JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
VALERIE SOUTO, et. al.

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Thomas A. Dinan, Esq.
McEldrew Law, LLC
123 S. Broad Street, Suite 1920, Philadelphia, PA 19109

DEFENDANTS
BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

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

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

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

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

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

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

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C § 1331

Brief description of cause:
Plaintiffs alleges violations of federal law in product liability suit

VII. REQUESTED IN COMPLAINT:

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

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE Eduardo C. Robreno DOCKET NUMBER 16-CV-01458-ER

DATE 4/22/16

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

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

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

VALERIE SOUTO, et. al.	:	CIVIL ACTION
v.	:	
BAYER CORP, et. al.	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (x)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

April 22, 2016	James J. McEldrew, III, Esq. Thomas A. Dinan, Esq.	Plaintiffs
Date	**Attorney-at-law**	**Attorney for**
215-545-8800	215-545-8805	jim@mceldrewyoung.com tdinan@mceldrewyoung.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Valerie Souto, 9330 Riverdale, Redford, MI 48239

Address of Defendant: 100 Bayer Road, Building 4, Pittsburgh, PA 15205

Place of Accident, Incident or Transaction: PA /

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☒ No☐

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: 16CV1458 Judge Eduardo Robreno Date Terminated: Pending

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases

(Please specify) _____

B. *Diversity Jurisdiction Cases:*

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) _____

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, James McElhaw, III, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought

DATE: 4.22.16 _____ Attorney-at-Law 36641 / 91344 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ _____ Attorney-at-Law _____ Attorney I.D.#

CIV. 609 (5/2012)

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No:

VALERIE SOUTO, et al.

Plaintiffs,

vs.

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

Defendants.
_____/

ADDENDUM TO DESIGNATION FORM

Address of Plaintiffs: (cont'd)

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Greenville, TN 37745

Kristi L. Hanson
10411 Aspen Loop
Pasco, WA 99301

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No:

VALERIE SOUTO, CHRISTINE WHITEHEAD, KYSTAL PORRAS, AUTUMN BENJAMIN, ELISSA WEBBER RODRIGUEZ, KAREN GROSS, AMANDA DYKEMAN, CHRISTINE DAVENPORT, VICTORIA SMITH, ANGIE FIRMALINO, BRENDA MARTIN, ANGELA LYNCH, MELANIE GOSHGARIAN, PENELOPE BURAU, CECILIA BOGLE, SARAH CARLIN, STACY CERRETA, VICTORIA DOE, SAMANTHA PERRY, KRISTINA TSO, KIMBERLY JORDAN, LAUREN DUNCAN, KRISTI HANSON, KRISTINA WHITT.

Plaintiffs,

v.

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

Defendants.
_____/

COMPLAINT

AND NOW COMES the PLAINTIFFS, VALERIE SOUTO, CHRISTINE WHITEHEAD, KYSTAL PORRAS, AUTUMN BENJAMIN, ELISSA WEBBER RODRIGUEZ, KAREN GROSS, AMANDA DYKEMAN, CHRISTINE DAVENPORT, VICTORIA SMITH, ANGIE FIRMALINO, BRENDA MARTIN, ANGELA LYNCH, MELANIE GOSHGARIAN, PENELOPE BURAU, CECILIA BOGLE, SARAH CARLIN, STACY CERRETA, VICTORIA

DOE, SAMANTHA PERRY, KRISTINA TSO, KIMBERLY JORDAN, LAUREN DUNCAN, KRISTI HANSON, KRISTINA WHITT (collectively "Plaintiffs"), by and through undersigned counsel, file this Complaint against Defendants, BAYER CORP., BAYER HEALTHCARE, LLC., BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G. (Collectively the "Bayer Defendants" or "Defendants") and in support thereof makes the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, VALERIE SOUTO is a citizen of MI.
2. Plaintiff, CHRISTINE WHITEHEAD is a citizen of MO.
3. Plaintiff, KRYSTAL PORRAS is a citizen of VA.
4. Plaintiff, AUTUMN BENJAMIN is a citizen of PA.
5. Plaintiff, ELISSA WEBBER RODRIGUEZ is a citizen of IA.
6. Plaintiff, KAREN GROSS is a citizen of MD.
7. Plaintiff, AMANDA DYKEMAN is a citizen of IL.
8. Plaintiff, CHRISTINE DAVENPORT is a citizen of OR.
9. Plaintiff, VICTORIA SMITH is a citizen of RI.
10. Plaintiff, ANGIE FIRMALINO is a citizen of NY.
11. Plaintiff, BRENDA MARTIN is a citizen of NC.
12. Plaintiff, ANGELA LYNCH, is a citizen of CA.
13. Plaintiff, MELANIE GOSHGARIAN, is a citizen of MA.
14. Plaintiff, PENELOPE BURAU, is a citizen of MN.
15. Plaintiff, CECILIA BOGLE, is a citizen of AZ.

16. Plaintiff, SARAH CARLIN, is a citizen of OH.

17. Plaintiff, STACY CERRETA, is a citizen of FL.

18. Plaintiff, VICTORIA DOE is a citizen of MT.

19. Plaintiff, SAMANTHA PERRY is a citizen of NV.

20. Plaintiff, KRISTINA TSO is a citizen of NM.

21. Plaintiff, KIMBERLY JORDAN is a citizen of SC.

22. Plaintiff, LAUREN DUNCAN is a citizen of TN.

23. Plaintiff, KRISTI HANSON is a citizen of WA.

24. Plaintiff, KRISTINA WHITT is a citizen of AL.

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

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

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

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

29. At all relevant times, the Bayer subsidiaries are agents or apparent agents of BAYER CORP. and/or BAYER A.G. Each Defendant acted as the agent of the other Defendant and acted within the course and scope of the agency, regarding the acts and omissions alleged. Together, the Defendants acted in concert and or abetted each other and conspired to engage in

the common course of misconduct alleged herein for the purpose of enriching themselves and creating an injustice at the expense of Plaintiffs.

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

31. Moreover, there exists and at all times mentioned herein there existed a unity of interest in ownership and among all Defendants such that individuality and separateness between and among them has ceased. Because Defendants are "Alter Egos" of one another and exert control over each other, adherence to the fiction of the separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud, and promote injustice. BAYER CORP. and BAYER A.G. wholly ignored the separate status of the Bayer subsidiaries separate status and so dominated and controlled its affairs that its separate entities were a sham.

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

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

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

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

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

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

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

INTRODUCTION

39. This Complaint is brought by Plaintiffs who relied on express warranties of Defendants before being implanted with a female birth control device, known as "Essure." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage.

40. This Complaint is brought by Plaintiffs with respect to the same occurrence (implantation of Essure, reliance on the same representations prior to implantation, Defendants' failure to warn Plaintiffs of the same adverse events, and subsequent injuries due to Essure) and which has several questions of law and/or fact common to all Plaintiffs.

41. As a result of (1) Defendants' negligence described *infra* and (2) Plaintiffs' reliance on Defendants' warranties and misrepresentations, Defendants' Essure device malfunctioned causing subsequent injuries.

42. Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, the Essure product became "adulterated"

pursuant to the FDA[1] due to Defendants' failure to comply with the CPMA order and federal regulations.

43. Pursuant to Defendants' CPMA (which reads: "Failure to comply with conditions of approval invalidates this approval order"), 21 C.F.R. Section 814.82 (c), and Section 501(f) of the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the CPMA became invalid and the product could not have been marketed or sold to Plaintiffs.

44. Specifically, Defendants (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with federal laws regarding marketing and distribution as described *infra.*

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

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

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

(b) erroneously using non-conforming material in the manufacturing of Essure;

(c) failing to use pre-sterile and post-sterile cages;

(d) manufacturing Essure at an unlicensed facility; and

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

47. Defendants were also found, by the FDA, to be:

(a) Not reporting … complaints in which their product migrated;

[1] All Emphasis is supplied in this Complaint.

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

(c) Only disclosing 22 perforations while having knowledge of 144 perforations;

(d) Not considering these complaints in their risk analysis for the design of Essure;

(e) Failing to have a complete risk analysis for Essure;

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

(g) Failing to track the non-conforming product;

(h) Failing to follow procedures used to control products which did not confirm to specifications;

(i) Failing to have complete Design Failure Analysis

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

(k) Failing to disclose 16, 047 complaints to the FDA as MDR's (Medical Device reports which are suspected from device malfunction or associated with injury); and

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

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

49. As a result, Defendants' "adulterated" product, Essure, should never have been marketed or sold to Plaintiffs.

50. In short, Defendants failed to comply with any of the following express conditions and federal regulations:

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

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

(c) Report Due Dates- six month, one year, eighteenth month, and two year reports.

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

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

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

51. These violations rendered the product "adulterated"- precluding Defendants from marketing or selling Essure per the FDA, and, more importantly endangered the lives of Plaintiffs and the safety of the public.

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

DESCRIPTION OF ESSURE AND HOW IT WORKS

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

54. 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.*

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

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

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

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

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

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

61. 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").

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

63. 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

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

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

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

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

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

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

70. 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.

71. 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.

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

73. 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.

74. 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.

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

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

77. 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.

78. Defendants failed to comply with *several* conditions; thereby rendering Essure adulterated. Specifically:

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

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

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

(d) Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury

[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."

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

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

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

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

79. Defendants also were found to be:

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

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

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

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

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

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

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

80. Specifically,

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

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

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

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

(e) On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went) See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

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

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

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

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

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

85. In short, Essure is considered an "adulterated" product that cannot be marketed or sold per the FDA.

DEFENDANTS' TRAINING, ENTRUSTMENT, AND DISTRIBUTION PLAN

86. Defendants (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 Plaintiffs' safety and well-being.

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

88. In order to capture the market, Defendants 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.

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

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

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

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

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

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

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

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

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

98. Defendants 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.

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

100. Defendants' 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 Plaintiffs.

101. In short, Defendants 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".

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

103. 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.

104. In short, Defendants (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.

105. Unfortunately, this was done at the expense of Plaintiffs' safety.

PLAINTIFFS' HISTORY

106. Plaintiff, VALERIE SOUTO was implanted in August 2013. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain, joint paint, loss of libido, severe changes in menstrual cycles, and persistent confusion. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure

to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

107. Plaintiff, CHRISTINE WHITEHEAD was implanted on or about March 22, 2013. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes accompanied with blood clots, bloating, joint inflammation, memory loss, extreme fatigue and migraine headaches. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and

patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. "This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

108. Plaintiff, KRYSTAL PORRAS was implanted on or about May 25, 2005. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, numbness in face and extremities, migraine headaches, bloating, painful intercourse, joint pain, a weakened immune system, and severe menstrual changes. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn

doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

109. Plaintiff, AUTUMN BENJAMIN was implanted on or about July 12, 2010. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration,

persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

110. Plaintiff, ELISSA WEBBER RODRIGUEZ was implanted in August 2010. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain and severe abdominal pain. Plaintiff was required to take a series of hormone injections as a result of Essure. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft

guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

111. Plaintiff, KAREN GROSS was implanted in 2008. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes fatigue, high blood pressure, hair loss, bowel issues, vitamin D deficiency, depression and memory loss. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted

in device removal that required abdominal surgery. "This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

112. Plaintiff, AMANDA DYKEMAN was implanted on or about September 17, 2010. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain, numbness and tingling of extremities, extreme fatigue, extreme abdominal swelling, depression, and extreme menstrual changes. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. "This information should be

shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

113. Plaintiff, CHRISTINE DAVENPORT was implanted on or about January 14, 2014. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes accompanied with blood clots, painful intercourse, hair loss, fatigue, bloating, and difficulty sleeping. Plaintiff had to have a hysterectomy, bilateral salpingectomy, and cystoscopy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal

that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

114. Plaintiff, VICTORIA SMITH was implanted on or about April 5, 2006. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes accompanied with blood clots, burning sensation in extremities, and severe abdominal pain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with

patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

115. Plaintiff, ANGIE FIRMALINO was implanted on or about August 27, 2009. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain, severe lower back pain, fevers, extreme fatigue, severe joint pain, depression, and extreme menstrual changes. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. "This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and

risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

116. Plaintiff, BRENDA MARTIN was implanted in 2009. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes migraine headaches, bloating, weight gain, anxiety, dizziness, high blood pressure, and heart issues. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket

surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

117. Plaintiff, ANGELA LYNCH was implanted in September 2008. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under

appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

118. Plaintiff, MELANIE GOSHGARIAN was implanted in 2008. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain, rectal bleeding, severe abdominal and back pain, and weight gain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

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

119. Plaintiff, PENELOPE BURAU was implanted on or about August 27, 2007. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes accompanied by blood clots, skin irritation, hair loss, dizziness, extreme fatigue, weight gain, insomnia, vaginal discharge, and dental issues. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

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

120. Plaintiff, CECILIA BOGLE was implanted on or about October 21, 2009. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme migraine headaches, extreme menstrual changes, and vertigo. Plaintiff became pregnant after being implanted with Essure. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. "This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants'

fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

121. Plaintiff, SARAH CARLIN was implanted on or about September 2, 2010. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants

was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

122. Plaintiff, STACY CERRETA was implanted on or about March 21, 2013. After being implanted with Essure, this Plaintiff began to suffer from severe pelvic pain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations

from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

123. Plaintiff, VICTORIA DOE was implanted on or about June 4, 2012. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain and extreme menstrual changes. Plaintiff had to have a bilateral salpingectomy as a result of Essure. Plaintiff also had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations

from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

124. Plaintiff, SAMANTHA PERRY was implanted in April 2008. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes accompanied with blood clots, depression, skin irritation, weight gain, and severe back pain. Plaintiff had to have a hysterectomy leaving only her ovaries as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the

FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

125. Plaintiff, KRISTINA TSO was implanted on or about February 3, 2011. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, severe back pain, joint pain, vitamin D deficiency, and was diagnosed with an auto immune disease. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of

migrations and perforations from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

126. Plaintiff, KIMBERLY JORDAN was implanted in May 2014. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes, severe joint pain, skin irritation, hair loss, anxiety, and severe neck pain. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations

from this Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

127. Plaintiff, LAUREN DUNCAN was implanted on or about August 8, 2012. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes, constant fatigue, and skin irritation. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. "This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also

from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

128. Plaintiff, KRISTI HANSON was implanted in April 2006. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, extreme menstrual changes accompanied with blood clots, severe joint pain, vaginal pain, weight gain, hair loss, and shooting pain in legs. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. "This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from this Plaintiff but also from the

FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

129. Plaintiff, KRISTINA WHITT was implanted in May of 2009. Subsequent to implantation with Essure, this Plaintiff began to suffer from severe pelvic pain, severe back pain, hair loss, memory loss, severe joint pain, and bloating. Plaintiff had to have a hysterectomy as a result of Essure. This Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and frau dulently concealing adverse reports of migrations and perforations from this Plaintiff but also

from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants.

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

FACTS AND WARRANTIES

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

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

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

134. Defendants failed to adequately train Plaintiffs' implanting physician and provided hysteroscopic equipment to the implanting physician who was not qualified to use such complicated equipment.

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

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

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

137. Third, Defendants' 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 Plaintiffs.

138. Defendants' 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.

139. Lastly, Plaintiffs relied on the following warranties by Defendants and/or its agents, outlined in the subsequent Paragraphs:

WEBSITE WARRANTIES

140. Defendants marketed on its website the following:

(a) "Only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials.[4]"

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

[4] As to Plaintiff Cecilia Bogle only.

(b) "There were Zero pregnancies in the clinical trials.[5]"

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

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

i. However, Defendants failed to abide by the FDA guidelines when training the implanting physician and "signed-off" on the implanting physician who did not have the requisite training. Defendants concealed this information from Plaintiffs.

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

i. However, several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiffs.

ii. However, between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiffs.

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

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[6].

iv. Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

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

i. Yet, Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants

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[5] *Id.*

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

stated, "We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation." Defendants concealed this information from Plaintiffs.

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[7].

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

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

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

i. However, Defendants failed to train the implanting physician pursuant to the FDA guidelines. Defendants concealed this information from Plaintiffs.

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

i. However, Defendants "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. Defendants concealed this information from Plaintiffs.

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

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

[7] *Id.*

ADVERTISEMENT WARRANTIES

141. Defendants advertised:

(a) "Zero pregnancies" in its clinical or pivotal trials[8].

i. However, there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

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

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

(c) No pregnancies have occurred after a successful confirmation test in the Essure clinical studies at 4 and 5 years of follow up[9].

i. However, there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

(d) I don't want to worry about an unexpected pregnancy[10].

i. However, there were at least four pregnancies. Defendants concealed this information from Plaintiffs.

WARRANTIES BY AGENTS

142. Defendants' CEO stated: "Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme[11].

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

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

[8] As to Plaintiff Cecilia Bogle only.
[9] *Id.*
[10] *Id.*
[11] *Id.*

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

(d) Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

MARKETING WARRANTIES

143. Defendants marketed with commercials stating:

144. Defendants 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.

BROCHURE WARRANTIES

145. Defendants' Essure brochure warrants:

(a) "Worry free"

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

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

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

iv. However, Defendants also was issued a notice of violation when it "failed to obtain a valid license...prior to manufacturing medical devices."

Defendants were manufacturing devices for three years without a license. Defendants actively concealed this from Plaintiffs. *See Notice of Violation attached as Exhibit "D."*

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

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

vii. Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendants as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

viii. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

(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."

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

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

iii. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

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

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. Defendants actively concealed this from Plaintiffs.

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

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

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.

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

(d) Step Two: "pregnancy cannot occur"; Step Three: The Confirmation[12].

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

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

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

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

v. However, there have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[13].

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

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

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[12] *Id.*

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

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

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

(a) However, the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendants refer to Essure and classify it as a "drug."

ESSURE BOOKLET WARRANTIES

147. Defendants' Essure booklet warrants:

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

i. However, the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendants concealed this information from Plaintiffs.

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

i. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

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

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

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

iii. Yet, Defendants were issued Form 483's for not disclosing MDR's to the FDA for pain.

iv. However, Defendants altered the records of at least one trial participant to reflect less pain.

148. The subsequent claims are based on Plaintiffs' Essure and Defendants' failure to abide by FDA guidelines, Federal regulations and its own CPMA.

NEGLIGENT MISREPRESENTATION– COUNT I

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

150. Plaintiffs did not discover that the misrepresentations were the cause of their symptoms until February 29, 2016 when the FDA (1) announced its "actions to provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with" the device; (2) required a black box warning on Essure to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions." The FDA draft guidance black box warning for Essure also warns: "Some of these reported events resulted in device removal that required abdominal surgery. " This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device"; and (3) ordered Bayer "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment," beginning the relevant statute of limitations.

151. Defendants made misrepresentations which are specifically outlined in Paragraphs 142-149.

152. Plaintiffs justifiably relied on the misrepresentations. Specifically, Plaintiffs would have never had Essure implanted had they been aware that there were 8 perforations of

human cavities, that there had been 16,047 complaints regarding Essure, or the falsity of the representations specifically delineated in the preceding paragraphs.

153. As a proximate result, Plaintiffs suffered damages as outlined in detail above.

154. As a result of Defendants' negligence, breaches of warranty, fraud, and unfair trade practices, individually, jointly, and severally, Plaintiffs sustained the injuries noted above.

155. As a result of Defendants' negligence, breaches of warranty, fraud, and unfair trade practices, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

156. As a result of Defendants' negligence, breaches of warranty, fraud, and unfair trade practices, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

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

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

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

NEGLIGENCE-FAILURE TO WARN– COUNT II

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

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

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

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

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

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

(d) 21 C.F.R. 803.10- (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.(2) Submit annual reports (described in 803.33) to us.(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or(ii) Submit reports of device-related malfunctions to the

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

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

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

(g) 21 C.F.R. 806.10- (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:(1) To reduce a risk to health posed by the device; or(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b).(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.(c) The manufacturer or importer shall include the following information in the report:(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.(9) The total number of devices manufactured or distributed subject to the

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

(h) 21 C.F.R. 814.84-(a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.(b) Unless FDA specifies otherwise, any periodic report shall:(1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b).(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published

reports, FDA will notify the applicant that copies of such reports shall be submitted.(3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter.(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

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

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

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

product or the prevention of such problems; and(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.(b) All activities required under this section, and their results, shall be documented.

(l) 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;(2) Monitoring and control of process parameters and component and device characteristics during production;(3) Compliance with specified reference standards or codes;(4) The approval of processes and process equipment; and(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.(b) *Production and process changes.* Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40.(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.(h) *Manufacturing material.* Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(m)21 C.F.R. 820.90-(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.(b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of

nonconforming product and the signature of the individual(s) authorizing the use.(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

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

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

(p) 21 C.F.R. 820.198-(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:(1) All complaints are processed in a uniform and timely manner;(2) Oral complaints are documented upon receipt; and(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation

under this paragraph shall include a determination of:(1) Whether the device failed to meet specifications;(2) Whether the device was being used for treatment or diagnosis; and(3) The relationship, if any, of the device to the reported incident or adverse event.(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:(1) The name of the device;(2) The date the complaint was received;(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;(4) The name, address, and phone number of the complainant;(5) The nature and details of the complaint;(6) The dates and results of the investigation;(7) Any corrective action taken; and(8) Any reply to the complainant.(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:(1) A location in the United States where the manufacturer's records are regularly kept; or(2) The location of the initial distributor.

(q) 21 C.F.R. 820.30 - Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

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

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

(t) 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter

issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

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

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

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

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

(y) FDA requirement in CPMA order- Warranties are truthful, accurate, and not misleading.

(z) FDA requirement in CPMA order- Warranties are consistent with applicable Federal and State law.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

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

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

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

(r) On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went) See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

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

(t) Defendants failed to disclose to Plaintiff and her Implanting physician the fact that it Defendants altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

163. Had Defendants disclosed such information as was required by its CPMA and Federal law to Plaintiffs or their Implanting Physicians, Plaintiffs would never had Essure implanted.

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

165. As a result of Defendants' negligence, breaches of warranty, fraud, and unfair trade practices, individually, jointly, and severally, Plaintiffs sustained the injuries noted above.

166. As a result of Defendants' negligence, breaches of warranty, fraud, and unfair trade practices, individually, jointly, and severally, Plaintiffs had to undergo numerous surgical procedures, diagnostic procedures, and may have to undergo surgeries, diagnostic testing, treatment and rehabilitation into the indefinite future.

167. As a result of Defendants' negligence, breaches of warranty, fraud, and unfair trade practices, individually, jointly, and severally, Plaintiffs sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

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

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

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against the Defendants for an amount in excess of $75,000.00 each, compensatory, punitive damages, incidental, consequential, including pain and suffering which was a foreseeable consequential

damages, delay damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial with regards to all claims.

DATED this ___th day of April, 2016

Respectfully submitted,

MCELDREW LAW
Counsel for Plaintiff
123 South Broad Street,
Suite 1920
Philadelphia, PA 19109
Phone: (215) 545-8800
Facsimile: (215) 545-8805

By: _____

McELDREW LAW, LLC
James J. McEldrew, III, Esquire
Atty ID #: 36411
Thomas A. Dinan, Esquire
Atty ID # 91344
123 South Broad Street, Suite 1920
Philadelphia, PA 19109
(215) 545-8800
jim@mceldrewlaw.com
tdinan@mceldrewlaw.com

SERVICE LIST

Registered Agents:

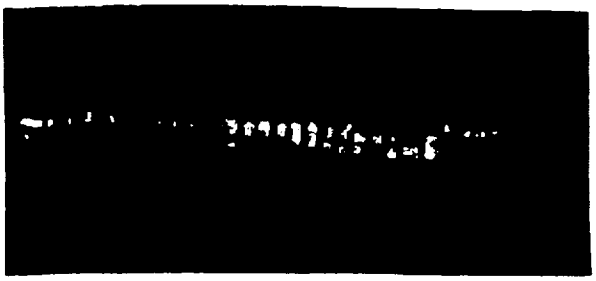
Bayer Corp.
100 Bayer Road, Bld. 4
Pittsburgh, PA 15205

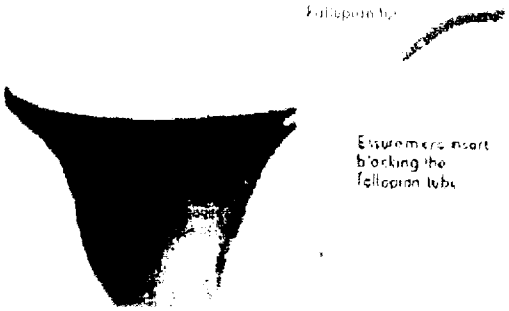
Bayer Healthcare, LLC
Corporation Service Co.
2711 Centerville Road Suite 400
Wilmington, DE 19808

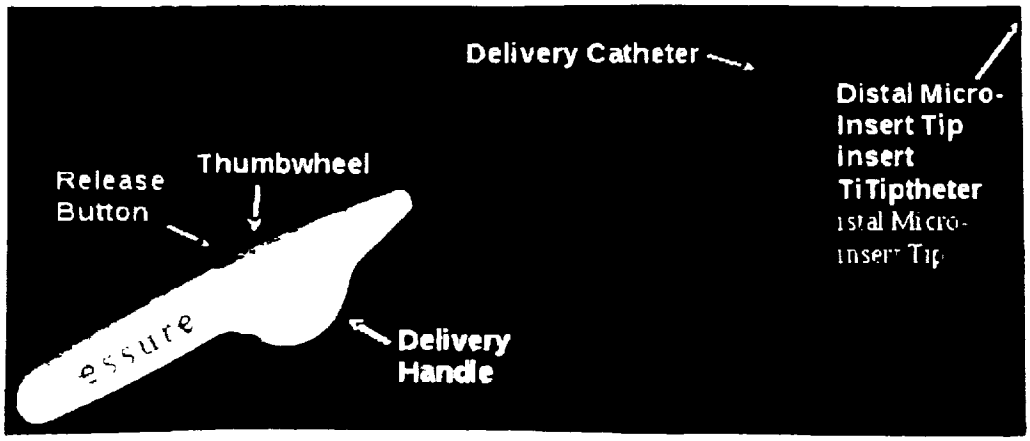
Bayer Healthcare Pharmaceuticals, LLC
Corporation Service Co.
2711 Centerville Road Suite 400
Wilmington, DE 19808

Bayer Essure, Inc.
Corporation Service Co.
2711 Centerville Road Suite 400
Wilmington, DE 19808

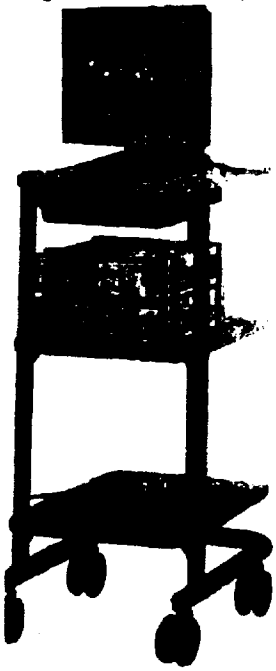
Bayer AG
Werk Leverkusen
51368 Leverkusen, Germany







Hysteroscopic Equip.



EXHIBIT

A

Post-Approval Studies

Post-Approval Studies

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

Links

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

Contact Information

Julie Unger
Project Manager, Post-Approval Studies Program
Food and Drug Administration
10903 New Hampshire Ave.
WO66-4708v Silver Spring, MD
20993-0002

Phone: (301) 798-6134
Fax: (301) 847-8140
julie.unger@fda.hhs.gov

Show All Studies

Export to Excel

General	
Application Number	P020014 S017
Most Recent Protocol Version Approved	02/24/2012
Study Name	Essure/post NovaSure PAS
Study Status	Progress Adequate
General Study Protocol Parameters	
Study Design	Prospective Cohort Study
Study involve follow-up of premarket cohort (Y/N)	No
Data Source	New Data Collection
Comparison Group	Objective Performance Criterion
Analysis Type	Analytical
Study Population	Transit. Adolescent B (se adults) 18 21 yrs, Adult >21
Detailed Study Protocol Parameters	
Study Design Description	Single-arm multi-center prospective observational study
Study Population Description	Women aged 21-60 with Essure microinserts properly placed (confirmatory HSG) seeking treatment for menorrhagia
Sample Size	A minimum of 220 female subjects relying on Essure micro-inserts seeking treatment for menorrhagia
Data Collection	Occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure
Followup Visits and Length of Followup	3 years One week post Novasure procedure, then one and three year Post EA Contraception Phone Call

Essure/post-NovaSure PAS Schedule

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

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Links on this page:

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

EXHIBIT
sticker
B

Home[1] Medical Devices[4] Databases[5]

ost-Approval Studies

Post-Approval Studies

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  - Letter to IRB Chairs[8] (formerly referred to as "IRB Letter from Dr. Schultz (dated 2/2/09)"
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  - Report on Implementation of Post-Approval Studies for Medical Devices Workshop (June 2009)[11]

Contact Information

Julie Ungar
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Food and Drug Administration
10903 New Hampshire Ave
WO66-4208v Silver Spring, MD
20993-0002

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

Show All Studies

Export to Excel

General	
Application Number	P020014 S012
Most Recent Protocol Version Approved	08/15/2007
Study Name	ESS-305
Study Status	Completed
General Study Protocol Parameters	
Study Design	Cross-Sectional Study
Study involve follow-up of premarket cohort (Y/N)	No
Data Source	New Data Collection
Comparison Group	Historical Control
Analysis Type	Analytical
Study Population	Transit Adolescent B (as adults) (B 21 yrs, Adult >21
Detailed Study Protocol Parameters	
Study Design Description	This is an observational cohort study. A new cohort of patients and physicians will be
Study Population Description	Study population is as per device indication. This device is indicated for permanent birth control.
Sample Size	657 women enrolled - protocol states 20 total enrolled patients
Data Collection	Study endpoints include: (1) bilateral intra-uterine placement rate; (2) identification of factors predictive of intra-uterine
Followup Visits and Length of Followup	N/A
Final Study Results	
Actual Number of Patients Enrolled	784 women
Actual Number of Sites Enrolled	76
Patient Followup Rate	51.66%
Final Safety Findings	The sponsor reported only 8 adverse events occurred during and after the Essure placement procedure
Study Strengths and Weaknesses	The study is well designed to evaluate the placement rate among newly trained physicians at
Recommendations for Labeling Changes	Update labeling with the results of the study in the context of patient and physician labeling

ESS-305 Schedule

Report Schedule	Report Data Due	FDA Receipt Date	Reporting Status
6 month report	12/14/2007	12/14/2007	On Time
1 year report	08/14/2008	08/17/2008	Overdue/Received
18 month report	12/13/2008	12/15/2008	Overdue/Received
Final Report	08/14/2009	08/15/2009	Overdue/Received

Show All Studies

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1. http://www.addthis.com/bookmark.php?v=250&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

C

STATE OF CALIFORNIA — HEALTH AND HUMAN SERVICES AGENCY

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

INVESTIGATIVE REPORT

Inspection Date(s): 1/21/2011

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

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

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

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

DISCUSSION

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

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

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

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

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

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

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

EXHIBIT C

DISCUSSION WITH MANAGEMENT

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

RECOMMENDATION

No further action is indicated.

Investigator's Name: Lana Widman **Badge No.** 136

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

Supervisor's Review/Comments:

[signature]

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

Conceptus, Inc.
331 East Evelyn Ave.
Mountain View, CA 94041
(650) 962-4000

NARRATIVE REPORT

SUMMARY OF FINDINGS

The firm, Conceptus Inc., applied for a device manufacturing license and was assigned pending license number 45136. The firm is a manufacturer of an implantable Class III medical device, specifically the Essure System for Permanent Birth Control.

A two item Notice of Violation (NOV) was issued during the pre-license inspection by the California Department of Public Health for failure to obtain a valid license from the department prior to manufacturing and distributing medical devices and failure to maintain the procedure Inventory Transfer. The violations were adequately corrected by June 11, 2008.

Recommendations: It was recommended that the device manufacturing license be issued for Conceptus, Inc. located at 331 East Evelyn Avenue, Mountain View, CA 94041.

INSPECTION OVERVIEW

Inspection date: This inspection was conducted on June 10-11, 2008.

Purpose: The inspection was conducted in response to a Medical Device License Application dated 12/05/05 and signed by Edward Sinclair. The inspection was pursuant to HSC 111635 that states "Prior to issuing a license required by Section 111615, the department shall inspect each place of business." This was a relocation inspection, the prior location at 1021 Howard Avenue in San Carlos, CA (license #62105) was licensed with department from1994 to 2005.

Scope of Inspection: The Quality System Inspection Technique (QSIT) was used as guidance for this inspection focusing on Management Controls, Design Controls, Corrective and Preventive Actions, and Production and Process Controls.

Type of firm/Products: The firm was a corporation registered with the FDA, #2951250, and their Class III Essure System for Permanent Birth Control was listed. They held the following PMA:

- P020014, Essure System for Permanent Birth Control on November 4, 2002.

Supplement 18, the most recent PMA supplement submitted by Conceptus had been acknowledged on 05/22/08 by the FDA. In #18, the firm was seeking approval to terminate their post-approval study early. They reportedly had demonstrated adequate bilateral placement success for the Essure device, and did not feel adding more patients to the study would be beneficial.

The device was a micro-insert coil intertwined with PET fibers attached to a delivery system (introducer, delivery catheter, delivery wire). A doctor placed the coil at the uterine-fallopian tube junction, where its coating caused it to be attached to the tube. An Essure kit contained two

EXHIBIT
D

devices, so the doctor would place a coil at both uterine-fallopian tube junctions. Over the weeks following the implants, a natural barrier form should form around the insert. Three months following the procedure, the patient would undergo a xray to determine the barrier had effectively formed. The device was single use and sterile with a shelf-life of 24 months.

Ownership/history of firm:

The corporation was founded in the 1990's to help facilitate pregnancy. The original device did not go to market and now they manufacture a birth control device. Conceptus produced between 4,000 to 5,000 Essure kits per month, and distributed them domestically, in Canada, Australia, and the European Union.

The President and CEO Mark Sieczkarek was the most responsible person on site. See Exhibit A for the firm's organizational chart. The company had been at this site since December 2005, and it occupied approximately 50,000 square feet. See [redacted] for the facility's floor plan. Conceptus had approximately 230 employees, mostly in sales, while 100 employees worked at this facility. They perform research and development, complaints, CAPAs and distribution functions at this site. Assembling, packaging and labeling were contracted out.

Individual(s) Contacted During the Inspection: Edward Sinclair was no longer with the company. The inspection contact was Henry Bishop, Quality Manager. He was cooperative in scheduling and providing documents during the inspection. Others participating in the inspection included:

Edward Yu, Director of Clinical Research and Regulatory Affairs
Tarhan Kayihan, Regulatory Compliance Engineer
Rob McCarthy, Director of Operations
Rachelle Acuna-Narvaez, Regulatory Affairs Associate
Shakil Ahmed, Senior Product Surveillance Engineer
Rich Suggs, Logistics Manager
Charan Singh, Associate Quality Engineer
Mark Pfirrman, Senior Quality Engineer
Murray Margone, Facilities Manager
Harpreet Singh, Senior Quality Engineer

All correspondence should be sent to:

Edward Yu
Director of Clinical Research and Regulatory Affairs
331 East Evelyn Ave
Mountain View, CA 94041

Previous licensing/inspection background: The firm was inspected by the department in 1994 at its former location. They were last inspected by FDA September 21-22, 2005 with no report of observations (483) issued.

National Standards Authority of Ireland (NSAI) had certified their quality system. They have CE Mark from NSAI.

AREAS INSPECTED/NONCONFORMANCY DISCUSSION

Management Controls

The firm had established and implemented procedures for this system. Henry Bishop had been appointed the firm's management representative. The following documents were reviewed and appeared adequate:

- Management Review, SOP 01104 Rev. N
- Management Review Attendance and Agenda dated 10/17/06 and 11/09/07
- Internal Audit, SOP 00415 Rev. Z
- 6/2/08-6/6/08 Audit Summary
- Employee Training, SOP 00404
- Sample of four employee training records

No deficiencies were noted.

Design Controls

Design Controls were not a large focus of this inspection. The firm had established and implemented procedures for this system. The following were reviewed:

- Product Development Process, SOP 00799 Rev. R
- Risk Analysis, SOP 1830 Rev. H
- Annual sterilization validation, VR-2982 Rev. O, dated 7/20/07-7/23/07
- Design FMEA for ESS305 dated 01/05/07

No deficiencies were noted.

Corrective and Preventative Actions (CAPA)

The firm had established procedure and forms for this system. The following were reviewed and appeared adequate:

- Corrective & Preventive Action, SOP 00935 Rev. R
- Product Return, Complaint Handling and Reporting, SOP 1630 Rev. W
- Product Recall, SOP 01045 Rev. H
- Material Identification and Traceability Policy, SOP 3093 Rev. A
- CAPA, complaint, MDR logs

The firm had 1,587 complaints since the beginning of 2008, 15 CAPAs since 2006, and 12 MDRs since 2007. They've had no recalls. A sample of CAPAs, MDRs and complaints were reviewed. All appeared well documented, investigated to root cause, and adequately trended.

No deficiencies were noted, but better documentation of CAPA verification and validation activities for ease of explanation was discussed with the firm.

Production and Process Controls

Conceptus used a contract manufacturer for assembly of the Essure device. R&D, complaints and CAPAs, and distribution were the only in-house functions. A tour of the facility was conducted and the following were reviewed:

- Good Documentation Practices, SOP 00370 Rev. G
- Engineering Change Order Procedure, SOP 00399 Rev. G
- Essure Demo Assembly, R2688
- Deployment and Release of Micro-Insert Test, R2621
- Essure Delivery System Tensile Test Method, R2685
- Demo Packaging, R1882
- Sterile Load Control, SOP 01026 Rev. T
- Line Clearance, SOP 00922 Rev. K
- Incoming Inspection, SOP 00384, Rev. W
- Nonconforming Material Review, SOP 00383 Rev. V
- Supplier Selection, Approval and Monitoring, SOP 00739 rev. V
- Approved Supplier List
- Supplier files: [redacted] and [redacted]
- [redacted] Supplier Agreement (See Exhibit C)
- Environmental Monitoring of the Controlled Environment Room, SOP 00928, Rev AD
- CER testing dated 03/11/08 and 09/17/07 (CER was not used in production/R&D only)
- Calibration Procedure, SOP 00379 Rev. S
- Calibration log and two equipment files

Supplier [redacted] assembled the devices and shipped the devices to [redacted] in [redacted]. [redacted] shipped the sterilized devices to Conceptus. Conceptus reviewed the products certifications and performed incoming inspection on a sample of kits (AQL of 1.0), and then shipped accepted materials. The firm estimated that by December 2008, [redacted] will ship only the sample devices to Conceptus for inspection and send the devices to [redacted] in [redacted]. [redacted] would distribute the devices following Conceptus's approval of the lot based on the samples they received.

No deficiencies were noted in the above.

One violation was noted for Inventory Transfer, SOP 00454 Rev. Y (See Exhibit D) because it was the procedure from their old facility and was not the procedure being used at the current facility. The firm provided adequate corrections on June 11, 2008 (See Exhibit E).

Conceptus, Inc.
331 East Evelyn Ave.
Mountain View, CA 94041
(650) 962-4000

ATTACHMENTS

A. Notice of Violation dated June 11, 2008

EXHIBITS

A. [redacted]
B.
C.
D.
E.

Christine Rodriguez
Food & Drug Investigator
Medical Device Safety Unit
Food and Drug Branch

...nia—Health and Human Services Agency

Department of Health Services

NOTICE OF VIOLATION

Food and Drug Branch

Direct responses to: CHRISTINE RODRIGUEZ WITHIN 10 DAYS

Supervisor: HARLAN LOUI | Telephone number: (916) [illegible]

Address (number, street): 1500 CAPITOL AVE, MS 7607 | City: SACRAMENTO | ZIP code: 95814

Firm name: CONCEPTUS, INC | Date: 04-11-03

Address (number, street): 331 EAST EVELYN AVE | City: MOUNTAIN VIEW | ZIP code: 94041

Person interviewed: HENRY BISHOP | Position: QUALITY MANAGER

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

(1) THE FIRM FAILED TO OBTAIN A VALID LICENSE FROM THE DEPARTMENT PRIOR TO MANUFACTURING MEDICAL DEVICES. THE FIRM MAILED IN THE APPLICATION IN 2003 AND HAS BEEN MANUFACTURING MEDICAL DEVICES FROM 2003 TO THE PRESENT AT AN UNLICENSED FACILITY.

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

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

Firm's authorized representative signature: [signature] | Authorized representative position: HENRY BISHOP QC MANAGER

Authorized agent signature: [signature] | Authorized agent name and badge number (printed): CHRISTINA RODRIGUEZ #156

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

SUMMARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EXHIBITS COLLECTED

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

ATTACHMENTS

1. FDA 482 (Notice of Inspection)

Timothy C. Grome, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
(510) 337-6700 Fax: (510) 337-6702
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
12/08/2010 - 01/06/2011*

FEI NUMBER
1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mark M. Sieczkarek, President and CEO

FIRM NAME
Conceptus, Inc.

STREET ADDRESS
331 E.Evelyn Ave.

CITY, STATE AND ZIP CODE OF FACILITY
Mountain View, CA 94041

TYPE ESTABLISHMENT INSPECTED
Medical Device Manufacturer

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

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

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

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

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

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

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

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

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

SIGNATURE OF INVESTIGATOR(S)
Timothy C. Grome, Investigator

DATE ISSUED
01/06/2011

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

EXHIBIT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
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(510) 337-6700 Fax:(510) 337-6702
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DATE(S) OF INSPECTION
12/08/2010 - 01/06/2011*

FEI NUMBER
1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM EI REPORT ISSUED
TO: Mark M. Sieczkarek, President and CEO

FIRM NAME
Conceptus, Inc.

STREET ADDRESS
331 E.Evelyn Ave.

CITY, STATE AND ZIP CODE, COUNTRY
Mountain View, CA 94041

TYPE ESTABLISHMENT INSPECTED
Medical Device Manufacturer

OBSERVATION 2

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

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

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

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

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

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

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

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

OBSERVATION 3

Risk analysis is incomplete.

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

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EMPLOYEE(S) SIGNATURE
Timothy C. Grome, Investigator

DATE ISSUED
01/06/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

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

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

OBSERVATION 4

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

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

ANNOTATIONS
OBSERVATION 1
(b) (4)

(b) (4)

OBSERVATION 2:
(b) (4)

OBSERVATION 3
(b) (4)

OBSERVATION 4
Corrected and Verified
Timothy C. Grome 1/6/2011

AMENDMENT 1

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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DATE(S) OF INSPECTION: 12/08/2010 - 01/06/2011*
FEI NUMBER: 1000221357

TO: Mark M. Sieczkarek, President and CEO

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

the peritoneal cavity.

OBSERVATION 4

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SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE: Timothy C. Grome, Investigator

DATE ISSUED: 01/06/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1431 Harbor Bay Parkway
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DATE(S) OF INSPECTION: 06/25/2003 - 07/07/2003*

FEI NUMBER: 1000221357

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William H. Dippel, Vice President, Operations

FIRM NAME: Conceptus, Inc.

STREET ADDRESS: 1021 Howard Avenue

CITY, STATE AND ZIP CODE, COUNTRY: San Carlos, CA 94070

TYPE ESTABLISHMENT INSPECTED: Medical Device Manufacturer

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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically, during a review of (b) (4) Lot History Reports (LHRs) for the manufacture of the Essure Permanent Birth Control System, two Lot History Records showed rejected raw materials and/or subassemblies hand-written on the Work Order Picklist. This information/ data was not documented on Page 2 of 3 of the QAF-2035 (Quality Assurance Form) which is used to track and trend in-process data.

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

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

OBSERVATION 2

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

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

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

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DATE ISSUED: 07/07/2003

FORM FDA 483 (07/95) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 2 PAGES

EXHIBIT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1431 Harbor Bay Parkway
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(510) 337-6700 Fax: (510) 337-6702

DATE(S) OF INSPECTION
06/25/2003 - 07/07/2003*

FEI NUMBER
1000221357

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

FIRM NAME
Conceptus, Inc.

STREET ADDRESS
1021 Howard Avenue

CITY, STATE, ZIP CODE, COUNTRY
San Carlos, CA 94070

TYPE ESTABLISHMENT INSPECTED
Medical Device Manufacturer

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

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

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Mark E Chan

Mark E. Chan, Investigator

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DATE ISSUED
07/07/2003

FORM FDA 483 (07/90) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 OF 2 PAGES