided a scanned image of the return receipt confirming receipt of summons. The image is provided to the right of this page.

UNITED STATES POSTAL SERVICE.

Date Produced: 03/13/2017

KENTUCKY SECRETARY OF STATES OFFICE - COMMONWEALTH:

The following is the delivery information for Certified Mail™ item number 7192 2677 0010 0234 9103. Our records indicate that this item was delivered on 03/09/2017 at 02:10 p.m. in WILMINGTON, DE 19808. The scanned image of the recipient information is provided below.

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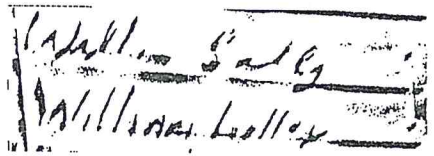
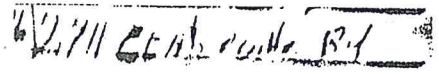


Address of Recipient :



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United States Postal Service

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1. Article Addressed to: 17-CI-229

Bayer Corp.

Corporation Service Company
421 West Main Street
Frankfort, Ky 40601

9590 2140 0000 5787 0541

2. Article Number *(Transfer from service label)*

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X Lindsay A. Smith ☐ Agent ☐ Addressee

B. Received by *(Printed Name)* C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
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3. Service Type
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1. Article Addressed to: 17-CI-229

Bayer essure Inc

Secretary of State
P.O. Box 718
Frankfort, Ky 40601

2. Article Number (Transfer from service label)
9590 9402 2140 0000 5787 0480

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A. Signature
X Brian E Howard
BRIAN HOWARD
☐ Agent
☐ Addressee

B. Received by (Printed Name) MAR 0 2 2017 C. Date of Delivery

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FILED
ANNA PINSON SPEARS
MAR 07 2017
PIKE CIRCUIT/DISTRICT COURT
BY: D.C.

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1. Article Addressed to: 17-CI-229

Bayer healthcare

Corporation Service Company
421 West Main Street
Frankfort, Ky 40601

9590 9402 2140 0000 5787 0497

2. Article Number (Transfer from service label)

PS Form 3811, July 2015 PSN 7530-02-000-9053

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☐ Agent
☐ Addressee

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Domestic Return Receipt

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BY: D.C.

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1. Article Addressed to: 17-CI-229
Bayer Healthcare Pharm. Inc

Corporation Service Company
421 West Main Street
Frankfort, Ky 40601

9590 9402 2140 0000 5787 0534

2. Article Number *(Transfer from service label)*

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☐ Addressee

B. Received by *(Printed Name)*
C. Date of Delivery

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FRANKFORT KY 40601 APR 27 2017 USPS

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1. Article Addressed to: 17-CI-229

Pike Med. Center
Pamela Todd May
127 Park St.
Pikeville Ky 41501

9116 2140 0000 5787 0473

2. Article Number *(Transfer from service label)*

COMPLETE THIS SECTION ON DELIVERY

A. Signature
* Pamela T. May ☐ Agent ☐ Addressee

B. Received by *(Printed Name)* Pamela T. May C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

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ANNA PINSON SPEARS
MAR 03 2017
PIKE CIRCUIT/DISTRICT COURT
BY: D.C.

AOC-105 Rev. 4-01 Page 1 of 1 Doc. Code: CI 02/27/2017 03:52 pm Ver. 1.01 Commonwealth of Kentucky Court of Justice CR 4.02; CR Official Form 1	**CIVIL SUMMONS**	Case No. 17-CI-229 Court ☑ Circuit ☐ District County Pike

PLAINTIFF

FRANKIE NEWSOME, KIMBERLY HOWELL,
STACEY VARNEY

FILED
ANNA PINSON SPEARS
FEB 28 2017
PIKE CIRCUIT/DISTRICT COURT
D.C.

VS.

DEFENDANT

BAYER CORPORATION, ET AL

Service of Process Agent for Defendant:

SERVE: PIKEVILLE MEDICAL CENTER, INC.
THROUGH ITS AGENT: PAMELA TODD MAY
127 PARK STREET
PIKEVILLE, KY 41501

THE COMMONWEALTH OF KENTUCKY
TO THE ABOVE-NAMED DEFENDANT(S):

You are hereby notified a **legal action has been filed against you** in this Court demanding relief as shown on the document delivered to you with this Summons. **Unless a written defense is made by you or** by **an attorney on your behalf** and filed in the Clerk's Office within 20 days following the day this paper is delivered to you, judgment by default may be taken against you for the relief demanded in the attached Complaint.

The name(s) and address(es) of the party or parties demanding relief against you are shown on the document delivered to you with this Summons.

Date: 2-27, 2017

Anna Pinson Spears Clerk

By: D Thacker D.C.

I accept Service.
Jacqueline Calame

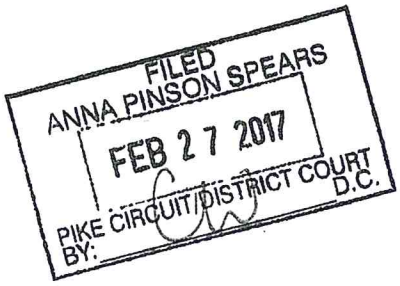
Proof of Service

This Summons was served by delivering a true copy and the Complaint (or other initiating document) to:

Serve Pikeville Medical Center INC

this 27 day of February 017

Served by: Mark Hamm



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Street

City,

Bayer Healthcare Pharma. In

Corporation Service Company
421 West Main Street
Frankfort, Ky 40601

PS Form 3800, April 2015 PSN 7530-02-000-9047 See Reverse for Instructions


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ANNA PINSON SPEARS
FEB 27 2017
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421 West Main Street
Frankfort, Ky 40601
7016 2140 0000 5787 0541
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$ Pike Med.

Total Postage and Fees
$ Pam May.

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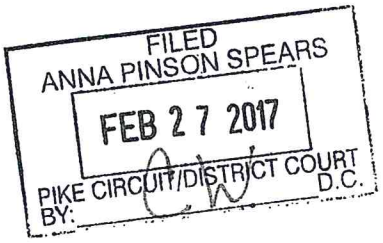
Sent To 127 Park Street

Street and Apt. No., or PO Box No.

City, State, ZIP+4® Pikeville Ky 41501

PS Form 3800, April 2015 PSN 7530-02-000-9047 See Reverse for Instructions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P.O. Box 718
Frankfort, Ky 40601
PS Form 3800, April 2015 PSN 7530-02-000-9047
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Corporation Service Company
421 West Main Street
Frankfort, Ky 40601

PS Form 3800, April 2015 PSN 7530-02-000-9047 See Reverse for Instructions

COMMONWEALTH OF KENTUCKY
PIKE CIRCUIT COURT
DIVISION NO. I

CIVIL ACTION NO. 17-CI-229

FRANKIE NEWSOME,
KIMBERLY HOWELL, and **PLAINTIFFS**
STACEY VARMEY

VS.

BAYER CORPORATION, **DEFENDANTS**
BAYER HEALTHCARE, LLC,
BAYER ESSURE, INC., (F/K/A CONCEPTUS, INC.,
BAYER HEALTHCARE PHARMACEUTICALS, INC.,
And PIKEVILLE MEDICAL CENTER, INC.,

****

ANSWER TO PLAINTIFFS' COMPLAINT
ON BEHALF OF DEFENDANT
PIKEVILLE MEDICAL CENTER, INC.

****

Comes the Defendant, Pikeville Medical Center, Inc., by and through counsel, and for its Answer to the Plaintiffs' Complaint, states as follows:

FIRST DEFENSE

The Plaintiffs' Complaint fails to state a claim against this Defendant upon which relief can or should be granted, and therefore, the Plaintiffs' Complaint should be dismissed.

SECOND DEFENSE

1. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 1-64 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

2. This Defendant **ADMITS** the allegations contained in numerical paragraph 65 of the Plaintiffs' Complaint.

3. In response to numerical paragraph 66 of the Plaintiffs' Complaint, this Defendant **ADMITS** that it provides medical professional services, including obstetrics and gynecological services, but lacks sufficient information or knowledge to admit or deny the remaining allegations contained in numerical paragraph 66, and therefore, **DENIES** same.

4. This Defendant lacks sufficient information to admit or deny the allegations contained in numerical paragraphs 67 and 68 of the Plaintiffs' Complaint as "at all times relevant herein" is not defined and no specific physician is identified, and therefore, **DENIES** same.

5. In response to numerical paragraph 69 of the Plaintiffs' Complaint, this Defendant **DENIES** that it has ostensible agents. This Defendant lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 69 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

6. This Defendant **DENIES** the allegations contained in numerical paragraph 70 of the Plaintiffs' Complaint to the extent said allegations are directed at it. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 70 of the Plaintiffs' Complaint, to the extent said allegations are directed at other defendants, and therefore, **DENIES** same.

7. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 71 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

8. This Defendant **DENIES** the allegations contained in numerical paragraphs 72 and 73 of the Plaintiffs' Complaint to the extent said allegations are directed at it. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 72 and 73 of the Plaintiffs' Complaint, to the extent said allegations are directed at other defendants, and therefore, **DENIES** same.

9. In response to numerical paragraph 74 of the Plaintiffs' Complaint, this Defendant **DENIES** that it committed torts in whole or in part against the Plaintiffs. This Defendant **ADMITS** that it is a Kentucky Corporation providing medical services in the Commonwealth of Kentucky. This Defendant lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 74 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

10. In response to numerical paragraph 75 of the Plaintiffs' Complaint, PMC **ADMITS** that it does business in the Commonwealth Kentucky but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 75, and therefore, **DENIES** same.

11. This Defendant **DENIES** the allegations contained in numerical paragraph 76 of the Plaintiffs' Complaint.

12. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 77 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

13. This Defendant states that numerical paragraphs 78 through 330 and relevant exhibits and/or referenced articles labeled "Facts" in the Plaintiffs' Complaint do not contain allegations to which a response is required, but, to the extent that said paragraphs

are construed otherwise, this Defendant is, at this time, without sufficient knowledge or information as to the truthfulness of the allegations contained therein, and therefore, **DENIES** same.

14. In response to numerical paragraph 331 of the Plaintiffs' Complaint, this Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-330.

15. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 332-341 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

16. In response to numerical paragraph 342 of the Plaintiffs' Complaint, this Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-341.

17. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 343-357 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

18. This Defendant **DENIES** the allegations contained in numerical paragraphs 358-360 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 358-360 as to other parties named in suit, and therefore, **DENIES** same.

19. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 361-362 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

20. This Defendant **DENIES** the allegations contained in numerical paragraph 363 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 363 as to other parties named in suit, and therefore, **DENIES** same.

21. This Defendant **ADMITS** the allegations contained in numerical paragraph 364 of the Plaintiffs' Complaint.

22. In response to numerical paragraph 365 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Dr. Hobbs implanted the Essure Device but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 365 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

23. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 366-368 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

24. This Defendant **ADMITS** the allegations contained in numerical paragraph 369 of the Plaintiffs' Complaint.

25. In response to numerical paragraphs 370-372, this Defendant **ADMITS** that Plaintiff was treated on the dates referenced and asserts that the medical record speaks for itself. This Defendant lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraphs 370-372 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

26. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 373-375 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

27. In response to numerical paragraph 376 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Plaintiff Newsome had an appointment on November 1, 2013, not November 11, 2013 but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 376, and therefore, **DENIES** same.

28. In response to numerical paragraph 377 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Plaintiff Newsome had an appointment on November 22, 2013, but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 377, and therefore, **DENIES** same.

29. This Defendant **ADMITS** the allegations contained in numerical paragraph 378 of the Plaintiffs' Complaint.

30. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 379-380 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

31. In response to numerical paragraph 381 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Plaintiff Newsome had an appointment on October 11, 2016, but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 381, and therefore, **DENIES** same.

32. In response to numerical paragraph 382, this Defendant **ADMITS** that Plaintiff was treated on October 11, 2016 and asserts that the medical record speaks for

itself. This Defendant lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 382 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

33. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 383-384 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

34.This Defendant **ADMITS** the allegations contained in numerical paragraph 385 of the Plaintiffs' Complaint.

35. In response to numerical paragraphs 386-387 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Dr. Hobbs implanted the Essure Device but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraphs 386-387 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

36. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 388-389 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

37. This Defendant **ADMITS** the allegations contained in numerical paragraph 390 of the Plaintiffs' Complaint.

38. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 391-392 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

39. In response to numerical paragraph 393 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Plaintiff Howell had an appointment on December 12, 2014,

but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 393, and therefore, **DENIES** same.

40. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 394-397 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

41. This Defendant **ADMITS** the allegations contained in numerical paragraph 398 of the Plaintiffs' Complaint.

42. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 399-407 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

43. In response to numerical paragraph 408 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Plaintiff Varney had a visit on April 12, 2012, but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 408, and therefore, **DENIES** same.

44. In response to numerical paragraph 409 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Plaintiff Newsome had an appointment on April 24, 2012, but lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 409, and therefore, **DENIES** same.

45. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 410-418 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

46. This Defendant notes that the copy of the Plaintiffs' Complaint served upon it does not contain any paragraphs numbered 419-437. To the extent such paragraphs may

exist, this Defendant lacks sufficient information to admit or deny the allegations contained within, and therefore, **DENIES** same.

47. This Defendant **DENIES** the allegations contained in numerical paragraphs 438-445 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 438-445 as to other parties named in suit, and therefore, **DENIES** same.

48. This Defendant **DENIES** the allegations contained in numerical paragraph 446 of the Plaintiffs' Complaint.

49. This Defendant **DENIES** the allegations contained in numerical paragraph 447 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 447 as to other parties named in suit, and therefore, **DENIES** same.

50. In response to numerical paragraph 448 of the Plaintiffs' Complaint, this Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-447.

51. This Defendant **DENIES** the allegations contained in numerical paragraph 449 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 449 as to other parties named in suit, and therefore, **DENIES** same.

52. In response to numerical paragraph 450 of the Plaintiffs' Complaint, this Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-449.

53. This Defendant **DENIES** the allegations contained in numerical paragraphs 451-516 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 451-516 as to other parties named in suit, and therefore, **DENIES** same.

54. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 517 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

55. This Defendant **DENIES** the allegations contained in numerical paragraphs 518-537 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 518-537 as to other parties named in suit, and therefore, **DENIES** same.

56. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 538 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

57. This Defendant **DENIES** the allegations contained in numerical paragraphs 539-540 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or

deny the allegations contained in numerical paragraphs 539-540 as to other parties named in suit, and therefore, **DENIES** same.

58. In response to numerical paragraph 541 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-540.

59. This Defendant **DENIES** the allegations contained in numerical paragraphs 542-600 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 542-600 as to other parties named in suit, and therefore, **DENIES** same.

60. This Defendant **DENIES** that lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 601 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

61. This Defendant **DENIES** the allegations contained in numerical paragraph 602 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant **DENIES** that lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 602 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

62. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 603-605 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

63. This Defendant **DENIES** the allegations contained in numerical paragraph 606 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at

Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 606 as to other parties named in suit, and therefore, **DENIES** same.

64. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 607-608 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

65. This Defendant **DENIES** the allegations contained in numerical paragraphs 609-610 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 609-610 as to other parties named in suit, and therefore, **DENIES** same.

66. In response to numerical paragraph 611 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-610.

67. This Defendant **DENIES** the allegations contained in numerical paragraphs 612-650 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 612-650 as to other parties named in suit, and therefore, **DENIES** same.

68. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 651 and 652 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

69. This Defendant **DENIES** the allegations contained in numerical paragraphs 653-656 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 653-656 as to other parties named in suit, and therefore, **DENIES** same.

70. In response to numerical paragraph 657 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-656.

71. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 658 of the Plaintiffs' Complaint, and therefore, **DENIES** same

72. In response to numerical paragraph 659 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in the Second Cause of Action, Section A of the Plaintiffs' Complaint.

73. This Defendant **DENIES** the allegations contained in numerical paragraphs 660-668 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 660-668 as to other parties named in suit, and therefore, **DENIES** same.

74. In response to numerical paragraph 669 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in the Second Cause of Action, Section D of the Plaintiffs' Complaint.

75. This Defendant **DENIES** the allegations contained in numerical paragraph 670 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 670 as to other parties named in suit, and therefore, **DENIES** same.

76. In response to numerical paragraph 671 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in the Second Cause of Action, section D(1) of the Plaintiffs' Complaint.

77. This Defendant **DENIES** the allegations contained in numerical paragraphs 672-674 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 672-674 as to other parties named in suit, and therefore, **DENIES** same.

78. In response to numerical paragraph 675 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in the Second Cause of Action, section D(2) of the Plaintiffs' Complaint.

79. This Defendant **DENIES** the allegations contained in numerical paragraph 676 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 676 as to other parties named in suit, and therefore, **DENIES** same.

80. In response to numerical paragraph 677 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in the Second Cause of Action, section D(3) of the Plaintiffs' Complaint.

81. This Defendant **DENIES** the allegations contained in numerical paragraphs 678-680 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 678-680 as to other parties named in suit, and therefore, **DENIES** same.

82. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 681-684 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

83. This Defendant **DENIES** the allegations contained in numerical paragraph 685 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 685 as to other parties named in suit, and therefore, **DENIES** same.

84. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 686-689 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

85. This Defendant **DENIES** the allegations contained in numerical paragraph 690 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or

deny the allegations contained in numerical paragraphs 690 as to other parties named in suit, and therefore, **DENIES** same.

86. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 691 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

87. In response to numerical paragraph 692 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-691.

88. This Defendant **DENIES** the allegations contained in numerical paragraphs 693-703 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 693-703 as to other parties named in suit, and therefore, **DENIES** same.

89. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 704-709 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

90. This Defendant **DENIES** any allegations of negligence or wrong doing implied or inferred by numerical paragraph 710 of the Plaintiffs' Complaint. This Defendant lacks sufficient knowledge to admit or deny the remaining allegations contained in numerical paragraph 710.

91. This Defendant **DENIES** the allegations contained in numerical paragraph 711 of the Plaintiffs' Complaint.

92. This Defendant **DENIES** the allegations contained in numerical paragraph 712 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 712 as to other parties named in suit, and therefore, **DENIES** same.

93. In response to numerical paragraph 713 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-712.

94. This Defendant **DENIES** the allegations contained in numerical paragraphs 714-731 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 714-731 as to other parties named in suit, and therefore, **DENIES** same.

95. In response to numerical paragraph 732 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-731.

96. This Defendant **DENIES** the allegations contained in numerical paragraph 733 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 733 as to other parties named in suit, and therefore, **DENIES** same.

97. In response to numerical paragraph 734 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in the Second Cause of Action, section D(1-3) of the Plaintiffs' Complaint.

98. This Defendant **DENIES** the allegations contained in numerical paragraph 735-736 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 735-736 as to other parties named in suit, and therefore, **DENIES** same.

99. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 737-738 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

100. This Defendant **DENIES** the allegations contained in numerical paragraphs 739-741 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 739-741 as to other parties named in suit, and therefore, **DENIES** same.

101. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 742-743 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

102. This Defendant **DENIES** the allegations contained in numerical paragraph 744 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or

deny the allegations contained in numerical paragraph 744 as to other parties named in suit, and therefore, **DENIES** same.

103. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 745 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

104. In response to numerical paragraph 746 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-745.

105. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 747-749 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

106. This Defendant **DENIES** the allegations contained in numerical paragraph 750 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraph 750 as to other parties named in suit, and therefore, **DENIES** same.

107. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 751-756 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

108. This Defendant **DENIES** the allegations contained in numerical paragraphs 757-764 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or

deny the allegations contained in numerical paragraphs 757-764 as to other parties named in suit, and therefore, **DENIES** same.

109. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 765-768 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

110. This Defendant **DENIES** the allegations contained in numerical paragraphs 769-771 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 769-771 as to other parties named in suit, and therefore, **DENIES** same.

111. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 772 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

112. This Defendant **DENIES** the allegations contained in numerical paragraphs 773 and 774 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 773 and 774 as to other parties named in suit, and therefore, **DENIES** same.

113. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 775-776 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

114. This Defendant **DENIES** the allegations contained in numerical paragraphs 777-778 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed

at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 777-778 as to other parties named in suit, and therefore, **DENIES** same.

115. In response to numerical paragraph 779 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-778.

116. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 780 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

117. This Defendant **DENIES** the allegations contained in numerical paragraphs 781-788 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 781-788 as to other parties named in suit, and therefore, **DENIES** same.

118. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraphs 789-790 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

119. This Defendant **DENIES** the allegations contained in numerical paragraphs 791-793 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 791-793 as to other parties named in suit, and therefore, **DENIES** same.

120. In response to numerical paragraph 794 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-793.

121. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 795 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

122. This Defendant **DENIES** the allegations contained in numerical paragraphs 796-797 of the Plaintiffs' Complaint.

123. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 798 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

124. This Defendant **DENIES** the allegations contained in numerical paragraph 799 of the Plaintiffs' Complaint.

125. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 800-801 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

126. This Defendant **DENIES** the allegations contained in numerical paragraphs 802-803 of the Plaintiffs' Complaint to the extent, if any, that said allegations are directed at Pikeville Medical Center, Inc. This Defendant lacks sufficient knowledge to admit or deny the allegations contained in numerical paragraphs 802-803 as to other parties named in suit, and therefore, **DENIES** same.

127. In response to numerical paragraph 804 of the Plaintiffs' Complaint, Defendant reincorporates its answers to the allegations contained in numerical paragraphs 1-803.

128. In response to numerical paragraph 805 of the Plaintiffs' Complaint, this Defendant **ADMITS** that Essure® was used in its facility. This Defendant **DENIES** that it has ostensible agents. Additionally, this Defendant **ADMITS** numerical paragraph 805 of the Plaintiffs' Complaint to the extent it states that this Defendant owed a duty to the Plaintiffs to exercise the degree of care and skill ordinarily expected of a reasonable and prudent hospital acting under similar circumstances while providing care. To the extent that numerical paragraph 805 is interpreted in any other way, this Defendant **DENIES** same. This Defendant lacks sufficient knowledge or information to admit or deny the remaining allegations contained in numerical paragraph 805 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

129. This Defendant **ADMITS** numerical paragraph 806 of the Plaintiffs' Complaint to the extent it states that this Defendant owed a duty to the Plaintiffs to exercise the degree of care and skill ordinarily expected of a reasonable and prudent hospital acting under similar circumstances while providing care. To the extent that numerical paragraph 806 is interpreted in any other way, this Defendant **DENIES** same.

130. This Defendant **DENIES** the allegations contained in numerical paragraphs 807 and 808 of the Plaintiffs' Complaint.

131. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 809-810 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

132. This Defendant **DENIES** the allegations contained in numerical paragraph 811-812 of the Plaintiffs' Complaint.

133. This Defendant lacks sufficient knowledge or information to admit or deny the allegations contained in numerical paragraph 813 of the Plaintiffs' Complaint, and therefore, **DENIES** same.

134. This Defendant **DENIES** the allegations contained in numerical paragraph 814 of the Plaintiffs' Complaint.

135. Except as specifically admitted herein, this Defendant **DENIES** each, every, and all allegations contained in the Plaintiffs' Complaint.

THIRD DEFENSE

1. The Plaintiffs may be guilty of negligence that caused, contributed to, or helped bring about the alleged damages, but for which negligence or damages complained of, if any, would not have occurred.

2. The damages complained of by the Plaintiffs, if any, were caused and brought about by superseding and/or intervening cause or causes out of the control of this Defendant and for which this Defendant is not liable, and this Defendant pleads and relies upon the same as a complete bar to any recovery herein.

3. This Defendant denies that the Plaintiffs were damaged, but, if so, it was through the actions or omissions of others for which this Defendant is not liable. This Defendant is entitled to an apportionment of liability.

4. This action is barred by the applicable statute of limitations and/or the doctrine(s) of waiver, estoppel, and laches.

5. The Plaintiffs herein are barred from recovery, either in whole or in part, by reason of failure to mitigate damages.

6. Any claim by Plaintiffs for punitive damages is in violation of and is barred by the due process clause contained in Section 14 of the Constitution of Kentucky, and by the Fifth and Fourteenth Amendments to the United States Constitution.

7. Any claim by Plaintiffs for punitive damages is in violation of and is barred by the equal protection clause of Sections 2 and 3 *et. seq.* of the Constitution of Kentucky, and by the Fourteenth Amendment to the United States Constitution.

8. Any claim by Plaintiffs for punitive damages is in violation of and is barred by the prohibitions against excessive fines and cruel and unusual punishment contained in the Eighth Amendment to the United States Constitution as set forth in Cooper v. Leatherman Tool Group, Inc., 532 US 424 (2001), and otherwise.

9. The Plaintiffs' Complaint fails to allege facts sufficient to support an award of punitive damages under KRS § 411.184, and in addition, Plaintiffs are not allowed to recover punitive damages from this Defendant as a matter of law.

10. The Plaintiffs herein are barred from recovery from this Defendant pursuant to KRS § 411.340.

11. This Defendant denies that the Plaintiffs were damaged but, if so, the Plaintiffs assumed the risk of the damages complained of.

12. Plaintiffs' claims are barred by any other matter constituting an avoidance or affirmative defense as may be discovered through the course of litigation.

13. The Defendant reserves the right to assert additional defenses that discovery may disclose as appropriate.

WHEREFORE, the Defendant, **Pikeville Medical Center, Inc.** by and through counsel, demands as follows:

1. The Complaint be dismissed and that the Plaintiffs take nothing thereby in any capacity;

2. For reasonable attorney fees and costs expended herein;

3. For apportionment of liability;

4. For trial by jury; and

5. For any and all relief to which the Defendant appears entitled.

Respectfully submitted,

East Kentucky Law Group, P.S.C
127 Park Street
P.O. Box 1439
Pikeville, Kentucky 41502
Telephone: (606) 432-0400
Telefax: (606) 432-9139

By: _____
Pamela T. May
Miranda D. Click

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing was duly mailed this 14th day of March, 2017, to the following:

Gregory J. Bubalo, Esq.
Leslie M. Cronen, Esq.
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BY: Miranda D. Click
Pamela T. May
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