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THIS IS A MAJOR JURY MATTER

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HEATHER WALSH, 26556 Clarkston Drive Bonita Springs, FL 34135 Plaintiff, vs. BAYER, CORP. 509 Union St. Perkasie, PA 18944 Defendant.	IN THE COURT OF COMMON PLEAS PHILADELPHIA COUNTY TERM, 2013 NO.

NOTICE TO DEFEND

NOTICE	AVISO
You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint of for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you. ***You should take this paper to your lawyer at once. If you do not have a lawyer or cannot afford one, go to or telephone the office set forth below to find out where you can get legal help.*** **Philadelphia Bar Association** **Lawyer Referral** **and Information Service** **One Reading Center** **Philadelphia, Pennsylvania 19107** **(215) 238-6333** **TTY (215) 451-6197**	**Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decider a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.** ***Lleve esta demanda a un abogado immediatamente. Si no tiene abogado o si no tiene el dinero suficiente de pagar tal servicio. Vaya en persona o llame por telefono a la oficina cuya direccion se encuentra escrita abajo para averiguar donde se puede conseguir asistencia legal.*** Asociacion De Licenciados **De Filadelfia** **Servicio De Referencia E** **Informacion Legal** **One Reading Center** **Filadelfia, Pennsylvania 19107** **(215) 238-6333**

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CIVIL ACTION COMPLAINT
20-OTHER PERSONAL INJURY

AND NOW COMES the PLAINTIFF, HEATHER WALSH, ("Walsh" or "Plaintiff"), by and through undersigned counsel, files this Complaint against Defendant, BAYER CORP. ("Bayer" or "Defendant") and in support thereof makes the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, Walsh, is a citizen of Florida.

2. Defendant is a for-profit corporation incorporated in the state of Indiana with its principal place of business in the Commonwealth of PA and does business at 509 Union St. Perkasie PA 18944. Defendant is authorized to do business throughout the Commonwealth of PA.

3. Venue is proper in Philadelphia County under Pa. R. C. P. 2170(a)(2) and (3) because Defendant regularly conducts business in Philadelphia County.

INTRODUCTION

4. This Complaint is brought by Plaintiff who relied on express warranties of Defendant before being implanted with a female birth control device, known as "Essure." As a result of (1) Defendant's negligence described *infra and* (2) her reliance on Defendant's warranties, Defendant's Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

5. Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, this CPMA became "invalid" and the product "adulterated" **pursuant to the FDA**[1] due to Defendant's failure to comply with the CPMA order. As a result, Defendant's CPMA is "invalid" and its "adulterated" product, Essure, should never have been marketed or sold to Plaintiff.

6. Plaintiff's first cause of action has nothing to do with the product itself, but

1 All Emphasis is supplied in this Complaint.

rather Defendant's negligence in (1) failing to adequately train Plaintiff's implanting physician ("the implanting physician"); (2) entrusting the implanting physician with specialized hysteroscopic equipment he was not qualified to use, and (3) distributing its product in an unreasonably dangerous manner, as fully discussed below.

7. The training, entrustment of specialized hysteroscopic equipment to the implanting physician, and method of distribution did not have CPMA by the FDA.

8. Plaintiff's second cause of action is based entirely on the express warranties made by Defendant to Plaintiff, which were relied upon by Plaintiff prior to having the device implanted. Under Pennsylvania law, Plaintiff's claims for breach of express warranties are not preempted by the Medical Device Act ("MDA").. *Rosci v Acromed, Inc.*, 447 Pa. Super. 403 (1995); *Bentzley v Medtronic, Inc.*, 2011 U.S. Dist. Lexis 136570 (E.D. Pa. Nov. 28, 2011).

9. Notwithstanding, the fact that Plaintiff's two causes of action **fall outside the purview of the MDA**¸ Defendant's CPMA is "invalid" and Essure is an "adulterated" product per the FDA.

10. In short, according to the FDA, the CPMA order became invalid because Defendant failed to comply with any of the following express conditions:

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

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

11. The fact that Defendant failed to comply with these conditions is not a mere allegation made by Plaintiff. It is an **FDA finding**.

12. As discussed in detail *infra*, Defendant was **cited by the FDA** and the **Department**

of Health for (1) **failing to report and actively concealing 8 perforations which occurred as a result of Essure**; (2) erroneously using non-conforming material in the manufacturing of Essure; (3) failing to use pre-sterile and post-sterile cages; (4) manufacturing Essure at an unlicensed facility and (5) manufacturing Essure for three years without a license to do so.

13. These violations invalidated the CPMA, rendered the product "adulterated"- precluding Defendant from marketing or selling Essure per the FDA, and, more importantly endangered the life of Plaintiff and the safety of the public.

14. Defendant actively concealed these violations and never advised Plaintiff of the same. Had Plaintiff known that **Defendant was concealing adverse reactions, not using conforming material approved by the FDA, not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license to do the same**, she never would have had Essure implanted.

DESCRIPTION OF ESSURE AND HOW IT WORKS

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

16. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use. *See Exhibit "A" for a description of Essure.*

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

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

19. The coils are comprised of nickel, steel, nitinol, and PET fibers.

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

21. After placement of the coils in the fallopian tubes by Defendant's disposable delivery system, the micro-inserts expand upon release and anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

22. The coils are alleged to remain securely in place in the fallopian tubes for the life of the consumer and do not migrate.

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

24. Regardless of the Confirmation Test, Defendant also warrants that Essure allows for visual confirmation of each insert's proper placement both **during the procedure**.

25. Essure was designed, manufactured, and marketed to be used by gynecologists throughout the world, as a **"quick and easy"** outpatient procedure and without anesthesia.

EVOLUTION OF ESSURE

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

27. Conceptus and Bayer merged on or about April 28, 2013.

28. For purposes of this lawsuit, Conceptus and Bayer are one in the same.

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

30. Defendant also trained physicians on how to use its device and other hysteroscopic equipment, including Plaintiff's implanting physician.

31. Prior to the sale of Conceptus to Bayer, Conceptus obtained CPMA for Essure.

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

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

34. An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.

35. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate

FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission.

36. According to the FDA, a class III device that **fails to meet CPMA requirements** is considered to be **adulterated under section 501(f)** of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") **and cannot be marketed.**

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

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

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

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

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

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

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

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

(f) Warranties are consistent with applicable Federal and State law.

40. Although failure to comply with just *one* of the conditions invalidated the CPMA Order, Defendant failed to comply with *several* conditions; thereby invalidating the CPMA pursuant to the very language of the CPMA order. Specifically:

(a) Defendant failed to timely provide the FDA with reports after 12 months, 18 months and then a final report. All reports failed to meet the respective deadlines. *Post approval Studies- ESS-305 Schedule attached as Exhibit "B."*

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

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

(d) Defendant failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendant **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached as Exhibit "C."*

(e) As outlined in "Facts and Warranties" *infra*, Defendant's warranties were not truthful, accurate, and not misleading.

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

41. By failing to comply with several CPMA conditions, Essure is also considered to be an "**adulterated"** device under section 501(f) of the FD&C Act **and cannot be marketed per the FDA.** However, Defendant continued to market the product to Plaintiff.

42. The CPMA also required Defendant to comply with Sections 502(q) and (r) of the FD&C Act which **prohibits Defendant from offering Essure "for sale** in any State, if its advertising is false or misleading."

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

43. Defendant violated Sections 502(q) by falsely and misleadingly advertising the product as described below under "Facts and Warranties." However, Defendant continued to sell its product against the CPMA with misleading and false advertising.

44. Lastly, per the FDA, "a PMA may be sold to another company" however "The sponsor **must submit a PMA amendment** to notify the FDA of the new owner…The… supplement should include: the effective date of the ownership transfer; a statement of the new owner's commitment to comply with all the conditions of approval applicable to the PMA; and either a statement that the new owner has a complete copy of the PMA including all amendments, supplements, and reports or a request for a copy from the FDA files."

45. There were 36 PMA supplements filed with the FDA in regard to Essure (P020014). **None of the PMA supplements included notification of the new owner** (Bayer).

46. In short, notwithstanding the fact that Plaintiff's claims fall outside the purview of the MDA, (1) the CPMA is invalid **per the FDA**; (2) Essure is considered an "adulterated" product that cannot be marketed or sold **per the FDA**; and (3) the invalid CPMA was not properly transferred to Bayer and, therefore, Defendant does not have any form of PMA for Essure.

DEFENDANT'S TRAINING, ENTRUSTMENT, AND DISTRIBUTION PLAN

47. Defendant (1) failed to adequately train the implanting physician on how to use its delivery system and the hysteroscopic equipment manufactured by a third party; (2) provided specialized hysteroscopic equipment to the implanting physician who was not qualified or competent to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiff's safety and well-being.

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

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

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

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

52. Defendant provided no training to the implanting physician on how *to remove* Essure should it migrate.

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

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

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

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

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

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

59. Defendant knew or failed to recognize that the implanting physician was not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physician in order to capture the market.

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

61. Defendant's distribution plan included requiring the implanting physician to purchase two (2) Essure "kits" per month**, regardless of whether he used them or not.** This distribution plan created an environment which induced the implanting physician to "push" Essure and implant the same into Plaintiff.

62. In short, Defendant used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as "bait." Once the implanting physician "took the bait" he was required to purchase 2 Essure "kits" per month, regardless of whether he sold any Essure "kits".

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

64. Defendant's distribution plan also included (1) negligently distributing Essure against FDA order and sections 501(f), 502(q) and (r) of the FD&C Act by marketing and selling an adulterated product; (2) the promotion of Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing 8 perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

65. In short, Defendant (1) failed to adequately train the physicians on how to use its delivery system and the hysteroscopic equipment manufactured by a third party; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing and monopolizing on the birth control market.

66. Unfortunately, this was done at the expense of Plaintiff's safety.

PLAINTIFF'S HISTORY

67. In October 2008, Plaintiff went to the implanting physician to have Essure implanted in her fallopian tubes. The implanting physician advised Plaintiff that a representative from Defendant would be present to supervise the procedure.

68. During this visit, Defendant's representative failed to attend and supervise the procedure. The implanting physician attempted to insert the device on his own with the delivery system and hysteroscopic equipment.

69. After several attempts, the implanting physician was unable to place the device and re-scheduled Plaintiff's implantation for another date to make sure Defendant's representative would be present.

70. Plaintiff returned to the implanting physician the following month. Defendant failed to attend and supervise the procedure again, and the implanting physician attempted to place the device.

71. Without Defendant's representative present, the implanting physician attempted to place the device several times. Finally, the micro-inserts were placed into Plaintiff.

72. After two years, Plaintiff was then hospitalized four times due to severe pain, fever, and fainting spells.

73. Eventually a CT scan revealed that one of the micro-inserts had migrated from the fallopian tube and became lodged in or behind her colon.

74. It was also discovered that there were **three micro-inserts** inside of Plaintiff, instead of two.

75. In March 2013, as a result of Essure, Plaintiff underwent a complete hysterectomy and an additional surgery to remove the coil lodged in her colon. Plaintiff now suffers from several autoimmune and adhesion disorders.

76. Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendant's tortious conduct. Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

77. In addition, Defendant's fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendant was not only actively and fraudulently concealing adverse reports of migrations and perforations from Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendant for failing to report eight (8) perforations.

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

FACTS AND WARRANTIES

79. First, Defendant negligently trained physicians, including the implanting physician, on how to use its device and in hysteroscopy.

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

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

82. Defendant failed to adequately train Plaintiff's implanting physician and provided hysteroscopic equipment to the implanting physician who was not qualified to use such complicated equipment.

83. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendant's training methods were failing[3].

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

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

86. Defendant's distribution plan also included (1) negligently distributing Essure against FDA order and sections 501(f), 502(q) and (r) of the FD&C Act by marketing and selling an adulterated product; (2) the promotion of Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing 8 perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

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

87. Lastly, Plaintiff relied on the following warranties by Defendant and/or its agents, outlined in the subsequent Paragraphs:

WEBSITE WARRANTIES

88. Defendant marketed on its website the following:

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

a.i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiff.

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

b.i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiff.

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

c.i. However, Defendant failed to adequately train the implanting physician and "signed-off" on the implanting physician who did not have the requisite training. Defendant concealed this information from Plaintiff.

(d) "Surgery-free"

d.i. However, Essure is not "surgery-free", rather surgery is not required. All Essure procedures are done under hysteroscopy, which is a surgical procedure.

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

e.i. However, several pregnancies have been reported subsequent to confirmation. Defendant concealed this information from Plaintiff.

e.ii. However, between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiff.

i. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. Defendant concealed this information from Plaintiff.

ii. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

iii. However, women who have Essure have **10 times greater risk** of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater[4].

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

f.i. Yet, Defendant's SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendant. Defendant stated, "**We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation**." Defendant concealed this information from Plaintiff. *See Defendant's Form 10-K attached hereto as Exhibit "E."*

f.ii. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[5].

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

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

(h) "an **Essure trained** doctor inserts spring-like coils, called micro-inserts…"

h.i. However, the implanting physician who implanted the device was not adequately trained. Defendant concealed this information from Plaintiff.

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

5 *Id.*

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

i.i. However, Defendant failed to adequately train the implanting physician. Defendant concealed this information from Plaintiff.

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

j.i. However, Defendant “signed off” on the implanting physician who was not a skilled operative hysteroscopist, in order to monopolize and capture the market, including the implanting physician. Defendant concealed this information from Plaintiff.

(k) “Essure is a surgery-free **permanent birth control**.”

k.i. However, Essure is not permanent as the coils migrate, perforate organs and are expelled by the body.

ADVERTISEMENT WARRANTIES

89. Defendant advertised:

(a) “Zero pregnancies” in its clinical or pivotal trials.

a.i. However, there were at least four pregnancies. Defendant concealed this information from Plaintiff.

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

b.i. However, Defendant “signed off” on “Essure physicians” who did not perform the procedure every 6-8 weeks, including the implanting physician. Defendant concealed this information from Plaintiff.

FACT SHEET WARRANTIES

90. Defendant represented in its Fact Sheet:

(a) Data from two clinical studies show that 99 percent of women who had the Essure procedure rated their long-term comfort with the micro-inserts as 'good,' 'very good' or 'excellent'."

a.i. However, the actual choices given to the clinical participants were 'poor,' 'very good' or 'excellent.' Defendant concealed this information from Plaintiff.

WARRANTIES BY AGENTS

91. Defendant's Senior Director of Global Professional Education represented to the public that "For the Essure procedure, the patient is not under anesthesia, therefore a **skilled approach** is crucial."

(a) Yet, Defendant also claims that "Correct placement…is **performed easily** because of the design of the micro-insert"

92. Defendant's CEO stated: "Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme.

(a) However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiff.

(b) However, between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiff.

(c) However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

MARKETING WARRANTIES

93. Defendant marketed with commercials stating:

(a) Essure has been in use for over 5 years.

a.i. However, Essure was only in use for 4 years at this time. Defendant concealed this information from Plaintiff.

(b) "The non-surgical permanent birth control for woman."

b.i. However, the procedure is most commonly done with surgery. Defendant concealed this information from Plaintiff.

b.ii. However, Essure is not permanent as the coils migrate, perforate organs and are expelled by the body.

b.iii. However, all Essure procedures are done under hysteroscopy, which is a surgical procedure

94. Defendant created a fake blog entitled "Diary of a Decision" in order to induce Plaintiff to use Essure. Defendant created a fictitious person, named "Judy" who pretended to have had the procedure and answered questions from Plaintiff.

(a) However, "Judy" never had the procedure as represented and was actually Debbie Donovan. Defendant concealed this information from Plaintiff.

95. Defendant warranted that Essure "allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure Confirmation Test."

(a) However, Essure does not allow for visual confirmation of proper placement during the procedure evidenced by the fact that three micro-inserts were placed into Plaintiff.

BROCHURE WARRANTIES

96. Defendant's Essure brochure warrants:

(a) "Worry free"

a.i. However, Defendant **actively concealed** and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a** Form 483 issued by the FDA to Defendant. Defendant actively concealed this from Plaintiff. *See Investigative Report attached hereto as Exhibit "C ."*

a.ii. Most egregiously, Defendant was issued another Form 483 when it **"erroneously used non-conforming material."** Defendant actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendant actively concealed this from Plaintiff. *See Investigative Report attached hereto as Exhibit "C ."*

a.iii. However, Defendant's facility was also issued a notice of violation as it **"no longer uses pre-sterile and post-sterile cages."** Defendant actively concealed this from Plaintiff. *See Notice of Violation attached as Exhibit "D."*

a.iv. However, Defendant also was issued a notice of violation when it **"failed to obtain a valid license…prior to manufacturing medical devices."** Defendant was manufacturing devices for three years without a license. Defendant actively concealed this from Plaintiff. *See Notice of Violation attached as Exhibit "D."*

a.v. However, Defendant was also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. *See Notice of Violation attached as Exhibit "D."* Defendant actively concealed this from Plaintiff.

(b) "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."

b.i. However, the micro-inserts do not remain secure but migrate and are expelled by the body. Defendant actively concealed this information from Plaintiff.

b.ii. However, Defendant actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483 issued to Defendant by the FDA. *See Investigative Report attached hereto as Exhibit "C ."*

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

c.i. However, the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. Defendant actively concealed this from Plaintiff.

c.ii. PET fibers are not designed or manufactured for use in human implantation.

c.iii. Moreover, Defendant also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known."

c.iv. However, the PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion.

c.v. Most egregiously, Defendant was issued another Form 483 when it **"erroneously used non-conforming material."** Defendant actively concealed this and was issue another Form 483 for "failing to adequately document the situation." *See Investigative Report attached hereto as Exhibit "C ."*

(d) "Surgery free"

d.i. However, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

(e) "Anesthesia-free"

e.i. However, Essure is not "anesthesia-free", rather anesthesia is not required.

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

f.i. However, Defendant also states that it is only **after** "The Confirmation" pregnancy cannot occur. i.e. the complete opposite of what is warranted in the brochure.

f.ii. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed.

f.iii. However, between 1997-2005, 64 pregnancies were reported to Defendant. Defendant concealed this information from Plaintiff.

f.iv. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

f.v. However, there have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[6].

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

g.i. However, Essure is not "surgery-free", rather surgery is not required.

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

97. The **PET fibers are what causes** the tissue growth.

(a) However, during the PMA meeting with the FDA, Defendant represented that the **trauma** caused by the expanding coil striking the fallopian tubes i**s what caused the inflammatory response** of the tissue. Defendant concealed this information from Plaintiff.

ESSURE BOOKLET WARRANTIES

98. Defendant's Essure booklet warrants:

(a) "This viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus."

a.i. However, the device does irritate the uterus. Defendant concealed this information from Plaintiff.

i. However, Defendant actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached hereto as Exhibit "C ."*

(b) "there was no cutting, **no pain,** no scars…"

b.i. However, Plaintiff has experienced pain as a result of Essure. Defendant concealed this information from Plaintiff.

DATA WARRANTIES

99. Summary of Safety and Effectiveness Data states:

(a) "The Essure System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks."

a.i. However, Essure is not "surgery-free" or "anesthesia-free", rather surgery and anesthesia is not required.

(b) "In addition to the above benefits, none of the women in the Essure clinical trials became pregnant while relying on Essure for contraception."

b.i. However, there were at least four pregnancies during the clinical trials. Defendant concealed this information from Plaintiff.

(c) "Namely, the Essure system is delivered hysteroscopically without general anesthesia."

c.i. However, Essure is not "surgery-free" or "anesthesia-free", rather surgery and anesthesia is not required.

PMA SUPPLEMENT

100. Defendant represented to Plaintiff that it was the expanding coil and tissue growth which caused the coil to be attached to the tube, not any type of coating.

(a) Yet, in Supplement 18, Defendant represented that "A doctor placed the coil at the uterine-fallopian tube junction, where **its coating caused it be attached** to the tube." The coating is a hydrophilic polymer coating produced by AST Products, Inc. Defendant actively concealed this from Plaintiff.

SEC FILINGS

101. Defendant warranted that the Essure system has **"no risks"** for patients because … the Essure system does not involve the use of radiofrequency energy. *SEC Form 10-K filed on 3/15/11 by Defendant.*

(a) At the same time, Defendant also states that there are limited risks with Essure.

102. "Our Mountain View, California facility underwent an International Organization for Standardization ("ISO") inspection in September 2011 which resulted in continuing approval and ISO certification through May 2013. In December 2010 / January 2011 we underwent an FDA audit; all findings from the audit were satisfactorily addressed." However, Defendant actively concealed the following:

(a) However, Defendant's site has been inspected 7 times since 06/25 - 07/09/2002. The most recent FDA audit occurred on 05/30 - 06/26/2013. The FDA has issued 4 Form 483 inspectional observations.

(b) However, Defendant actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached hereto as Exhibit "C ."*

(c) Most egregiously, Defendant was issued another Form 483 when it **"erroneously used non-conforming material."** Defendant actively concealed this and was issue another Form 483 for "failing to adequately document the situation." *See Investigative Report attached hereto as Exhibit "C ."*

(d) However, Defendant's facility was also issued a violation as it **"no longer uses pre-sterile and post-sterile cages."** *See Notice of Violation attached hereto as Exhibit "D."*

(e) However, Defendant also was issued a violation when it **"failed to obtain a valid license…prior to manufacturing medical devices."** Defendant was manufacturing devices for three years without a license. *See Notice of Violation attached hereto as Exhibit "D."*

103. The subsequent negligence claims are not products liability causes of action. **The claims have nothing to do with the Essure product or its invalid CPMA**, but rather (1) the failure of Defendant to adequately train and instruct the implanting physician and/or (2) the fact that Defendant provided the implanting physician, who was **not a hysteroscopist**, with hysteroscopic equipment in order to sell their product and/or (3) Defendant's unreasonably dangerous distribution of Essure.

NEGLIGENT TRAINING – COUNT I

104. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

105. First, Defendant undertook an independent duty to train physicians on how to properly use its device to place the micro-inserts and in hysteroscopy.

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

107. Defendant had a duty to adequately train the implanting physician on how to place Essure using its own delivery system and oversee this particular procedure. In addition, considering Defendant was providing the implanting physician with sophisticated hysteroscopic equipment, Defendant also had a duty to train the physician in hysteroscopy in a reasonably safe manner or at the very least ensure that the implanting physician was competent in hysteroscopy before providing them with the hysteroscopic equipment needed to place Essure.

108. Defendant breached this duty by (1) failing to adequately train Plaintiff's implanting physician on how to place the micro-inserts, including providing training different from than that of the "Physician Training Manual"; (2) failing to supervise the procedure; and (3) failing to train Plaintiff's physician on how to use the hysteroscopic equipment provided by Defendant.

109. This breach caused Plaintiff's damage. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

110. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders. **WHEREFORE,** for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENT ENTRUSTMENT – COUNT II

111. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

112. Second, Defendant also provided and entrusted sophisticated hysteroscopic equipment to the implanting physician in order to sell its product.

113. The implanting physician was not competent to use such complicated devices, Defendant was aware of this, and provided the equipment anyway in order to sell its product.

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

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

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

117. Defendant invested $5 million in capital expenditures related to purchases of hysteroscopy equipment to "hand out" to physicians. *SEC Form 10-K filed on 3/15/11 by Defendant.*

118. Moreover, Defendant stated: "We train and provide programs and all the elements that go into successful experience by the patient, including office staff training, equipment selection and other procedure room infrastructure, physician counseling skills, reimbursement and referral network building. *Defendant's Q4 2009 Earnings Call Transcript.*

119. Defendant had a duty not to provide sophisticated hysteroscopic equipment to the implanting physician who was not qualified to use such equipment. The implanting physician was not an expert hysteroscopist nor competent to use such equipment. Defendant was aware of

this dangerous condition but provided the physician with the equipment in order to sell its product.

120. Defendant breached its duty by providing the implanting physician with hysteroscopic equipment in an effort to sell its product. Defendant also failed to reasonably investigate whether or not the implanting physician was competent to use such equipment.

121. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

122. This breach caused Plaintiff's damage. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

123. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders. **WHEREFORE,** for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

NEGLIGENT DISTRIBUTION – COUNT III

124. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

125. Lastly, Defendant had a duty to distribute Essure in a reasonably safe manner.

126. Defendant breached this duty by requiring the implanting physician to purchase two (2) Essure "kits" per month **regardless of whether they used them or not** and by

contracting with third parties from the hysteroscopic manufacturers to promote Essure who were not competent to perform the same.

127. This was an unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff.

128. This was an unreasonably dangerous distribution scheme as it compelled the implanting physician to sell two (2) devices per month at the expense of Plaintiff's safety and well-being and also entailed representatives of third parties, who did not knowledge of Essure, to promote Essure.

129. Defendant also breached this duty by (1) negligently distributing Essure against FDA order and sections 501(f), 502(q) and (r) of the FD&C Act by marketing and selling an adulterated product; (2) promoting Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing 8 perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

130. This breach caused Plaintiff damage. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

WHEREFORE, for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

131. In short, Defendant (1) failed to adequately train the physicians on how to use its delivery system (including providing training different from its manual) and the hysteroscopic equipment manufactured by a third party; (2) provided specialized hysteroscopic equipment to the implanting physician who was not qualified to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing and monopolizing on the birth control market. As a direct and proximate cause of this, Plaintiff suffered damages.

BREACH OF EXPRESS WARRANTIES – COUNT IV

132. Plaintiff re-alleges and re-incorporates the preceding Paragraphs.

133. Under PA law, both state and federal courts have held that Plaintiff's claims for breach of express warranties are not preempted by the MDA. *Rosci v Acromed, Inc.*, 447 Pa. Super. 403 (1995); *Bentzley v Medtronic, Inc.*, 2011 U.S. Dist. Lexis 136570 (E.D. Pa. Nov. 28, 2011).

134. The FDA's CPMA order confirms this: the FDA "**does not evaluate information related to contractual liability warranties,** however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

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

136. Plaintiff relied on the warranties mentioned *supra*.

137. Defendant's "affirmations of fact or promise" and "descriptions" as described in "Facts and Warranties" regarding Essure created a basis of the bargain for Plaintiff.

138. The warranties were specifically negotiated and expressly communicated to Plaintiff in such a manner that Plaintiff understood and accepted them.

139. As a result of Defendant's warranties and Plaintiff's reliance on same, Plaintiff has suffered damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

WHEREFORE, for the above reasons, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, compensatory, incidental, consequential, including pain and suffering which was a foreseeable consequential damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

DEMAND FOR JURY TRIAL

Plaintiff demand a jury trial with regards to all claims.

DATED this ___th day of May, 2014.

VERIFICATION

I, Heather Walsh, hereby verify that I am the Plaintiff in this matter and that the facts set forth in this Complaint are true and correct based upon my knowledge, information, and belief. I understand that this Verification is subject to the penalties set forth in 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.

_____ _____

Date X Heather Walsh

Respectfully submitted,

MCELDREW LAW
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By: _____

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SERVICE LIST

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