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
Heather Walsh
26556 Clarkston Drive
Bonita Springs, FL 34135

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
James J. McEldrew, Esquire
McEldrew Law
123 S. Broad Street, Suite 1920, Phila., PA 19109

DEFENDANTS
Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205

County of Residence of First Listed Defendant Allegheny
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Heather R. Olson, Esquire
Eckert Seamns Cherin & Mellott, LLC
Two Liberty Place, 50 S. 16th Street, 22nd Fl., Phila., PA 19102

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. § 1441 and 1331
Brief description of cause:
Plaintiff 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 _____ DOCKET NUMBER _____

DATE 01/26/2015

SIGNATURE OF ATTORNEY OF RECORD Heather R. Olson, Esquire

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

Heather Walsh	:	CIVIL ACTION
v.	:	
Bayer Corporation	:	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.) ( )

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

January 26, 2015		Bayer Corporation
Date	**Attorney-at-law** Heather R. Olson, Esq.	**Attorney for** Defendant
(215) 851-8400	(215) 851-8383	holson@eckertseamans.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: 26556 Clarkston Drive, Bonita Springs, FL 34135

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

Place of Accident, Incident or Transaction: Michigan

(*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: _____ Judge _____ Date Terminated: _____

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) Plaintiff's Complaint raises substantial federal questions arising from federal statutes and regulations governing medical devices.

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, Heather Olson, 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.

*based solely on Plaintiff's allegations.

DATE: January 26, 2015 _____ 92073

Attorney-at-Law Heather R. Olson, Esquire — 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: January 26, 2015 _____ 92073

Attorney-at-Law Heather R. Olson, Esquire — Attorney I.D.#

CIV. 609 (5/2012)

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

HEATHER WALSH,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Civil Action No._____
	)	
BAYER, CORP.,	)	
BAYER HEALTHCARE LLC.,	)	
BAYER ESSURE, INC.,	)	
BAYER HEALTHCARE	)	
PHARMACEUTICALS, INC., and	)	
BAYER A.G.,	)	
	)	
Defendants.	)	

NOTICE OF REMOVAL

Defendant, Bayer Corporation (hereinafter "Defendant"), by and through its undersigned counsel, hereby provides notice pursuant to 28 U.S.C. § 1446 of the removal of the above-captioned case from the Court of Common Pleas of Philadelphia County, Pennsylvania to the United States District Court for the Eastern District of Pennsylvania. The grounds for this removal are as follows:

1. Plaintiff Heather Walsh commenced this action by filing a Complaint (the "Complaint") on or about December 18, 2014 in the Court of Common Pleas of Philadelphia County, Pennsylvania and the case was assigned to docket number 02792 of the December 2014 Term.

2. Plaintiff served copies of the Complaint and Notice to Defend on Defendant on January 7, 2015 via process server. True and correct copies of the Complaint, Notice to Defend, and Exhibits to the Complaint are attached hereto as Exhibit A.

3. The Complaint also names the following additional defendants: Bayer HealthCare Pharmaceuticals Inc.; Bayer Essure, Inc.; Bayer HealthCare, LLC; and Bayer AG (collectively, with Defendant Bayer Corporation, the "Bayer Defendants"). As of the date of this Notice, upon information and belief, none of the Bayer Defendants except Bayer Corporation have been served. Therefore, their consent to removal is not required. *See* 28 U.S.C. § 1446(b)(2)(A).

4. The remaining document which has been filed in the state court action, the Affidavit of Service on Bayer Corporation, is attached hereto as Exhibit B. A true and correct copy of the Philadelphia Court of Common Pleas docket is attached hereto as Exhibit C.

5. Under 28 U.S.C. § 1446(b), this Notice of Removal must be filed within 30 days of service of the Complaint and the Notice to Defend upon Defendant. Because Defendant was served on January 7, 2015 and is filing this Notice on January 26, 2015, removal is timely.

6. The time for Defendant to answer, move, or otherwise plead with respect to the Complaint has not yet expired.

7. Concurrent with the filing of this Notice, Defendant is serving this Notice on Plaintiff's counsel and filing a copy with the Office of the Prothonotary for the Court of Common Pleas of Philadelphia County, Pennsylvania.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 118(a) and 1441(a) because the United States District Court for the Eastern District of Pennsylvania is the federal judicial district encompassing the Court of Common Pleas of Philadelphia County, Pennsylvania, where this action was originally filed.

9. By filing a Notice of Removal in this matter, Defendant does not waive any of its rights to object to service of process, the sufficiency of process, jurisdiction over the person, or

venue, and Defendant specifically reserves its rights to assert any defenses and/or objections to which it may be entitled.

10. As more fully discussed below, this case is removable to federal court because there is federal question jurisdiction under 28 U.S.C. § 1331.

FEDERAL QUESTION JURISDICTION

11. Defendant incorporates by reference paragraphs 1 through 10 above herein as if fully restated herein.

12. Under 28 U.S.C. § 1331, the district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331.

13. Here, Plaintiff alleges various injuries as a result of her receiving a female birth control device known as Essure® System for Permanent Birth Control ("Essure"). *See, e.g.*, Complaint at ¶¶ 13-14, 85-96. Essure is a medical device as that term is defined under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c, *et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* *See also* 21 U.S.C. § 321(h) and 360c(a)(1)(C)(ii). The Food and Drug Administration (the "FDA") regulates medical devices in the United States and it is responsible for implementation and enforcement of statutes and regulations pertaining to medical devices, including Essure. *Id.*

14. Federal regulation of medical devices is governed by the MDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The MDA establishes three classes of increasingly stringent federal oversight. *Id.* at 316-17.

15. "Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight." *Id.* at 316.

16. "Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject to 'special controls' such as performance standards and postmarket surveillance measures." *Id.* at 316-17 (citing § 360c(a)(1)(B)).

17. Only devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Class III devices "receiv[e] the most federal oversight" and innovative Class III devices must go through "a rigorous regime of premarket approval" before they may be brought to market, *Riegel*, 552 U.S. at 317, and are the most regulated medical devices. Class III devices are those for which performance standards (Class II) or general controls (Class I) are not sufficient assurance that the device is safe and effective for its intended use. As a result, under Section 515 of the MDA, all devices placed into Class III are subject to premarket approval requirements—a required process of scientific review designed to ensure the safety and effectiveness of Class III devices. 21 U.S.C. § 515; *see also Riegel*, 552 U.S. at 318-19.[1]

18. Essure is a Class III medical device whose design, manufacturing method, and labeling were given specific premarket approval ("PMA") by the FDA pursuant to the agency's PMA process. See Complaint at ¶¶ 15, 46-48 (*see also* U.S. Food & Drug Admin., *Premarket Approval Order for the Essure® System*, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014A.pdf; last visited December 18, 2014).[2]

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[1] The FDA's public website offers further information regarding the premarket approval process under the MDA. *See* http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm; last visited December 18, 2014.

[2] This web page is part of the FDA's public database of premarket approvals, which is accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. This Court may take judicial notice of the fact of Essure's premarket approval because the FDA's public website is a database maintained by the FDA in the normal course of its business and reflects final agency action. FED. R. EVID. 201; *see, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011)

19. Under the PMA process, a device can be approved, not approved, or issued an approvable letter. *See* 21 U.S.C. § 360e(d); *see also* Complaint at ¶ 52. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses. (*See http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm*; last visited December 18, 2014).

20. The PMA process for Class III devices is the most exacting form of FDA review. To obtain FDA approval via the PMA process, a manufacturer must:

> [S]ubmit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

Riegel v. Medtronic, Inc., 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008)). The FDA rigorously scrutinizes PMA applications, "'weig[hing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). "The FDA spends an average of 1,200 hours reviewing each application" and "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (quoting 21 U.S.C. § 360e(d)).

21. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing

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(affirming judicial notice of PMA approval); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 n.26 (W.D. Pa. 2012) (taking judicial notice of FDA approval documents).

processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

22. Section 360k(a) of the MDA expressly preempts any state-law claim that would impose a requirement that is "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321-28. Through this provision, Congress expressly preempted state-law tort claims challenging the design, manufacture, or labeling of a medical device previously approved by the FDA under the PMA process.

23. Conceptus, Inc. originally obtained the PMA for Essure in 2002[3].

24. Plaintiff alleges that the Bayer Defendants'[4] conduct somehow invalidated the PMA for the Essure device and, as a result, the product became "adulterated" as defined and regulated by the FDA due to the Bayer Defendants' alleged failure to comply with the PMA order and federal regulations and hence cannot be lawfully sold. *See* Complaint at ¶¶ 15–18.

25. Plaintiff's allegations center on the validity of the PMA, an order issued by the FDA, a federal agency, and the federal statutes and regulations which the FDA implements and enforces. Complaint at ¶¶ 15-26. Moreover, Plaintiff alleges that, as a result of the Bayer Defendants' failure to comply with an FDA issued PMA approval order and FDA regulations, the PMA issued by the FDA for Essure is rendered "invalid." *Id.* at ¶ 64. This allegation directly attacks the PMA, a federal order which the FDA has never found to be invalid. The PMA is still in place.[5] Plaintiff's allegations challenge the entire federal regulatory process under which the

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[3] U.S. Food & Drug Admin., *Premarket Approval Order for the Essure® System*, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014A.pdf; last visited December 18, 2014.

[4] The stock of Conceptus, Inc. was acquired by a subsidiary of defendant Bayer HealthCare LLC in 2013. Complaint at ¶ 42.

[5] The FDA's public database for PMA approvals contains a full and complete record of the status of the PMA for the Essure device since its approval in 2002 and any supplements to the approval since that time. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4831; last visited December 18, 2014.

FDA approves Class III medical devices and attempts to substitute her own interpretation, and that of the Philadelphia Court of Common Pleas, of the FDA's approval regimen for that of the FDA.

26. Specifically, the Bayer Defendants' purported activities by: (1) failing to meet regular reporting requirements; (2) failing to report known hazards to the FDA; and (3) failing to comply with federal laws regarding marketing and distribution of the device, all allegedly invalidated the PMA making distribution of the Essure device and sale to the Plaintiff illegal under the FDCA, 21 U.S.C. §§ 301, *et seq.*, and the MDA. *See* Complaint at ¶¶ 15-20, 27-28, 51, 54–55, 59-64.

27. Plaintiff further alleges that the purportedly invalid PMA was not properly transferred from Conceptus, Inc. to the Bayer Defendants, and, therefore, the Bayer Defendants did not have any form of PMA from the FDA, making their sale and distribution of the device illegal under federal statutory and regulatory law. *See, e.g.,* Complaint at ¶¶ 62-64.

28. The federal statutes relied on by Plaintiff include the FDCA and the MDA, generally, and specifically §§ 501(f), 502(q) and (r) of the FDCA. *See* Complaint at ¶ 16, 21, 25, 59, 60, 61, 82, 104, 157, 207.

29. Thus, while Plaintiff's claims against the Bayer Defendants are purportedly pleaded under state law,[6] each claim is necessarily predicated on alleged breaches of duties imposed by federal law and challenges the safety and effectiveness of a device subject to pervasive federal regulation and administrative oversight. Indeed, her Complaint seeks to invalidate a federal order and override the discretion of the FDA. The ultimate merit of Plaintiff's causes of action will depend on Plaintiff's ability to establish a violation of relevant federal requirements on the Essure

[6] Defendant in no way concedes that any of Plaintiff's claims are cognizable as a matter of state law.

device that is causally linked to her alleged injuries. Accordingly, violation of federal law is a critical and indispensable element of Plaintiff's claims.

30. A claim may arise under federal law in either of two ways – (1) federal question by pleading a cause of action created by federal law and (2) where the claims at issue implicate significant federal issues giving rise to a substantial federal question. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). The second form of federal-question jurisdiction "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.*

31. When evaluating whether a federal statute creates a substantial federal interest giving rise to federal-question jurisdiction over claims pleaded under state law, the Supreme Court has "disclaimed the adoption of any bright-line rule." *Id.* at 317. "Instead, the question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314; *see also Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 568 (6th Cir. 2007) (en banc). This question requires courts to make "'sensitive judgments about congressional intent.'" *Id.* at 318; *accord Mikulski*, 501 F.3d at 561 ("our inquiry is ultimately one of congressional intent").

32. By enacting the MDA, Congress both recognized and reinforced a substantial federal interest in the regulation of PMA-approved Class III medical devices. Indeed, as the Supreme Court explained in *Riegel,* the very purpose of the MDA was to "swe[ep] back some state obligations and impose[] a regime of detailed federal oversight." 552 U.S. at 316. Just as Congress

took the regulation of medical devices out of the hands of state legislatures and entrusted it instead to the exclusive authority of an expert federal agency, namely the FDA, so too Congress presumably wanted the litigation of medical device claims involving innovative Class III medical devices, the most complex devices subject to the most detailed federal oversight, to be removable from state courts so that such litigation could proceed under the eye of the federal judiciary. Indeed, it would be peculiar for Congress to have "imposed a regime of detailed federal oversight," (*id.*), while at the same time preventing removal to federal court of claims predicated on the purported violation of federal requirements established by that regulatory regime.

33. Although a plaintiff suing for an injury allegedly caused by an FDA-approved medical device may still attempt to recite a cause of action nominally recognized under state law, to plead and prove a non-preempted "parallel" claim "[t]he plaintiff must be suing for conduct that violates the FDCA (or else her claim is expressly preempted by § 360k(a))." *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). Thus, for a claim to escape express preemption, the duty at issue must necessarily be one imposed by federal law.

34. Because a federal duty and requirement is inevitably at issue and is in fact a required element of Plaintiff's claims, the resolution of such claims necessarily "implicate[s] significant federal issues" and "turn[s] on substantial questions of federal law." *Grable*, 545 U.S. at 312. In an analogous case, a New York district court held that a state-law negligence and product-liability action against generic drug manufacturers "necessarily raises a federal question" because, to avoid preemption, the plaintiffs were required to prove a violation of the "ongoing federal duty of sameness" under the Hatch-Waxman Act. *Bowdrie v. Sun Pharm. Indus.*, 909 F.Supp.2d 179, 183 (E.D.N.Y. 2012) (citation omitted); *see also Riegel*, 552 U.S. at 316, 322-24.

35. There can be no question that the federal question raised by Plaintiff's purportedly parallel claims is substantial. The question of whether Plaintiff can establish a violation of a federal duty that parallels her state-law claims is likely to be "dispositive of this case." *Mikulski*, 501 F.3d at 571; *see, e.g., Landers v. Morgan Asset Mgmt., Inc.*, 2009 WL 962689, at *8 (W.D. Tenn. 2009) (finding a substantial federal question where plaintiffs' negligence claim necessarily "depends on a finding that the Defendants did not meet the standard of care imposed by federal…law"). Indeed, Congress, through the MDA's express preemption clause, has specifically barred claims against medical device manufacturers including the sort of claims asserted by Plaintiff unless Plaintiff can plead and prove the violation of a parallel federal-law duty.

36. Moreover, the enforcement of the federal duties at issue here is committed to the broad oversight of the FDA, a federal agency. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (describing the "variety of enforcement options" available to the FDA). As the Sixth Circuit has recognized, the role of a federal agency, such as the involvement of the FDA in the regulation of Class III medical devices, is a factor supporting the substantiality of the federal interest. *Mikulski*, 501 F.3d at 570. Regulation of the design, manufacture, and labeling of PMA-approved medical devices is in the first instance, and primarily, federal.

37. As the Supreme Court has authoritatively recognized, the text of the MDA demonstrates Congress' intent to displace "the tort law of 50 States" and "impose[] a regime of detailed federal oversight." *Riegel*, 552 U.S. at 316, 326; *see also Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

38. To this end, a district court's federal jurisdiction over claims concerning Class III medical devices that have received premarket approval from the FDA would not risk opening the federal courts to a flood of litigation as there is no danger here that the FDCA "would attract[] a

horde of original filings and removal cases raising other state claims with embedded federal issues." *Grable,* 545 U.S. at 318.

39. The federal interest recognized by the MDA is implicated only by claims concerning Class III medical devices that have received premarket approval from the FDA. Such devices constitute a small fraction of a small subset of medical devices. Only devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Only a relatively small number of medical devices fall into that category. And of those that do, "only a small percentage" are subject to the premarket approval process. *Smith v. Phoenix Seating Systems, LLC*, 894 F.Supp.2d 1088, 1097 (S.D. Ill. 2012). Indeed, "[t]he vast majority of Class III medical devices…reach the market without ever going through the rigorous PMA process." *Riegel*, 451 F.3d at 111.[7]

40. For these reasons, there is no danger that this Court's exercise of federal jurisdiction over claims concerning a Class III medical device with premarket approval will have any significant impact on the workload of the federal courts; rather, it "will portend only a microscopic effect on the federal–state division of labor." *Grable*, 545 U.S. at 315. Federal jurisdiction over this narrow class of cases concerning PMA-approved Class III medical devices under the MDA is

[7] "Most new Class III devices enter the market through" what "is known as the § 510(k) process," a far less rigorous process that does not trigger preemption under § 360k(a). *Riegel*, 552 U.S. at 317. "In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Id.* (citing P. Hutt, R. Merrill, & L. Grossman, FOOD AND DRUG LAW 992 (3d ed. 2007)). "In other words, in 2005, approximately ninety-nine percent of such devices went through the § 510(k) process and ***only one percent*** went through the PMA process." *Riegel*, 451 F.3d at 112 (emphasis added). In 2011, only 51 devices received premarket approval.
See http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsand Clearances/Recently-ApprovedDevices/default.htm; last visited December 18, 2014.

therefore fully "consistent with congressional judgment about the sound division of labor between state and federal courts." *Id.* at 313.

41. By enacting the MDA, Congress declared that medical devices are to be governed exclusively by requirements of federal law that are administered and enforced exclusively by the expert decisions of the FDA, a federal agency.

42. In her Complaint, Plaintiff claims that the FDA-issued PMA is "invalid." That is, she claims that the FDA's rigorous federal safety review of a Class III device – which commands the federal agency's highest standard of review – can be challenged many years after approval in a state court. Moreover and telling to the substantial federal questions she presents, Plaintiff contends that the decision reached by the FDA in approving Essure under its rigorous regulatory scheme can be invalidated by a state court under state law. This is a substantial and important federal question involving a federal agency (the FDA) and compliance with federal statutes and regulations. There is no question that Plaintiff's tort claims, which challenge the safety and effectiveness of such a Class III medical device and invoke federal statutory and regulatory requirements related to such devices, implicate substantial federal interests that call for the availability of jurisdiction in a federal forum.

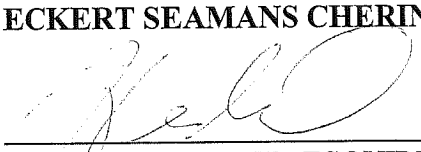
43. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. § 1331, and this case is removable under 28 U.S.C. § 1441.

WHEREFORE, Notice is given that this action is removed from the Court of Common Pleas of Philadelphia County, Pennsylvania to the United States District Court for the Eastern District of Pennsylvania.

Dated: January 26, 2015

Respectfully submitted,

ECKERT SEAMANS CHERIN & MELLOTT LLC



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Attorneys for Defendant Bayer Corporation

CERTIFICATE OF SERVICE

I, HEATHER R. OLSON, do hereby certify that, on January 26, 2015, I caused a true and correct copy of the foregoing Notice of Removal to be served upon the following counsel of record, in the manner indicated:

Via Hand Delivery and Electronic Mail

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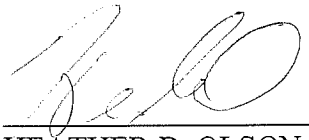

HEATHER R. OLSON

M1328123

EXHIBIT "A"

Court of Common Pleas of Philadelphia County
Trial Division

Civil Cover Sheet

For Prothonotary Use Only (Docket Number)
DECEMBER 2014 002792
E-Filing Number: 1412041561

PLAINTIFF'S NAME	DEFENDANT'S NAME
HEATHER WALSH	BAYER, CORP.
PLAINTIFF'S ADDRESS 26556 CLARKSTON DRIVE BONITA SPRINGS FL 34135	DEFENDANT'S ADDRESS 100 BAYER ROAD, BLD. 4 PITTSBURGH PA 15205
PLAINTIFF'S NAME	DEFENDANT'S NAME BAYER HEALTHCARE, LLC.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 100 BAYER BLVD. WHIPPANY NJ 07981
PLAINTIFF'S NAME	DEFENDANT'S NAME BAYER ESSURE, INC.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 100 BAYER BLVD. WHIPPANY NJ 07981

TOTAL NUMBER OF PLAINTIFFS	TOTAL NUMBER OF DEFENDANTS	COMMENCEMENT OF ACTION
1	5	☒ Complaint ☐ Petition Action ☐ Notice of Appeal ☐ Writ of Summons ☐ Transfer From Other Jurisdictions

AMOUNT IN CONTROVERSY
☐ $50,000.00 or less
☒ More than $50,000.00

COURT PROGRAMS

☐ Arbitration	☐ Mass Tort	☐ Commerce	☐ Settlement
☒ Jury	☐ Savings Action	☐ Minor Court Appeal	☐ Minors
☐ Non-Jury	☐ Petition	☐ Statutory Appeals	☐ W/D/Survival
☐ Other:			

CASE TYPE AND CODE
2P - PRODUCT LIABILITY

STATUTORY BASIS FOR CAUSE OF ACTION

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)

FILED
PRO PROTHY
DEC 18 2014
D. SAVAGE

IS CASE SUBJECT TO COORDINATION ORDER?
YES NO

TO THE PROTHONOTARY:

Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: HEATHER WALSH

Papers may be served at the address set forth below.

NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY	ADDRESS
JAMES J. MCELDREW	MCELDREW LAW 123 SOUTH BROAD STREET SUITE 1920 PHILADELPHIA PA 19109
PHONE NUMBER: (215)545-8800 / FAX NUMBER: (215)545-8805	
SUPREME COURT IDENTIFICATION NO. 36411	E-MAIL ADDRESS jim@mceldrewlaw.com
SIGNATURE OF FILING ATTORNEY OR PARTY *JAMES MCELDREW*	DATE SUBMITTED Thursday, December 18, 2014, 04:20 pm

FINAL COPY (Approved by the Prothonotary Clerk)

COMPLETE LIST OF DEFENDANTS:

1. BAYER A.G.
   WERK LEVERKUSEN 51368
   LEVERKSUN
2. BAYER HEALTHCARE PHARMACEUTICALS, INC.
   100 BAYER BLVD.
   WHIPPANY NJ 07981
3. BAYER ESSURE, INC.
   100 BAYER BLVD.
   WHIPPANY NJ 07981
4. BAYER HEALTHCARE, LLC.
   100 BAYER BLVD.
   WHIPPANY NJ 07981
5. BAYER, CORP.
   100 BAYER ROAD, BLD. 4
   PITTSBURGH PA 15205

McELDREW LAW, LLC
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THIS IS A MAJOR JURY MATTER

Attorneys for Plaintiffs

HEATHER WALSH, 26556 Clarkston Drive Bonita Springs, FL 34135 Plaintiff, vs. BAYER, CORP. 100 Bayer Road, Bld. 4 Pittsburgh, PA 15205 BAYER HEALTHCARE LLC. 100 Bayer Blvd. Whippany, NJ 07981 BAYER ESSURE, INC. 100 Bayer Blvd. Whippany, NJ 07981 BAYER HEALTHCARE PHARMACEUTICALS, INC. 100 Bayer Blvd. Whippany, NJ 07981 BAYER A.G. Werk Leverkusen 51368 Leverkusen, Germany Defendants.	IN THE COURT OF COMMON PLEAS PHILADELPHIA COUNTY TERM, 2014 NO.

NOTICE TO DEFEND

NOTICE	AVISO
You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint of for any other claim or relief	Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la

requested by the plaintiff. You may lose money or property or other rights important to you. *You should take this paper to your lawyer at once. If you do not have a lawyer or cannot afford one, go to or telephone the office set forth below to find out where you can get legal help.* **Philadelphia Bar Association** **Lawyer Referral** **and Information Service** **One Reading Center** **Philadelphia, Pennsylvania 19107** **(215) 238-6333** **TTY (215) 451-6197**	corte puede decider a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted. *Lleve esta demanda a un abogado inmediatamente. Si no tiene abogado o si no tiene el dinero suficiente de pagar tal servicio. Vaya en persona o llame por telefono a la oficina cuya direccion se encuentra escrita abajo para averiguar donde se puede conseguir asistencia legal.* Asociacion De Licenciados **De Filadelfia** **Servicio De Referencia E** **Informacion Legal** **One Reading Center** **Filadelfia, Pennsylvania 19107** **(215) 238-6333** **TTY (215) 451-6197**

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THIS IS A MAJOR JURY MATTER

Attorneys for Plaintiffs

HEATHER WALSH, 26556 Clarkston Drive Bonita Springs, FL 34135 Plaintiff, vs. BAYER, CORP. 100 Bayer Road, Bld. 4 Pittsburgh, PA 15205 BAYER HEALTHCARE LLC. 100 Bayer Blvd. Whippany, NJ 07981 BAYER ESSURE, INC. 100 Bayer Blvd. Whippany, NJ 07981 BAYER HEALTHCARE PHARMACEUTICALS, INC. 100 Bayer Blvd. Whippany, NJ 07981 BAYER A.G. Werk Leverkusen 51368 Leverkusen, Germany Defendants.	IN THE COURT OF COMMON PLEAS PHILADELPHIA COUNTY TERM, 2014 NO.

CIVIL ACTION COMPLAINT
20-OTHER PERSONAL INJURY

AND NOW COMES the PLAINTIFF, HEATHER WALSH, ("Walsh" or "Plaintiff"), by and through undersigned counsel, files this Complaint against 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, Walsh, is a citizen of Michigan.

2. 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.

3. 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.

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

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

6. 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 Plaintiff.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

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

INTRODUCTION

13. This Complaint is brought by Plaintiff 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.

14. As a result of (1) Defendants' negligence described *infra* and (2) her reliance on Defendants' warranties and representations, Defendants' Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

15. Essure had **Conditional** Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, this CPMA became "invalid" and the product "adulterated" **pursuant to the FDA**[1] due to Defendants' failure to comply with the CPMA order and federal regulations.

16. 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 Plaintiff.

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

18. The fact that Defendants failed to comply with these conditions is not a mere allegation made by Plaintiff. These failures to comply with both the CPMA and federal regulations are memorialized in **several FDA findings,** including Notices of Violations and Form 483's (Forms issued to by the FDA for violations noted).

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

[1] All Emphasis is supplied in this Complaint.

(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;**

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

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

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

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

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

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

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

(f) Failing to analyze or indentify **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.

21. 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.**

22. As a result, Defendants' CPMA is "invalid" and its "adulterated" product, Essure, should never have been marketed or sold to Plaintiff.

23. Plaintiff's first four causes of action have nothing to do with the product itself, but rather Defendants' negligence in (1) failing to adequately train Plaintiff's implanting physician ("the implanting physician"); (2) entrusting the implanting physician with specialized hysteroscopic equipment he was not qualified to use, and (3) distributing/over promoting its product in an unreasonably dangerous manner, as fully discussed below.

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

25. Plaintiff's causes of action five through nine are based entirely on the express warranties, misrepresentations, and Defendants' deceptive conduct, which were relied upon by Plaintiff prior to having the device implanted. Under Pennsylvania law, Plaintiff's claims for breach of express warranties are not preempted by the Medical Device Act ("MDA"). *Rosci v Acromed, Inc.*, 447 Pa. Super. 403 (1995); *Bentzley v Medtronic, Inc.*, 2011 U.S. Dist. Lexis 136570 (E.D. Pa. Nov. 28, 2011).

26. The remaining causes of action are related to the product itself after Defendants' CPMA became invalid and hinge on the FDA requirements.

27. In short, according to the FDA, the CPMA order became invalid because 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.

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

29. Defendants actively concealed these violations and never advised Plaintiff of the same. Had Plaintiff 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**, she never would have had Essure implanted.

DESCRIPTION OF ESSURE AND HOW IT WORKS

30. 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.

31. 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.*

32. 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).

33. 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 Plaintiff's 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.*

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

35. 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.

36. 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.

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

38. 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").

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

40. 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

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

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

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

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

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

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

47. 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.

48. 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.

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

50. 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.

51. 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.**

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

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

54. 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.

55. Although failure to comply with just *one* of the conditions invalidated the CPMA Order, Defendants failed to comply with *several* conditions; thereby invalidating the CPMA pursuant to the very language of the CPMA order. 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."*

[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."

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

(e) As outlined 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.**

56. 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."*

57. 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.

58. 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."

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

60. 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."

61. 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.

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

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

64. In short, (1) the CPMA is invalid **per the FDA**; (2) Essure is considered an "adulterated" product that cannot be marketed or sold **per the FDA**; and (3) the invalid CPMA was not properly transferred to Bayer and, therefore, Defendants does not have any form of PMA for Essure.

DEFENDANTS' TRAINING, ENTRUSTMENT, AND DISTRIBUTION PLAN

65. 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 Plaintiff's safety and well-being.

66. 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.

67. 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.

68. 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.**"

69. In fact, because gynecologists and Plaintiff's implanting physician 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 Plaintiff that "Physicians must be signed-off to perform Essure procedures."

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

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

72. 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.

73. 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.

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

75. 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.*

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

77. 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.

78. In return for providing the hysteroscopic equipment, **Defendants required that the implanting physician 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 Plaintiff.

79. 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 Plaintiff.

80. 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".

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

82. 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.

83. 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.

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

PLAINTIFF'S HISTORY

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

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

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

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

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

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

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

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

93. On March 4, 2013, as a result of Essure, Plaintiff underwent a complete hysterectomy and an additional surgery to remove the coil lodged in her colon. Plaintiff now suffers from several autoimmune and adhesion disorders.

94. Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until her hysterectomy on or about March 4, 2013. Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

95. 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 Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants for failing to report eight (8) perforations.

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

FACTS AND WARRANTIES

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

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

99. 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 Plaintiff that "Physicians must be signed-off to perform Essure procedures." Defendants had no experience in training others in hysteroscopy.

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

101. 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].

102. 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.

103. 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 Plaintiff.

104. 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

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

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.

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

WEBSITE WARRANTIES

106. Defendants marketed on its website the following:

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

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.

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

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 adequately train the implanting physician and "signed-off" on the implanting physician who did not have the requisite training. Defendants concealed this information from Plaintiff.

(d) "Surgery-free"

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

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

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

ii. However, between1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff.

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

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

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

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%."

(f) "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 stated, "**We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation.**" Defendants concealed this information from Plaintiff. *See Defendants' Form 10-K attached hereto as Exhibit "E."*

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

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

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 Plaintiff.

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

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

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

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

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

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

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 Plaintiff.

(k) "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.

ADVERTISEMENT WARRANTIES

107. Defendants advertised:

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

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

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

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 Plaintiff.

FACT SHEET WARRANTIES

108. Defendants represented in its Fact Sheet:

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

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

WARRANTIES BY AGENTS

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

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

110. 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.

(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 Plaintiff.

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

(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

111. Defendants marketed with commercials stating:

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

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

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

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

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

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

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

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

113. 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 evidenced by the fact that three micro-inserts were placed into Plaintiff.

BROCHURE WARRANTIES

114. 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 Plaintiff. *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 Plaintiff. *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 Plaintiff. *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 Plaintiff. *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 Plaintiff.

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 Plaintiff.

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 Plaintiff.

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) "Surgery free"

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

(e) "Anesthesia-free"

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

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

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[6].

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

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

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%."

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

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

116. "The inserts are made from...**safe, trusted material.**"

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

117. In January 2014, Defendants warranted that over 750,000 procedures had been performed.

(a) However, ten months later Defendants advised only 625,000 had been performed.

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

ESSURE BOOKLET WARRANTIES

118. 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. Defendants concealed this information from Plaintiff.

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 Plaintiff.

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.

DATA WARRANTIES

119. Summary of Safety and Effectiveness Data states:

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

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

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

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

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

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

PMA SUPPLEMENT

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

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

SEC FILINGS

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

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

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

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

(b) However, 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."*

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

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

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

(g) 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.

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

NEGLIGENT TRAINING – COUNT I

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

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

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

127. Defendants had a duty to adequately train the implanting physician on how to place Essure using its own delivery system and oversee this particular procedure. In addition, considering Defendants were providing the implanting physician with sophisticated hysteroscopic equipment, Defendants also had a duty to train the physician in hysteroscopy in a reasonably safe manner or at the very least ensure that the implanting physician was competent in hysteroscopy before providing them with the hysteroscopic equipment needed to place Essure. Defendants also had a duty to disclose adverse events to the physcians so that they in turn could properly advise their patients of the actual risks.

128. Defendants breached this duty by (1) failing to adequately train Plaintiff's implanting physician on how to place the micro-inserts, including providing training different from than that of the "Physician Training Manual"; (2) failing to supervise the procedure; (3) failing to train Plaintiff's physician on how to use the hysteroscopic equipment provided by Defendants; and (4) failing to advise implanting physicians of the adverse events and non-conforming product.

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

130. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

NEGLIGENT ENTRUSTMENT – COUNT II

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

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

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

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

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

140. 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.*

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

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

143. Defendants had a duty not to provide sophisticated hysteroscopic equipment to the implanting physician who was not qualified to use such equipment. The implanting physician was not an expert hysteroscopist nor competent to use such equipment. Defendants were aware of this dangerous condition but provided the physician with the equipment in order to sell its product.

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

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

146. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

149. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to her

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

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

NEGLIGENT DISTRIBUTION / OVERPROMOTION – COUNT III

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

152. Defendants had a duty to distribute and promote Essure in a reasonably safe manner.

153. Defendants breached this duty by requiring the implanting physician to purchase two (2) Essure "kits" per month **regardless of whether they used them or not** and by contracting with third parties from the hysteroscopic manufacturers to promote Essure who were not competent to perform the same.

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

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

156. Defendants also breached this duty by promoting Essure as described in preceding Paragraphs.

157. Defendants also breached this duty by (1) negligently distributing Essure against FDA order and sections 501(f), 502(q) and (r) of the FD&C Act **by marketing and selling an adulterated product;** (2) promoting Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing 8 perforations and the 16,047 complaints which occurred as a result of Essure and the ; (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.

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

159. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

162. Plaintiff has been forced to expend significant sums of money for treatment of the multitude of surgeries, testing, medicine, therapies along with related expenses, all to her

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

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

NEGLIGENCE- RISK MANAGEMENT– COUNT IV

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

165. Defendant had a duty to prepare and have in place a risk management procedure to deal with consumer complaints.

166. Defendant breached this duty by not having in place such procedure.

167. This is evidenced by FDA findings which reported that Defendant was failing to report consumer reports to the FDA. The FDA obtained an internal excel spreadsheet containing 16,047 entries for complaints which were not reported as MDR's to the FDA. The FDA noted violations of the FDCA for such act. Specifically, Defendants were: "**not reporting complaints** in which their product migrated from the fallopian tube in to the peritoneal cavity … the **firm did not consider these complaints in their risk analysis** … and **failed to document CAPA activities** for a supplier corrective action."

168. 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. This was actively concealed by Defendants.

169. 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. This was actively concealed by Defendants.

170. 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). This was actively concealed by Defendants.

171. On July 7, 2003, Defendants were cited for **not following procedures used to control products which did not confirm to specifications.**

172. This was an unreasonably dangerous and negligent as it put Plaintiff at unnecessary risk of injury.

173. This breach caused Plaintiff's damages. Specifically, the Essure device migrated from Plaintiff's fallopian tube resulting in a hospitalization and hysterectomy. Plaintiff also suffered from severe pelvic pain, night sweats, numbness and tingling, and weight gain. Had Plaintiff known of 16,000 complaints she would not have had the device implanted.

174. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

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

BREACH OF EXPRESS WARRANTIES – COUNT V

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

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

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

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

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

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

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

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

188. As a result of Defendants' breaches, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

PA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION – COUNT VI

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

194. Plaintiff had purchased Essure and had the same inserted in her.

195. This transaction was for a good, Essure.

196. Essure was inserted into Plaintiff primarily for personal purposes.

197. Plaintiff suffered damages arising from the purchase and insertion of Essure.

198. Moreover, Plaintiff's loss was caused by justifiable reliance on deceptive conduct, specifically the warranties and advertisements outlined in the preceding paragraphs and the active concealment of adverse incidents, use on non-confirming product, and incomplete risk analysis.

199. As a result of Defendants' unfair trade practices, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

201. As a result of Defendants' unfair trade practices, individually, jointly, and severally, Plaintiff sustained significant pain and suffering, both physical and mental, and will continue to do so into the indefinite future.

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

203. Plaintiff has 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, Plaintiff demand judgment in their favor and against the Defendants for an amount in excess of $50,000.00 each, treble damages, 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.

FRAUDULENT CONCEALMENT– COUNT VII

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

205. Plaintiff did not discover the fraud until Sept. 29, 2014 beginning the relevant statute of limitations.

206. Under PA law, fraudulent concealment is simply a type of fraudulent misrepresentation, the concealment substituting for the false words. Active concealment of defects is the legal equivalent to an affirmative misrepresentation.

(a) First and specifically, Defendants fraudulently concealed **16,047** complaints from Plaintiff regarding Essure where pain was experienced by consumers. This concealment took place at 331 E Evelyn Ave. Mountain View, CA 94041-1530 and was uncovered by the FDA during the following time period 5/30/2013 – 6/26/2013.

(b) This concealment was memorialized by Timothy Grome on 6/26/2013 in an Establishment Inspection Report by the FDA where he states, specifically: "the 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."

(c) Second and specifically, Defendants **fraudulently concealed 8 perforations which occurred as a result of Essure** and which Defendants failed to disclose to Plaintiff and even the FDA. This concealment took place at 331 E Evelyn Ave. Mountain View, CA 94041-1530 and was uncovered by the FDA, specifically, Lana Widman, on 1/25/11.

(d) This concealment was memorialized by Lana Widman on 1/25/11 in an Investigative Report and Form 483 by the FDA where she states, particularly: "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."

(e) Third and specifically, 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." These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendants had notice of 168 perforations but only disclosed 22 to the FDA. 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.

(f) This concealment is memorialized in Exhibits "F" and "G."

(g) Fourth and specifically, 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.

(h) This concealment is memorialized in Exhibits "F" and "G."

207. Defendants had a duty to disclose the specific perforations under federal, state and administrative law. Moreover, the circumstances surrounding the concealment imposed a duty to disclose to Plaintiff and Defendants remained silent.

208. Defendants intentionally concealed the complaints and non-comforming product so that it would induce Plaintiff to have Essure implanted.

209. Plaintiff justifiably relied on the active concealment. Specifically, Plaintiff would have never had Essure implanted had she been aware that there were 8 perforations of human cavities or that there had been 16,047 complaints regarding Essure. Accordingly, the matters concealed were material.

210. As a proximate result, Plaintiff suffered damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

211. As a result of Defendants' fraud, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

FRAUD MISREPRESENTATION– COUNT VIII

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

217. Plaintiff did not discover the fraud until Sept. 29, 2014 beginning the relevant statute of limitations.

218. Defendants made a misrepresentation, a fraudulent utterance thereof, which are specifically outlined in the preceding paragraphs.

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

220. In the alternative, the representations were material to Plaintiff having Essure placed as she would not have had the device inserted had she none of the misrepresentations.

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

222. Plaintiff justifiably relied on the misrepresentations. Specifically, Plaintiff would have never had Essure implanted had she 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.

223. As a proximate result, Plaintiff suffered damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

224. As a result of Defendants' fraud, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

NEGLIGENT MISREPRESENTATION– COUNT IX

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

230. Plaintiff did not discover the misrepresentations until Sept. 29, 2014 beginning the relevant statute of limitations.

231. Defendants made misrepresentations which are specifically outlined in the preceding Paragraphs.

232. Plaintiff justifiably relied on the misrepresentations. Specifically, Plaintiff would have never had Essure implanted had she 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.

233. As a proximate result, Plaintiff suffered damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

234. As a result of Defendants' misrepresentations, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

STRICT LIABILITY– COUNT X

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

240. Defendants sold Essure to Plaintiff new.

241. Defendants expected Essure to reach Plaintiff in the same condition it was in when it left its custody and control.

242. Plaintiff maintained Essure in a condition which was without substantial change from its condition when it left the custody and control of Defendants.

243. Defendants manufactured, supplied, warranted, sold, and placed on the market and into the stream of commerce a defective and unreasonably dangerous product, knowing that Essure would reach consumers without substantial change in the condition in which it was sold and that, at the time Essure left Defendants' control, it was defective and in an unreasonably dangerous condition.

244. When Defendants researched, designed, tested, developed, manufactured, supplied, warranted exported, imported, assembled, marketed, advertised, distributed and/or sold Essure, they were aware that it was not reasonably safe and effective.

245. Defendants have known, and knew at the time of manufacture of Essure, that it posed a serious and imminent danger to the lives and safety of consumers.

246. Defendants have known, and knew at the time of manufacture of Essure, that a safe and effective Essure, free from defect, must contain effective and adequate warnings and safety devices designed to prevent, and which actually prevent harm to Essure consumers.

247. The aforementioned Essure was not equipped with every element necessary to make it safe for its reasonably foreseeable uses.

248. The aforementioned Essure was defective and unsafe in that it was not safe for its reasonably foreseeable uses in that it subjected Plaintiff to serious injuries when the aforementioned product was used and/or serviced in an intended and foreseeable manner. Essure's defects as well as the Defendants' failures include, but are not limited to, as follows:

(a) designing, manufacturing, assembling, marketing, selling and distributing Essure;

(b) Essure is defective in design because it is defectively designed to malfunction during foreseeable use including implementation, and can migrate and break;

(c) Not using conforming materials and then failing to document the same;

(d) Such other acts or omissions as may be ascertained through discovery, or as may be demonstrated by the evidence adduced at trial.

249. Defendants are strictly liable to Plaintiffs pursuant to Section 402A of the Restatement (Second) of Torts.

250. The defective condition of Essure was the factual cause of Plaintiff's hysterectomy and pregnancy.

251. Defendants failed to adequately test the product prior to manufacturer, marketing, distributing and failed to test the product subsequent to assembling, including consistent with CPMA conditions.

252. Defendants failed to adequately instruct the implanting physician.

253. Defendants failed to adequately visually inspect Essure after completion of assembly.

254. Defendants failed to adequately visually inspect Essure immediately prior to delivery to the Plaintiff.

255. Defendants' failure to perform adequate testing, inspections and give adequate and appropriate information, warning and directions was a direct and proximate cause of the severe and permanent injuries sustained by Plaintiff.

256. Upon information and/or belief, when Essure was manufactured, Defendants had the technological capability to design and manufacture Essure in a reasonably safe manner.

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

258. Defendants manifested a conscious or reckless disregard for the rights of others and a conscious or reckless imposition of the risk of death or serious bodily injury upon the users of its product by:

(a) failing to design the Essure in a reasonably safe manner;

(b) failing to supply warnings and/or adequate directions or warnings and by providing directions inconsistent with its CPMA.;

(d) failing to equip Essure with materials that would not easily become damaged, migrate, and/or deteriorate over time;

(e) failing to warn of the same;

(f) failing to use conforming material.

259. As a proximate result, Plaintiff suffered damages. Specifically, the Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

260. As a result of Defendants' strict liability, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

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

NEGLIGENT DESIGN– COUNT XI

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

266. Plaintiff's injuries were caused by the negligent and reckless conduct of the Defendants in researching, testing, designing, developing, manufacturing, importing, marketing, advertising, distributing, assembling and selling Essure and by engaging in the following negligent and reckless conduct, all of which hinge on violations of FDA requirements:

(a) Failing to design a safe and effective micro insert;

(b) Carelessly and negligently selling and distributing Essure in violation of the CPMA and federal law;

(c) Carelessly and negligently selling and distributing Essure;

(d) Carelessly and negligently selling and distributing Essure which migrated and/or broke;

(e) Carelessly and negligently selling and distributing Essure that violated the CPMA.

(k) In breach of their duty, negligently incorporated into the design and assembly of the Essure parts that could not stand up to normal usage; failed to design, develop, manufacture, market, sell and distribute Essure such that it would not injure users; and negligently failed to properly design, develop and manufacture the component parts; and

(l) Such other acts or omissions constituting carelessness, negligence, recklessness and gross negligence as may be ascertained through discovery, or as may be demonstrated by the evidence adduced at trial.

267. Defendants failed to adequately test and/or visually inspect the product prior to manufacture, marketing and distributing, and failed to test the product subsequent to assembly and/or immediately prior to delivery to Plaintiff.

268. Defendants' failure to perform adequate testing and to give adequate and appropriate information, warning and directions was a direct and proximate cause of the severe and permanent injuries sustained by Plaintiff.

269. 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.

270. As a result of Defendants' negligence, individually, jointly, and severally, Plaintiff sustained the following injuries all of which could be permanent in nature: hysterectomy, auto-immune disorders, and adhesion disorders.

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

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

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

DEMAND FOR JURY TRIAL

Plaintiff demand a jury trial with regards to all claims.

DATED this ___th day of Dec., 2014.

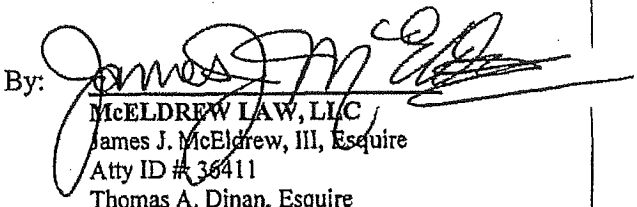
VERIFICATION

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

16 Dec 2014
Date

Heather Walsh
X Heather Walsh

Respectfully submitted,

By: 

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2711 Centerville Road Suite 400
Wilmington, DE 19808

Bayer Healthcare Pharmaceuticals, LLC
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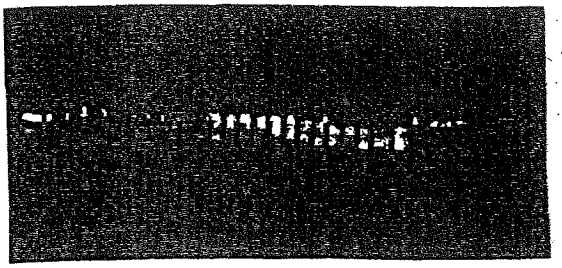
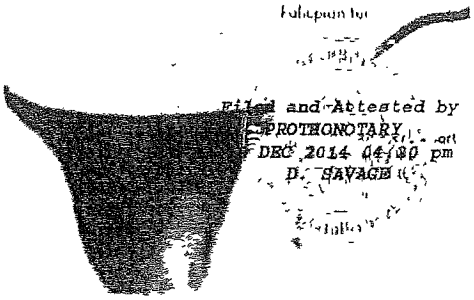
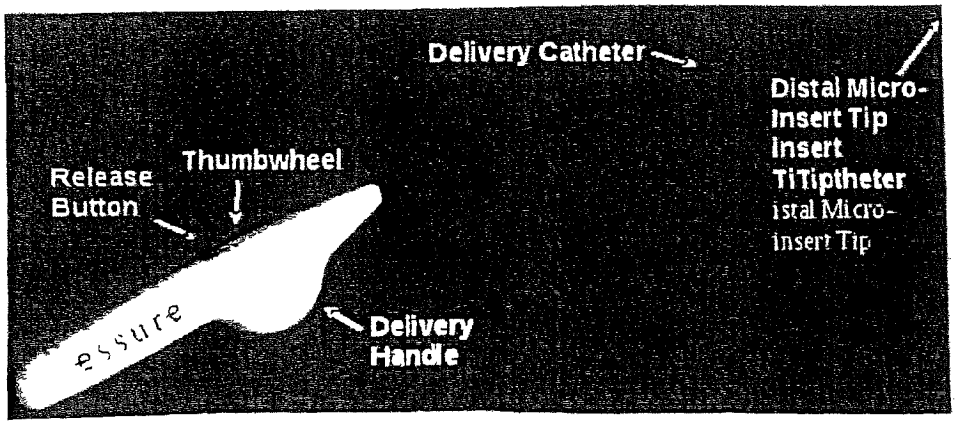
Wilmington, DE 19808

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

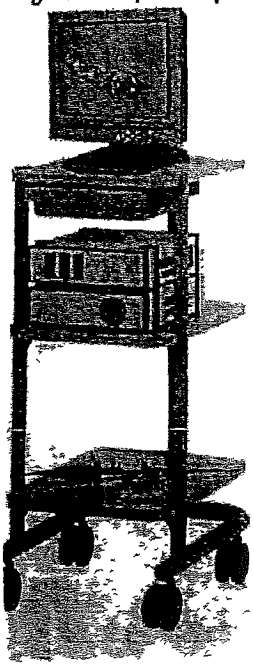
Bayer AG
Werk Leverkusen
51368 Leverkusen, Germany







Hysteroscopic Equip.



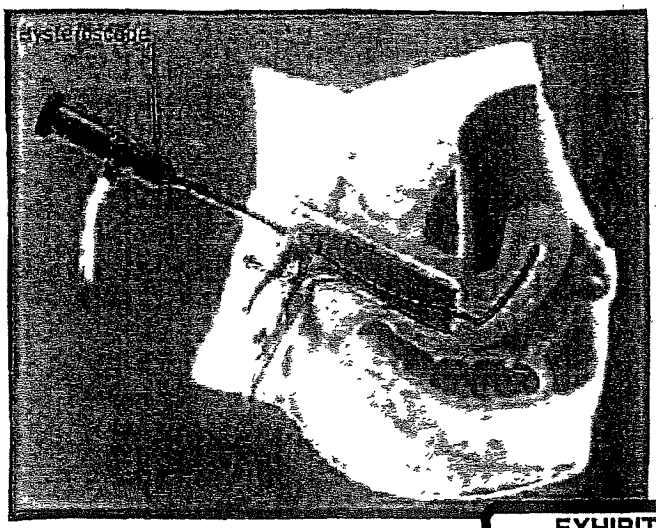


EXHIBIT
A

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[4]
- PAS Webpage FAQs[5]
- Tools for Conducting PAS
  - Letter to IRB Chairs[6] (formally 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
WO66-4206 Silver Spring, MD
20993-0002

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

Show All Studies

Export to Excel

General	
Application Number	P020014 S017
Most Recent Protocol Version Approved	02/24/2012
Study Name	Essure/post NovaSure PAS
Study Status	Progress Adequate
General Study Protocol Parameters	
Study Design	Prospective Cohort Study
Study involve follow-up of premarket cohort (Y/N)	No
Data Source	New Data Collection
Comparison Group	Objective Performance Criterion
Analysis Type	Analytical
Study Population	Transit Adolescent 0 (ex adults) 16 21 yrs, Adult >21
Detailed Study Protocol Parameters	
Study Design Description	Single-arm multi-center prospective observational study
Study Population Description	Women aged 21-50 with Essure microinserts properly placed (confirmatory HSG) seeking treatment for menorrhagia
Sample Size	A minimum of 220 female subjects relying on Essure micro- inserts seeking treatment for menorrhagia
Data Collection	Occurrence of confirmed pregnancy at 1 year and 3 years among subjects relying on Essure
Follow-up Visits and Length of Follow-up	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 Date Due	FDA Receipt Date	Reporting Status
six month report	08/24/2012	12/14/2012	Overdue/Received
one year report	07/23/2013	11/08/2013	Overdue/Received
18 month report	08/24/2013	09/12/2013	Overdue/Received
two year report	03/21/2014	03/24/2014	Overdue/Received
three year report	02/23/2015		
four year report	02/23/2016		
five year report	02/22/2017		

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links on this page:

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

EXHIBIT B

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

Post-Approval Studies

Post-Approval Studies

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- PAS Webpage FAQs[6]
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Contact Information

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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	Trainer Adolescent 6 (ex adults) 16-21 yrs, Adults >21
Detailed Study Protocol Parameters	
Study Design Description	This is an observational cohort study A new cohort of patients and physicians will be [1]
Study Population Description	Study population is as per device indication This device is indicated for permanent birth control [2]
Sample Size	697 women enrolled - protocol states 20 sites enrolled patients
Data Collection	Study endpoints included (1) bilateral micro-insert placement rate, (2) identification of factors predictive of micro-insert [3]
Followup Visits and Length of Followup	N/A
Final Study Results	
Actual Number of Patients Enrolled	384 women
Actual Number of Sites Enrolled	78
Patient Followup Rate	81 60%
Final Safety Findings	The sponsor reported only 6 adverse events occurred during and after the Essure placement procedure [3]
Study Strengths and Weaknesses	The study is well designed to evaluate the placement rate among newly trained physicians at [3]
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 Date Due	FDA Receipt Date	Reporting Status
6 month report	12/14/2007	12/14/2007	On Time
1 year report	06/14/2008	06/17/2008	Overdue/Received
18 month report	12/13/2008	12/15/2008	Overdue/Received
Final Report	06/14/2009	06/16/2009	Overdue/Received

Show All Studies

Links on this page:

1 http://www.addthis.com/bookmark.php?v=152&username=fdainfo
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

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. 138

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

[Califor]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) 650-6500
Address (number, street): 1500 CAPITOL AVE, MS 7602	City: SACRAMENTO		ZIP code: 95899
Firm name: CONCEPTUS, INC			Date: 06-11-13
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. Those are alleged to be violations of one or more provisions of California law pertaining to the manufacture, processing, holding, sale, labeling, or advertising of a food, drug, medical device, cosmetic, or hazardous substance. The Department may seek administrative, civil, or criminal action for each of the violations. This report has been prepared to alert the management of the investigator's findings. It is the responsibility of the firm to assure compliance with all applicable laws and regulations.

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

(2) THE FIRM FAILED TO MAINTAIN PROCEDURES TO CONTROL [illegible] AS REQUIRED BY THE QUALITY SYSTEM REGULATION. SPECIFICALLY, SOP [illegible] REVISION Y PERTAINING TO INVENTORY TRANSFER REFERENCES PRE-STERILE AND POST-STERILE QUARANTINE CAGES AND THE SAN CARLOS WAREHOUSE AND THE FACILITY IN MOUNTAIN VIEW [illegible] 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 QE MANAGER
Authorized agent signature: C. Rodriguez	Authorized agent name and badge number (printed): CHRISTINE RODRIGUEZ #155

Page 1 of 1

Case ID. 141202792

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

SUMMARY

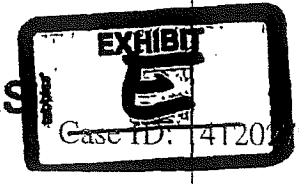
I initiated this inspection of a manufacturer of a type 3 permanent implantable contraceptive device conducted in accordance with FACTS Assignment 8676539 as part of SAN-DO's FY '13 workplan for medical devices. I conducted this inspection pursuant to CP 7382.845 under PACs 82845A and 81011.

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

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

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

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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

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

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

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

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

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

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

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

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

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

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

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

EXHIBIT
Exhibit
F

Case ID: 141202792

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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

OBSERVATION 2

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

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

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

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

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

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

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

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

OBSERVATION 3

Risk analysis is incomplete.

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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

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

OBSERVATION 4

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

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

ANNOTATIONS

OBSERVATION 1
(b)(4)

(b)(4)

OBSERVATION 2
(b)(4)

OBSERVATION 3
(b)(4)

OBSERVATION 4
Corrected and Verified
1/6/2011

AMENDMENT 1

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark M. Sieczkarek, President and CEO

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

the peritoneal cavity.

OBSERVATION 4

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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

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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-2335 (Quality Assurance Form) which is used to track and trend in-process data.

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

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

OBSERVATION 2

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

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

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

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

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

EXHIBIT
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Case ID: 141202792

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William H. Dippel, Vice President, Operations

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

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

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

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Mark E. Chan, Investigator

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

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

EXHIBIT "B"