JS 44 (Rev. 06/17)

CIVIL COVER SHEET

18-cv-0037

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

Jamie Jenson, et al.

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Moze Cowper, Pearlette V. Toussant
Cowper Law LLP 1700 Market St. Ste 1005
Philadelphia PA 19103 215 327 2900

DEFENDANTS

Bayer Healthcare Pharmaceuticals, Inc.

County of Residence of First Listed Defendant Whippany, NJ
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 196 Franchise				☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
					☐ 893 Environmental Matters
					☐ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 896 Arbitration
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	☐ 871 IRS—Third Party 26 USC 7609	☐ 950 Constitutionality of State Statutes
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence			
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

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 - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC 1331, 1367

Brief description of cause:

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 PADOVA DOCKET NUMBER 17-2915

DATE 1-8-18

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JAN - 8 2018 JUDGE MAG. JUDGE

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.

18 37

Address of Plaintiff: Marengo, AL

Address of Defendant: 100 Bayer Blvd, Whippany, NJ

Place of Accident, Incident or Transaction: _____

(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: 17-2915 Judge PADOVA 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) _____

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, Pearlette V. Toussant, counsel of record do hereby certify:

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

☐ Relief other than monetary damages is sought.

DATE: 1-8-18 _____ Attorney-at-Law 85756 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: 1-8-18 _____ Attorney-at-Law 85756 Attorney I.D.#

JAN - 8 2018

CIV. 609 (5/2012)

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

CASE MANAGEMENT TRACK DESIGNATION FORM

JAMIE JENSON, ET AL

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.

CIVIL ACTION

18 37

NO.

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

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

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

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

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

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

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

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

1-8-18		Plaintiffs
Date	**Attorney-at-law**	**Attorney for**
215-327-2900	215 717 4620	ptoussant@cowperlaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JAN -8 2018

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

Plaintiffs, JAMIE JENSON, AMBER JACKSON, MAGEN ALLEN, KELLY FERNANDES, DANIELLE BLACK, STERLING BLACK, SHENDONNA ROBERTSON, JAQUELINE LOPEZ, JENNIFER GRIFFITH, JORDAN GRIFFITH, RUTH ZIPFEL, SIN-TING LIU, ELIZABETH SCHEER, LYNDSEY MARTINEZ, ROBERT MARTINEZ, VERONICA CAMPOS, GWEN BAILEY, SHAWNTAE GOUGH, ANDREA DAHL, RICHARD DAHL, HEATHER VERNILLO, SARAH SHORE, STEPHANIE JOHNSON, DAVID JOHNSON, JACQUELINE EVANS, GARY EVANS, AMANDA BAKER, GINGER YORK, JAMES YORK, TAKAI HOSE, ELIZABETH BERTELSMAN, LATRONICA SMITH, JODY KEMP, JEREMY KEMP, FRAN LEACH, ROBERT LEACH, ERICKA COLLIER, DENORVELL COLLIER, BETH CARR, JESSIE CARR JR., MICHELLE HORNSBY, AIMEE MORRISON, TRACY HAMMOND, MAXINE BELL, KEITH BELL, CHRISTIE LAJOIE, LILLIE CROFT, SHAWN FOSTER, CHERYL ROOT, KATHERINE KELLEY, TODD KELLEY, MICHELLE NOUISSER, ASHLEY NARANJO, ONA GARCIA, ANGELIQUE FRANCES, DAVID FRANCES, KRISTI BYERS, JENNIFER MORREALE, RACHEL SWEATT, LEON SWEATT, BRENDA WHIPPLE, JOHN WHIPPLE, KEISHA MCNAUGHTON, RUSHIK MCNAUGHTON, RACHEL LEWIS, NATHAN DELIOTTE, MAYAANNE MAYS, MELANIE DUBAJ, JAMES DUBAJ, BRANDY GRAVES, DAMIAN COLEMAN, STEPHANIE DORSEY, MICHELE MCGOVERN, KEVIN MCGOVERN, CLARISSA MIMMS, LEONARD MIMMS, JULIA MIKOTOWICZ, MICHAEL MIKOTOWICZ, SHARON HOOD, JOSHUA HOOD, REAGAN BURGENHEIM, ANGELA OWENS, JASON OWENS, TAMETRIA

NO.: _____

JURY TRIAL DEMANDED

NASH, CHRISTOPHER NASH, HOLLY WILLIAMS, GREGORY WILLIAMS, MICHELLE BARTELL, MICHAEL BARTELL, MARIA OUELLETTE, MICHAEL ANTHONY, CARA RAMEY, BRYCE RAMEY, YOLANDA LAMBERT, KRISTIN PURDY, JESSIE PURDY, BRIANNE MEADOWS, IAN MEADOWS, SHARON HARRIS, MELANIE MESKER, BRITTNEY BIRD, AMY BRUCE, IVAN BRUCE, ABBY NOYES

vs.

BAYER HEALTHCARE PHARMACEUTICALS, INC.,
Defendant.

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COMPLAINT FOR DAMAGES

NOW COME Plaintiffs, JAMIE JENSON, AMBER JACKSON, MAGEN ALLEN, KELLY FERNANDES, DANIELLE BLACK, STERLING BLACK, SHENDONNA ROBERTSON, JAQUELINE LOPEZ, JENNIFER GRIFFITH, JORDAN GRIFFITH, RUTH ZIPFEL, SIN-TING LIU, ELIZABETH SCHEER, LYNDSEY MARTINEZ, ROBERT MARTINEZ, VERONICA CAMPOS, GWEN BAILEY, SHAWNTAE GOUGH, ANDREA DAHL, RICHARD DAHL, HEATHER VERNILLO, SARAH SHORE, STEPHANIE JOHNSON, DAVID JOHNSON, JACQUELINE EVANS, GARY EVANS, AMANDA BAKER, GINGER YORK, JAMES YORK, TAKAI HOSE, ELIZABETH BERTELSMAN, LATRONICA SMITH, JODY KEMP, JEREMY KEMP, FRAN LEACH, ROBERT LEACH, ERICKA COLLIER, DENORVELL COLLIER, BETH CARR, JESSIE CARR JR., MICHELLE HORNSBY, AIMEE MORRISON, TRACY HAMMOND, MAXINE BELL, KEITH BELL, CHRISTIE LAJOIE, LILLIE CROFT, SHAWN FOSTER, CHERYL ROOT, KATHERINE KELLEY, TODD KELLEY, MICHELLE NOUISSER, ASHLEY NARANJO, ONA GARCIA, ANGELIQUE FRANCES, DAVID FRANCES, KRISTI BYERS, JENNIFER MORREALE, RACHEL SWEATT, LEON SWEATT, BRENDA WHIPPLE, JOHN WHIPPLE, KEISHA MCNAUGHTON, RUSHIK MCNAUGHTON, RACHEL LEWIS, NATHAN DELIOTTE, MAYAANNE MAYS, MELANIE DUBAJ, JAMES DUBAJ, BRANDY GRAVES, DAMIAN COLEMAN, STEPHANIE DORSEY, MICHELE MCGOVERN, KEVIN MCGOVERN, CLARISSA MIMMS, LEONARD MIMMS, JULIA MIKOTOWICZ, MICHAEL MIKOTOWICZ, SHARON HOOD, JOSHUA HOOD, REAGAN BURGENHEIM, ANGELA OWENS, JASON OWENS, TAMETRIA NASH, CHRISTOPHER NASH, HOLLY WILLIAMS, GREGORY WILLIAMS, MICHELLE BARTELL, MICHAEL BARTELL, MARIA

OUELLETTE, MICHAEL ANTHONY, CARA RAMEY, BRYCE RAMEY, YOLANDA LAMBERT, KRISTIN PURDY, JESSIE PURDY, BRIANNE MEADOWS, IAN MEADOWS, SHARON HARRIS, MELANIE MESKER, BRITTNEY BIRD, AMY BRUCE, IVAN BRUCE, ABBY NOYES, who, in filing this Complaint, seek judgment against Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC; for the personal injuries they sustained as a result of being prescribed, receiving, and subsequently using the defective and unreasonably dangerous permanent birth control device Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, and sold by Defendant or Conceptus, Inc., which was acquired by Defendant on or about April 28, 2013.

I.

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Jamie Jenson is a citizen of Demopolis, Alabama.

2. Plaintiff Amber Jackson is a citizen of Cabot, Arkansas.

3. Plaintiff Magen Allen is a citizen of Bismarck, Arkansas.

4. Plaintiff Kelly Fernandes is a citizen of Clovis, California.

5. Plaintiff Danielle Black is a citizen of Lake Forest, California.

6. Plaintiff Sterling Black is a citizen of Lake Forest, California.

7. Plaintiff Shendonna Robertson is a citizen of Los Angeles, California.

8. Plaintiff Jacqueline Lopez is a citizen of Los Angeles, California.

9. Plaintiff Jennifer Griffith is a citizen of Oakland, California.

10. Plaintiff Jordan Griffith is a citizen of Oakland, California.

11. Plaintiff Ruth Zipfel is a resident of Sacramento, California.

12. Plaintiff Sin-Ting Liu is a resident of Alameda, California.

13. Plaintiff Elizabeth Scheer is a citizen of Grand Junction, Colorado.

14. Plaintiff Lyndsey Martinez is a citizen of Mead Colorado.

15. Plaintiff Robert Martinez is a citizen of Mead, Colorado.

16. Plaintiff Veronica Campos is a citizen of Meriden, Connecticut.

17. Plaintiff Gwen Bailey is a resident of Callahan, Florida.

18. Plaintiff Shawntae Gough is a citizen of Orlando, Florida.

19. Plaintiff Andrea Dahl is a citizen of Orlando, Florida.

20. Plaintiff Richard Dahl is a citizen of Orlando, Florida.

21. Plaintiff Heather Vernillo is a citizen of Palm Harbor, Florida.

22. Plaintiff Sarah Shore is a citizen of Port Charlotte, Florida.

23. Plaintiff Stephanie Johnson is a citizen of St. Cloud, Florida.

24. Plaintiff David Johnson is a citizen of St. Cloud, Florida.

25. Plaintiff Jacqueline Evans is a citizen of Lawrenceville, Georgia.

26. Plaintiff Gary Evans is a citizen of Lawrenceville, Georgia.

27. Plaintiff Amanda Baker is a citizen of Cartersville, Georgia.

28. Plaintiff Ginger York is a citizen of McDonough, Georgia.

29. Plaintiff James York is a citizen of McDonough, Georgia.

30. Plaintiff Takai Hose is a citizen of Moultrie, Georgia.

31. Plaintiff Elizabeth Bertelsman is a citizen of Ashkum, Illinois.

32. Plaintiff Latronica Smith is a citizen of Chicago, Illinois.

33. Plaintiff Jody Kemp is a citizen of Crystal Lake, Illinois.

34. Plaintiff Jeremy Kemp is a citizen of Crystal Lake, Illinois.

35. Plaintiff Fran Leach is a citizen of Steger, Illinois.

36. Plaintiff Robert Leach is a citizen of Steger, Illinois.

37. Plaintiff Ericka Collier is a citizen of Justice, Illinois.

38. Plaintiff Denorvell Collier is a citizen of Justice, Illinois.

39. Plaintiff Beth Carr is a citizen of Columbus, Indiana.

40. Plaintiff Jessie Carr, Jr. is a citizen of Columbus, Indiana.

41. Plaintiff Michelle Hornsby is a citizen of Independence, Kentucky.

42. Plaintiff Aimee Morrison is a citizen of Sulphur, Louisiana.

43. Plaintiff Tracy Hammond is a resident of Bangor, Maine.

44. Plaintiff Maxine Bell is a citizen of Mattapan, Massachusetts.

45. Plaintiff Keith Bell is a citizen of Mattapan, Massachusetts.

46. Plaintiff Cristie Lajoie is a citizen of New Salem, Massachusetts.

47. Plaintiff Lillie Croft is a citizen of Grand Rapids, Michigan.

48. Plaintiff Shawn Foster is a citizen of Durand, Michigan.

49. Plaintiff Cheryl Root is a citizen of Pontiac, Michigan.

50. Plaintiff Katherine Kelley is a citizen of Reed City, Michigan.

51. Plaintiff Todd Kelley is a citizen of Reed City, Michigan.

52. Plaintiff Michelle Nouisser is a citizen of Natchez, Mississippi.

53. Plaintiff Ashley Naranjo is a citizen of North Platte, Nebraska.

54. Plaintiff Ona Garcia is a citizen of Raton, New Mexico.

55. Plaintiff Angelique Frances is a citizen of Las Vegas, Nevada.

56. Plaintiff David Frances is a citizen of Las Vegas, Nevada.

57. Plaintiff Kristi Byers is a citizen of Las Vegas, Nevada.

58. Plaintiff Jennifer Morreale is a citizen of Spring Creek, Nevada.

59. Plaintiff Rachel Sweatt is a citizen of East Syracuse, New York.

60. Plaintiff Leon Sweatt is a citizen of East Syracuse, New York.

61. Plaintiff Brenda Whipple is a citizen of Mallory, New York.

62. Plaintiff John Whipple is a citizen of Mallory, New York.

63. Plaintiff Keisha McNaughton is a citizen of Wyandanch, New York.

64. Plaintiff Rushik McNaughton is a citizen of Wyandanch, New York.

65. Plaintiff Rachel Lewis is a citizen of Brooklyn, New York.

66. Plaintiff Nathan Deliotte is a citizen of Brooklyn, New York.

67. Plaintiff Mayaanne Mays is a citizen of Charlotte, North Carolina.

68. Plaintiff Melanie Dubaj is a citizen of Alliance, Ohio.

69. Plaintiff James Dubaj is a citizen of Alliance, Ohio.

70. Plaintiff Brandy Graves is a citizen of Columbus, Ohio.

71. Plaintiff Damian Coleman is a citizen of Columbus, Ohio.

72. Plaintiff Stephanie Dorsey is a citizen of Wintersville, Ohio.

73. Plaintiff Michelle McGovern is a resident of Massillon, Ohio.

74. Plaintiff Kevin McGovern is a resident of Massillon, Ohio.

75. Plaintiff Clarissa Mimms is a resident of Fairfax, Oklahoma.

76. Plaintiff Leonard Mimms is a resident of Fairfax, Oklahoma.

77. Plaintiff Julia Mikotowicz is a citizen of Harbor Creek, Pennsylvania.

78. Plaintiff Michael Mikotowicz is a citizen of Harbor Creek, Pennsylvania.

79. Plaintiff Sharon Hood is a citizen of Mifflintown, Pennsylvania.

80. Plaintiff Joshua Hood is a citizen of Mifflintown, Pennsylvania.

81. Plaintiff Reagan Burgenheim is a resident of Gallatin, Tennessee.

82. Plaintiff Angela Owens is a citizen of Baytown, Texas.

83. Plaintiff Jason Owens is a citizen of Baytown, Texas.

84. Plaintiff Tametria Nash is a citizen of Fort Worth, Texas.

85. Plaintiff Christopher Nash is a citizen of Fort Worth, Texas.

86. Decedent Holly Williams was a citizen of Joshua, Texas.

87. Plaintiff Gregory Williams is a resident of Joshua, Texas.

88. Plaintiff Michelle Bartell is a citizen of Leander, Texas.

89. Plaintiff Michael Bartell is a citizen of Leander, Texas.

90. Plaintiff Maria Ouellette is a citizen of Houston, Texas.

91. Plaintiff Michael Anthony is a citizen of Houston, Texas.

92. Plaintiff Cara Ramey is a citizen of Saratoga Springs, Utah.

93. Plaintiff Bryce Ramey is a citizen of Saratoga Springs, Utah.

94. Plaintiff Yolanda Lambert is a citizen of Bristow, Virginia.

95. Plaintiff Kristin Purdy is a citizen of Manassas, Virginia.

96. Plaintiff Jessie Purdy is a citizen of Manassas, Virginia.

97. Plaintiff Brianne Meadows is a citizen of Chesapeake, Virginia.

98. Plaintiff Ian Meadows is a citizen of Chesapeake, Virginia.

99. Plaintiff Sharon Harris is a citizen of Federal Way, Washington.

100. Plaintiff Melanie Mesker is a citizen of Maple Valley, Washington.

101. Plaintiff Brittney Bird is a resident of Kelso, Washington.

102. Plaintiff Amy Bruce is a resident of Charleston, West Virginia.

103. Plaintiff Ivan Bruce is a resident of Charleston, West Virginia.

104. Plaintiff Abby Noyes is a citizen of Milwaukee, Wisconsin.

105. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC., is a for-profit corporation incorporated in the state of Delaware. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.'s headquarters are located at 100 Bayer Boulevard, Whippany, New Jersey. Defendant is authorized to and does business throughout the Commonwealth of Pennsylvania.

106. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because complete diversity in citizenship exists between the Plaintiffs and the Defendant, and the amount in controversy exceeds seventy-five thousand dollars ($75,000) exclusive of interest and costs.

107. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) and (3) because a substantial part of the events or omissions giving rise to the claim occurred in this district, and Defendant regularly transacts substantial business in this district and are subject to personal jurisdiction in this district. Additionally, Defendant has advertised in this district and have received substantial revenue and profits from their sales of Essure® devices in this district; therefore, a substantial part of the events and/or omissions giving rise to the claims occurred, in part, within this district.

108. This Court has personal jurisdiction over Defendant because they have conducted substantial business in this judicial district and, intentionally and purposefully, placed the Essure® devices into the stream of commerce within Pennsylvania and throughout the United States.

II.

INTRODUCTION

109. This Complaint is brought by Plaintiffs who were implanted with a female birth control device known as "Essure®." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in reality, the device migrates from the tubes, perforates organs, breaks into pieces and/or corrodes, wreaking havoc on the female body.

110. As a result of (1) Defendant's negligence described *infra* and (2) Plaintiffs' reliance on Defendant's warranties and representations, Defendant's Essure® devices migrated, fractured, punctured internal organs, and/or caused other serious injuries.

111. Essure® had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, Essure® became "adulterated" and "misbranded" due to (1) Defendant's failure to conform to the FDA requirements prescribed in the CPMA and (2) violations of federal statutes and regulations noted *infra.*

112. Pursuant to Defendant's CPMA (which reads: "Failure to comply with conditions of approval invalidates this approval order"), the C.F.R., and Federal Food, Drug and Cosmetic

Act ("FDCA"), the product is "adulterated" and "misbranded" and, thus, should not have been marketed or sold to Plaintiffs.

113. Specifically, Essure® was adulterated and misbranded as Defendant (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with federal laws regarding marketing and distribution as specifically described *infra.*

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

115. As discussed in greater detail *infra*, Defendant was cited by the FDA and the Department of Health for:

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

b. erroneously using non-conforming material in the manufacturing of Essure®;

c. failing to use pre-sterile and post-sterile cages;

d. manufacturing Essure® at an unlicensed facility; and

e. manufacturing Essure® for three (3) years without a license to do so.

116. Defendant was 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 twenty-two (22) perforations while having knowledge of one hundred and forty-four (144) perforations;

d. Not considering these complaints in their risk analysis for the design of Essure®;

e. Failing to have a complete risk analysis for Essure®;

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

g. Failing to track the non-conforming product;

h. Failing to follow procedures used to control products which did not conform 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 Medical Device Reports ("MDR"); and

l. Failing to provide the FDA with timely post-approval reports for its six (6) months, one (1) year, eighteen (18) months, and two (2) years report schedules.

117. Most egregiously, on May 30, 2013, the FDA uncovered an internal excel spreadsheet with 16,047 entries of complaints which were not properly reported to the FDA. Here, Defendant did not disclose to the FDA complaints where its product migrated outside of the fallopian tube. Defendant's 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." The FDA again warned Defendant for violations of the FDCA.

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

119. Lastly, Defendant concealed and altered the medical records of its own clinical trial participants to reflect favorable data. Specifically, Defendant altered medical records to reflect less pain than what was being reported during the clinical studies for Essure® and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process. Subsequently, Defendant failed to disclose this and concealed it from Plaintiffs and their implanting physicians.

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

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

122. In addition, Defendant failed to comply with the following express conditions and federal regulations:

a. "Within ten (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 (6) months, one (1) year, eighteen (18) months, and two (2) year reports.

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

e. Effectiveness of Essure® is established by annually reporting on the 745 women who participated in the clinical tests.

f. Successful bilateral placement of Essure® is documented for newly trained physicians.

g. Warranties are truthful, accurate, and not misleading.

h. Warranties are consistent with applicable federal and state law.

123. These violations rendered the product "adulterated" and "misbranded" – precluding Defendant from marketing or selling Essure® and, more importantly, endangered the lives of Plaintiffs and hundreds of thousands of women.

124. Defendant actively concealed these violations and never advised Plaintiffs of the same. Had Plaintiffs known that Defendant was concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license, they never would have had Essure® implanted into their bodies.

III.

DESCRIPTION OF ESSURE® AND HOW IT WORKS

125. 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.

126. 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.

127. The micro-inserts are comprised of two (2) metal coils which are placed in a woman's fallopian tubes via Defendant's disposable delivery system and under hysteroscopic guidance (camera).

128. The hysteroscopic equipment needed to place Essure® was manufactured by a third party, is not a part of Defendant's CPMA, and is not a part of Essure®. However, because Plaintiffs' implanting physicians did not have such equipment, Defendants provided it so that it could sell Essure®.

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

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

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

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

133. Three (3) months after implant, patients are to receive a "Confirmation" test to determine if the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpingogram ("HSG Test" or "Confirmation Test").

134. Regardless of the Confirmation Test, Defendant warranted that Essure® allows for visual confirmation of each inserts' proper placement during the procedure.

135. Essure® was designed, manufactured, and marketed to be used by the average gynecologist as a "quick and easy" and "non-surgical" outpatient procedure to be done without anesthesia.

IV.

EVOLUTION OF ESSURE®

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

137. Conceptus and Defendant merged on or about April 28, 2013.

138. For purposes of this lawsuit, Conceptus and Defendant are one in the same.

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

140. Defendant trained physicians, including Plaintiffs' implanting physicians, on how to implant Essure® and use hysteroscopic equipment.

141. Prior to the merger between Conceptus and the Bayer defendant, Conceptus obtained CPMA for Essure®.

142. 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.

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

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

145. FDA regulations provide one hundred and eighty (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 the FDA with the committee's Recommendation on whether the FDA should approve the submission.

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

147. 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 FDCA and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.

148. Regarding the PMA, devices can either be "approved", "conditionally approved," or "not approved."

149. Essure® was "conditionally approved". It had CPMA, not PMA, which is the "gold standard".

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

a. "Effectiveness of Essure® is established by annually reporting on the seven hundred and forty-five (745) women who took part in clinical tests."

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

c. "Within ten (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.

g. Conduct a post approval study in the United States to document the bilateral placement rate for newly trained physicians.

h. Include results from the annual reporting on the patients who took part in the Pivotal and Phase II clinical investigations in the labeling as these data become available.

i. Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

j. Submit a PMA supplement whenever there are changes to the performance of the device.

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

V.

REQUIREMENTS UNDER FEDERAL REGULATIONS

151. The CPMA also required Defendant to comply with the Medical Device Reporting regulations and post market requirements for Class III medical devices:

a. Report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury;

b. Report to the FDA within thirty (30) days whenever they receive notice of serious injury;

c. Report to the FDA information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;

d. Monitor the product after pre-market approval and discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;

e. Submit a PMA Supplement for any change in manufacturing site, 21 CFR §§ 814.39 et seq.;

f. Establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;

g. Establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 CFR §§ 820.30 et seq.;

h. Document all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues, 21 CFR §§ 820.100 et seq.;

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

j. Establish Quality Management System (QMS) procedures to assess potential causes of non-conforming products and other quality problems, 21 CFR §§820.70 et seq. and 21 CFR §§ 27 820.90 et seq.;

k. Report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80;

l. Advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

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

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

b. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. Labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

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

153. Upon obtaining knowledge of these potential device failure modes, Defendant was required under the Essure® CPMA, 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq., and the FDA Recognized Consensus Standard ISO 14971, to use this information to routinely update the risk analyses for the Essure® device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendant was required to establish Quality Management Systems

("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

VI.

FAILURES OF ESSURE®

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

a. The stainless steel used in Essure® can become un-passivated;

b. The nitinol could have a nickel rich oxide, which the body attacks;

c. The "no lead" solder could, in fact, have trace lead in it;

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

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

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

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

h. PET fibers are also known endocrine disruptors. Endocrine Disrupting Chemicals ("EDCs") like PET often disrupt endocrine systems by mimicking or blocking a natural hormone. In the case of hormone mimics,

an EDC can "trick" that hormone's receptor into thinking that the EDC is the hormone, and this can inappropriately activate the receptor and trigger processes normally activated only by a natural hormone.

i. PET fibers found on the Essure® device (that were intended to cause an inflammatory response) are also causing endocrine disruption which has "unmasked" and caused autoimmune diseases and other autoimmune like symptoms in women who have been implanted with the Essure® device.

j. The mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body.

VII.

VIOLATIONS OF FEDERAL REQUIREMENTS

155. In June 2002, the FDA found the following objectionable conditions:

a. Design outputs were not completely identified.

b. Corrective and preventative action activities were not being documented, including implementation of corrective and preventative actions.

c. Procedures addressing verification of corrective and preventative actions were not implemented.

156. In July 2002, during an inspection of Defendant's facility, the FDA observed that adverse events were not captured in the data.

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

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

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

a. Two (2) lot history records showed rejected raw materials which was not documented and, therefore, could not be tracked.

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

159. In December 2010, the FDA found that Defendant was "not reporting complaints of their product being seen radiographically in the patient's abdominal cavity" and "did not have a risk analysis of the coils being in the abdominal cavity".

160. Defendant failed to comply with several conditions, including:

a. Defendant failed to timely provide the FDA with reports after twelve (12) months, eighteen (18) months and then a final report for one (1) schedule. Defendants also failed to timely submit post approval reports for its six (6) month, one (1) year, eighteenth (18th) month and two (2) year reports. All reports failed to meet the respective deadlines.

b. Defendant failed to document successful placement of Essure®, concealing the failure rates.

c. Defendant failed to notice the FDA of several adverse reactions and actively concealed the same. Defendants failed to report eight (8) perforations, which occurred as a result of Essure®, and was cited for the same by the FDA via Form 483.[2]

d. Defendant failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury, thereby concealing those injuries. Again, Defendants failed to report eight (8) perforations which occurred as a result of Essure® to the FDA as evidenced in Form 483.

e. As outlined *infra*, Defendant's warranties were not truthful or accurate, and were, in fact, misleading.

f. Defendant's warranties were not consistent with applicable federal and state law.

g. Defendant failed to notice the FDA of their internal Excel file containing sixteen thousand and forty-seven (16,047) entries of complaints.

161. Defendant was also found to be:

2 Form 483 is issued to firm management at the conclusion of inspections when an FDA investigator has observed any conditions that violate the FDCA rendering a device "adulterated".

a. Erroneously using non-conforming material in the manufacturing of Essure® and not tracking where it went.

b. Failing to use pre-sterile and post-sterile cages.

c. Manufacturing Essure® at an unlicensed facility.

d. Manufacturing Essure® for three (3) years without a license to do so.

e. Not reporting … complaints in which their product migrated.

f. Not considering these complaints in their risk analysis for the design of Essure®.

g. Failing to document CAPA activities for a supplier corrective action.

162. Specifically, it was determined that:

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

b. Defendant had notice of 168 perforations, but only disclosed twenty-two (22) to the FDA.

c. On January 6, 2011, Defendant was cited for their risk analysis of Essure® being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure® did not include, as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

d. On January 6, 2011, Defendant was 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 Defendant's CAPA did not mention the non-conformity of materials used in Essure® or certain detachment failures. The FDA found that Defendant's engineers learned of this, and it was not documented.

e. On July 7, 2003, Defendant was cited for not analyzing and identifying existing and potential causes of non-conforming product and other quality problems. Specifically, two (2) lot history records showed rejected raw material 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).

f. On July 7, 2003, Defendant was cited for not following procedures used to control products which did not conform to specifications.

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

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

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

VIII.

FDA HEARINGS AND RESULTING ACTION

166. Defendant's conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because Defendant failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Essure® device, the public's knowledge of the risks associated with Essure®

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

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

168. These belated and untimely releases of relevant and important information lead to an increasing number of adverse events being reported to the FDA about Essure® from patients and physicians. Because of these complaints, the FDA convened a public hearing concerning the safety and efficacy of Essure®. At that hearing, Defendant continued to misrepresent the safety and efficacy of Essure®. For example, Defendant stated that:

a. The efficacy rates for Essure® are 99.6%; in reality, studies show that the chances of becoming pregnant with Essure® are higher than with tubal ligations and higher than the rates reported by Bayer to the FDA at the public hearing;

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

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

d. Defendant testified that most of the reports of adverse events to the FDA have come from consumers and not Defendant, which is unusual. In

reality, Defendant failed to report thousands of complaints of adverse events that it had received.

169. On February 29, 2016, the FDA first publicly announced "actions to provide important information about the risks of using Essure® and to help women and their doctors be better informed of the potential complications associated with" the device. The FDA took the following actions:

a. The FDA is requiring a black box warning on Essure® to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions". The FDA draft guidance black box warning for Essure® also warns: "Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device."

b. The FDA is requiring Defendant to implement a Patient Decision Checklist "to help to ensure women receive and understand information regarding the benefits and risks" of Essure®. The FDA's draft Patient Decision Checklist is a five (5) page document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "adverse events including persistent pain, device puncture of the uterus and/or fallopian tubes ('perforation'), or movement of the device into the abdomen or pelvis ('intra-peritoneal migration')"; "allergy or hypersensitivity reactions"; symptoms such as changes in the skin (rash, itching), "chest pain, palpitations, breathing difficulties or wheezing, and intestinal discomfort such as nausea, diarrhea, and vomiting"; "joint or muscle pain, muscle weakness, excessive fatigue, hair loss, weight changes, and mood changes"; the fact that "there is no reliable test to predict ahead of time who may develop a reaction to the device"; the possibility that the Essure® device "can move after placement," possibly becoming ineffective at preventing pregnancy or leading to "serious adverse events such as bleeding or bowel damage, which may require surgery to address"; and the fact that if the Essure® device has to be

removed after placement, it will require surgery to remove and, possibly, a hysterectomy.

c. The FDA has also ordered Bayer "to conduct a new post-market surveillance study designed to provide important information about the risks of the device in a real-world environment". The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's quality of life. The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

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

171. Lastly, although Essure® appears at first glance to be a "medical device", Defendant actually categorizes it as a "drug".

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

IX.

DEFENDANT'S TRAINING AND DISTRIBUTION PLAN

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

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

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

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

177. In fact, because gynecologists and Plaintiffs' implanting physicians were unfamiliar with the device and how to deliver it, Defendant (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses where Defendant observed physicians until Defendant believed they were competent; (4) created

Essure® Procedure Equipment Supplies Checklists; and (5) represented to Plaintiffs that "Physicians must be signed-off to perform Essure® procedures."

178. Defendant provided no training to the implanting physicians on how to remove Essure® should it fail.

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

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

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

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

183. In regard to the entrustment of such specialized equipment, Defendant admitted: "We cannot be certain how successful these programs will be, if at all."

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

185. Defendant knew or failed to recognize that the implanting physicians were not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physicians in order to capture the market.

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

187. The physicians had to purchase the kits regardless of whether they used them or not. This distribution plan created an environment which induced the implanting physicians to "push" Essure® and implant the same into Plaintiffs.

188. Defendant used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as bait. Once the implanting physicians "took the bait", they were required to purchase two (2) Essure® "kits" per month, regardless of whether they sold any Essure® "kits".

189. Defendant's distribution plan also included (1) negligently distributing Essure® in violation of FDA orders and federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure® through representatives of the hysteroscopic equipment manufacturers who were not adequately trained, nor had sufficient knowledge regarding Essure®; (4) failing to report and actively concealing adverse events which occurred as a result of Essure®; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure®; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure® at an unlicensed facility; and (8) manufacturing Essure® for three (3) years without a license to do so.

190. In short, Defendant (1) failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use it; and (3) created an unreasonably

dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

191. All of this was done in violation of federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiffs' safety, health, and bodies.

X.

PLAINTIFFS' HISTORIES

192. As discussed in depth below, each of the Plaintiffs in this case has sustained serious physical injuries as a result of being implanted with the permanent birth control device, Essure®. As a result of (1) Defendant's negligence described *infra*; and (2) Plaintiffs' reliance on defendant's warranties, Defendant's Essure® devices have caused Plaintiffs serious personal injuries. As such, Plaintiffs have suffered a range of injuries such as ectopic pregnancy, actual pregnancy, abdominal pain, depression, fatigue, heavy bleeding, pain during intercourse, weight fluctuations, severe back pain, and migraines. Additionally, some Plaintiffs' Essure® devices have migrated, perforated, and even become embedded in areas outside of the fallopian tubes. Moreover, some Plaintiffs have been forced to undergo hysterectomies in an effort to have their Essure® devices removed.

A. ALABAMA

1. Jamie Jenson

193. Jamie Jenson is a resident of Demopolis, Alabama.

194. On or about December 12, 2007, Plaintiff was implanted with the Essure® device by Dr. Gabriel Yandam at Coshocton County Memorial Hospital in Coshocton, Ohio.

195. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

196. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe bouts of bacterial vaginosis, abdominal pain, cramping, and painful intercourse.

197. In 2010, Plaintiff underwent an ablation in an attempt to control the heavy vaginal bleeding she was experiencing.

198. Plaintiff is currently considering and discussing with her physician the possibility of undergoing a hysterectomy to remove the Essure® device in the near future.

B. ARKANSAS

1. Amber Jackson

199. Amber Jackson is a resident of Cabot, Arkansas.

200. In or about August 14, 2015, Plaintiff underwent the Essure® procedure at UAMS Hospital in Little Rock, Arkansas by Dr. Stacy Pollack.

201. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

202. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, abdominal pain and cramping, and unusual periods.

203. Plaintiff's symptoms became so severe and problematic that on or about August 14, 2015, Plaintiff underwent a hysterectomy to remove the Essure® device at Conway Regional Health System in Conway, Arkansas by Dr. William Greenfield.

2. Magen Allen

204. Magen Allen is a resident of Bismarck, Arkansas.

205. In or about October 2013, Plaintiff underwent the Essure® procedure at Compassions Woman's Clinic in Arkadelphia, Arkansas by Dr. Michael Carroza.

206. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

207. Shortly after undergoing the Essure® procedure, Plaintiff suffered an unintended pregnancy.

208. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at Baptist Medical Center in Arkadelphia, Arkansas in or around February 2015 to remove the Essure® device.

C. CALIFORNIA

1. Kelly Fernandes

209. Kelly Fernandes is a resident of Clovis, California.

210. On or about January 24, 2013, Plaintiff underwent the Essure® procedure at Clovis Community Medical Center in Clovis, California by Dr. Gade.

211. Shortly after, undergoing the Essure® procedure Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

212. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer excessive vaginal bleeding, abdominal pain and cramping.

213. Plaintiff's symptoms became so severe and problematic that on or about September 8, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at St. Agnes Medical Center in Fresno, California with Dr. Gade.

214. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Danielle Black

215. Danielle Black is a resident of Lake Forest, California.

216. On or about 2009, Plaintiff Danielle Black was implanted with the Essure® device at Better Women's Care in Southfield, Michigan by Dr. Korial Atty.

217. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, pain during intercourse, abdominal pain, cramping and bloating, and hormonal fluctuations.

218. After undergoing the Essure® procedure Plaintiff suffered from severe migraines -- for which she had no history of suffering prior to undergoing the implantation of Essure®.

219. Additionally, Plaintiff suffered from severe pain as a result of device migration.

220. On or about July 8, 2014, Plaintiff underwent a hysterectomy to remove the Essure® device which was performed at DMC Berry Surgery Center in Farmington Hill, Michigan by Dr. Korial Atty.

3. Sterling Black

221. Sterling Black is a resident of Lake Forest, California.

222. Sterling Black is married to Plaintiff Danielle Black and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

223. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

224. Plaintiff's wife experienced severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, pain during intercourse, abdominal pain, cramping and bloating, hormonal fluctuations, migraines, and device migration.

225. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from frequent abdominal pain and bleeding.

226. Additionally, Plaintiff had to tend to his wife after she underwent a hysterectomy to remove the Essure® device.

227. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

4. Shendonna Robertson

228. Shendonna Robertson is a resident of Los Angeles, California.

229. On or about March 21, 2015, Plaintiff Shendonna Robertson was implanted with an Essure® device by Dr. Melissa Natavio at S. Mark Taper Foundation Center for Medical Training in Los Angeles, California.

230. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, abdominal pain, cramping and bloating.

231. After undergoing the Essure® procedure Plaintiff suffered from severe migraines -- for which she had no history of suffering prior to undergoing the implantation of Essure®.

232. On or about August 3, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device which was performed at Kaiser Permanente West Los Angeles Medical Center by Dr. Simie Lavern Annette Patterson.

233. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

5. <u>Jacqueline Lopez</u>

234. Jacqueline Lopez is a resident of Los Angeles, California.

235. In or around November 2013, Plaintiff underwent the Essure® procedure at California Hospital Medical Center in Los Angeles, California.

236. Shortly after undergoing the procedure, Plaintiff began experiencing irregular periods, heavy, abnormal bleeding, cramping and bloating, severe menstrual pain, hormonal changes, painful intercourse, and a serious infection resulting in prolonged hospitalization.

237. After undergoing the Essure® procedure Plaintiff suffered from severe migraines —for which she had no history of suffering prior to undergoing the implantation of Essure®.

238. Plaintiff is expected to undergo a total hysterectomy to remove the Essure® device.

6. Jennifer Griffith

239. Jennifer Griffith is a resident of Oakland, California.

240. In or about March 2011, Plaintiff underwent the Essure® procedure at Riverside Medical Center in Newport News, Virginia.

241. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place.

242. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from heavy, abnormal, and irregular menstruation, severe abdominal pain, organ perforation, device fracture, painful intercourse, and hormonal changes.

243. After undergoing the Essure® procedure Plaintiff suffered from severe migraines —for which she had no history of suffering prior to undergoing the implantation of Essure®.

244. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have

no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

7. Jordan Griffith

245. Jordan Griffith is a resident of Oakland, California.

246. Jordan Griffith is married to Plaintiff Jennifer Griffith and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

247. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

248. Plaintiff's wife began to experience pain and cramping, heavy, abnormal menstruation, hormonal changes, and painful intercourse.

249. Additionally, since undergoing the Essure® procedure, Plaintiff's wife has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

250. Plaintiff suffered lost wages as a result of having to tend to his wife post-surgery., and became primarily responsible for completing household chores when his wife was incapacitated due to pain.

251. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from painful intercourse.

252. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

8. Ruth Zipfel

253. Ruth Zipfel is a resident of Sacramento, California.

254. In or around May 2015, Plaintiff underwent the Essure® procedure at Centennial Medical Center in Nashville, Tennessee by Dr. Erin Yu.

255. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

256. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from pain from migrated implants, cramping and unusual periods.

257. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

258. Plaintiff also suffered from organ perforation.

259. Plaintiff's symptoms became so severe and problematic that she underwent a bilateral salpingectomy at UC Davis Medical Center in Sacramento, CA by Dr. Melody Hou in or about August 2015 to remove the Essure® device.

260. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as

to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

9. Sin-Ting Liu

261. Sin-Ting Liu is a resident of Alameda, California.

262. On or about August 29, 2008, Plaintiff underwent the Essure® procedure at the office of Nisseth Urribarri in Coral Springs, Florida, currently known as Green & Urribarri, by Dr. Nisseth Urribarri. Plaintiff's right fallopian tube was implanted with Essure® on August 29, 2008. However, Dr. Urribarri was unable to implant Plaintiff's left fallopian tube with Essure® on August 29, 2008. On September 26, 2008, Plaintiff again went to Dr. Urribarri's office in Coral Springs, Florida, to reattempt to have Essure® implanted in her left fallopian tube, which was successfully implanted.

263. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

264. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual and excessive bleeding during menstrual cycles, often losing over one (1) liter of blood in a three (3) day period. Plaintiff has and continues to suffer from severe menstrual cramps and pressure since having the Essure® implanted.

265. As a further result, Plaintiff has been diagnosed with and suffers from the effects of both Hashimoto's and Grave's diseases, which are autoimmune diseases with symptoms including memory loss, extreme fatigue, enlarged thyroid, rapid weight gain, tachycardia, tremors, gastrointestinal issues, nausea, and rapid weight loss.

266. Plaintiff's symptoms are so severe and problematic that Plaintiff is discussing with Dr. Dionysios Veronikis the possibility of undergoing a partial hysterectomy in the near future to remove the Essure® device.

267. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

D. COLORADO

1. Elizabeth Scheer

268. Elizabeth Scheer is a resident of Grand Junction, Colorado.

269. In or about May 2012, Plaintiff underwent the Essure® procedure at Women's Health Care-Western in Grand Junction, Colorado by Dr. Berry King.

270. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were not properly occluded and the Essure® device placed in the Plaintiff's left fallopian tube had migrated.

271. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain and cramping and unusual periods.

272. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at St. Mary's Medical Center in Grand Junction, Colorado by Dr. Lee Harden, after an ablation procedure failed to control her excessive vaginal bleeding.

2. Lyndsey Martinez

273. Lyndsey Martinez is a resident of Mead, Colorado.

274. In or about November 2014, Plaintiff underwent the Essure® procedure at Longmont United Hospital in Longmont, Colorado by Dr. Patrick Finnegan.

275. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from pain and cramping, unusual periods, unusual periods, body rashes and abnormal pap smears.

276. Additionally, since undergoing the Essure® procedure, Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

277. Plaintiff's symptoms became so severe and problematic that she underwent a bilateral salpingectomy at Longmont United Hospital in Longmont, Colorado by Dr. Patrick Finnegan to remove the Essure® device.

3. Robert Martinez

278. Robert Martinez is a resident of Mead, Colorado.

279. Robert Martinez is married to Plaintiff Lyndsey Martinez and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

280. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

281. Plaintiff's wife began to experience pain and cramping, unusual periods, body rashes and abnormal pap smears.

282. Additionally, since undergoing the Essure® procedure, Plaintiff's wife suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

283. Plaintiff had to care for his wife after she underwent a bilateral salpingectomy at Longmont United Hospital in Longmont, Colorado. Further, Plaintiff became primarily responsible for performing household chores, and tending to the couple's children when his wife was incapacitated due to pain.

284. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

E. CONNECTICUT

1. Veronica Campos

285. Veronica Campos is a resident of Meriden, Connecticut.

286. On or about January 1, 2017, Plaintiff underwent the Essure® procedure at Women's Health Connecticut in West Hartford, Connecticut by Dr. Michael P. Hemphill.

287. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

288. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from pelvic pain, blurry vision, heavy bleeding, hair loss, painful intercourse, fatigue, depression, urinary and yeast infections, and mood swings.

289. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

290. Plaintiff's symptoms have become so become so severe and problematic that she is scheduled to undergo a hysterectomy on December 13, 2017, at the Hartford Hospital in West Hartford, Connecticut to remove the Essure® device.

F. FLORIDA

1. Gwen Bailey

291. Gwen Bailey is a resident of Callahan, Florida.

292. In or about June 2011, Plaintiff underwent the Essure® procedure at North Florida OB/GYN Associates in Jacksonville, Florida by Dr. Amy Greenwall.

293. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

294. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain and cramping, and unusual periods.

295. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

296. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at Baptist Medical Center South in Jacksonville, Florida by Dr. Amy Greenwall.

2. Shawntae Gough

297. Shawntae Gough a resident of Orlando, Florida.

298. On or about April 24, 2014, Plaintiff underwent the Essure® procedure at Alpha Care Center in Elkton, Maryland by Dr. Judith Hidalgo.

299. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

300. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from excessive uterine bleeding, severe pain, severe depression, and rheumatoid arthritis.

301. Additionally, Plaintiff developed systemic lupus erythematosus, trigeminal neuralgia, and optic neuritis.

302. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy on September 26, 2017, to remove the Essure® device at Winnie Palmer Hospital in Orlando, Florida by Dr. Manuel Herrera.

3. Andrea Dahl

303. Andrea Dahl is a resident of Orlando, Florida.

304. On November 2, 2009, Plaintiff underwent the Essure® procedure at Hunter's Creek in Orlando, Florida by Dr. Douglas Winger.

305. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

306. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from insomnia, unusual rashes, leg numbness, anxiety, depression, irritable bowel syndrome, fatigue, and fibromyalgia.

307. Additionally, since undergoing the Essure® procedure Plaintiff developed cysts on her ovaries and severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

308. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy on October 27, 2017 at Florida Hospital Kissimmee in Kissimmee, Florida by Dr. Douglas Winger.

4. Richard Dahl

309. Richard Dahl is a resident of Orlando, Florida.

310. Richard Dahl is married to Plaintiff Andrea Dahl and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

311. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

312. Plaintiff's wife experienced insomnia, unusual rashes, leg numbness, anxiety, depression, irritable bowel syndrome, fatigue, and fibromyalgia.

313. Plaintiff had to care for his wife after she underwent a hysterectomy on October 27, 2017, at Florida Hospital Kissimmee in Kissimmee, Florida by Dr. Douglas Winger.

314. Additionally, Plaintiff became primarily responsible for completing household chores, and caring for the couple's children when his wife was incapacitated due to pain.

315. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. Heather Vernillo

316. Heather Vernillo is a resident of Palm Harbor, Florida.

317. In or about April 2012, Plaintiff underwent the Essure® procedure at Morton Plant Hospital in Clearwater, Florida with Dr. James Clark.

318. Immediately after undergoing the Essure® procedure, Plaintiff developed an abdominal skin rash, and began suffering from severe nausea, vomiting, pelvic pain, and abnormal vaginal discharge.

319. Suffering dense pelvic adhesions involving her sidewall and colon, Plaintiff underwent bilateral salpingectomy with lysis of adhesions on or about May 25, 2012 at Morton Plant Hospital in Clearwater, Florida with Dr. James Clark to remove the Essure® coils.

6. Sarah Shore

320. Sarah Shore is a resident of Port Charlotte, Florida.

321. On or about August 16, 2006, Plaintiff underwent the Essure® procedure at LaPorte Hospital in LaPorte, Indiana by Dr. Julius Ellis.

322. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's fallopian tubes were not properly occluded, and that the right nickel coil had fractured.

323. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from severe abdominal pain, cramping, and irregular periods.

324. As a result of the Essure® device fracturing and in order to prevent an unwanted pregnancy, Plaintiff underwent a tubal ligation on December 26, 2006, at LaPorte Hospital in LaPorte, Indiana.

325. On or about September 27, 2015, Plaintiff had a stroke and was hospitalized at Fawcett Memorial Hospital in Port Charlotte, Florida for an extended period of time.

326. Plaintiff further developed severe uterine bleeding, anemia, and lethargy following the implantation of the Essure® device.

327. Plaintiff's symptoms became so severe and problematic that she underwent a partial hysterectomy to remove the Essure® device at Bayfront Hospital in Port Charlotte, Florida by Dr. Jennifer D'Abarrio.

7. Stephanie Johnson

328. Stephanie Johnson is a resident of St. Cloud, Florida.

329. In or about July 2013, Plaintiff was implanted with Essure® coils with and in the office of Dr. Douglas Winger in Kissimmee, Florida.

330. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place.

331. Shortly after Essure® implantation, Plaintiff began to experience severe pelvic pain, abnormal bleeding, back pain, and suffered from a severe infection.

332. Plaintiff's symptoms were so severe that she underwent total hysterectomy in or around July 2014 at Winnie Palmer Hospital for Women and Babies with Dr. Douglas Winger.

333. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as

to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

8. David Johnson

334. David Johnson is a resident of St. Cloud, Florida.

335. David Johnson is married to Plaintiff Stephanie Johnson and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

336. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

337. Plaintiff's wife experienced pelvic pain, unusual bleeding, back pain, and a severe infection when implanted with Essure® devices.

338. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from frequent abdominal pain and painful intercourse.

339. Additionally, Plaintiff was forced to take on full household duties, while caring for his wife, post hysterectomy.

G. GEORGIA

1. Jacqueline Evans

340. Jacqueline Evans is a resident of Lawrenceville, Georgia.

341. On January 21, 2011, Plaintiff underwent the Essure® procedure at Kaiser Permanente Gwinnett Comprehensive Medical Center in Duluth, Georgia by Dr. Linda Brownlee.

342. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain and cramping, painful intercourse, and ceased menstruating for approximately two years.

343. In or about July 2011, Plaintiff presented to her Obstetrician-Gynecologist, Dr. Mitchell Fonda's office in Duluth, Georgia, with complaints of severe pelvic pain and amenorrhea.

344. Dr. Mitchell Fonda suspected the Plaintiff's etiology of symptoms were related to an allergic reaction of the Essure® nickel coils, and recommended a bilateral salpingectomy to remove the Essure® device.

345. On or about August 29, 2011, the Plaintiff underwent a bilateral salpingectomy to remove the Essure® device at Gwinnett Medical Center in Duluth, Georgia by Dr. Kelly Adkins on August 29, 2011.

346. A surgical pathology report reported on August 30, 2011, by Kelly M. Adkins, M.D. of Gwinnett Hospital in Lawrenceville, Georgia, showed the Plaintiff's fallopian tubes showed focal areas of mild chronic inflammation and fibroids.

2. <u>Gary Evans</u>

347. Gary Evans is a resident of Lawrenceville, Georgia.

348. Gary Evans is married to Plaintiff Jacqueline Evans and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

349. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

350. Plaintiff's wife experienced unusual bleeding, cramping, and painful intercourse.

351. Plaintiff had to care for his wife after she underwent a partial hysterectomy at Gwinnett Medical Center in Duluth, Georgia by Dr. Kelly Adkins on August 29, 2011.

352. Additionally, Plaintiff became primarily responsible for completing household chores, and caring for the couple's children when his wife was incapacitated due to pain.

353. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from painful intercourse.

354. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. <u>Amanda Baker</u>

355. Amanda Baker is a resident of Cartersville, Georgia.

356. In March of 2008, Plaintiff had Essure® device implanted at Etowah Valley Harbin Clinic in Cartersville, Georgia.

357. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place.

358. Within six (6) months of undergoing the Essure® procedure, Plaintiff began to experience painful intercourse, tooth decay, heavy bleeding and cramping, bloating, large blood clots, constant bacterial vaginosis, cysts, fatigue.

359. Additionally, since undergoing the Essure® procedure, Plaintiff has been diagnosed with fibromyalgia, bursitis, sciatica, arthritis, degenerative discs, and major joint pain.

360. Plaintiff's symptoms became so severe and problematic that in or about November 2011, Plaintiff underwent a full hysterectomy at Northwest Georgia OB/GYN in Calhoun, Georgia to remove the Essure® device.

361. Plaintiff recalls reading a brochure for Essure® that promoted the device as a safe, effective form of birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Ginger York

362. Ginger York is a resident of McDonough, Georgia.

363. On or about January of 2006, Plaintiff was implanted with an Essure® device by Dr. Stephen Rabin at Southern Regional Medical Center in Riverdale, Georgia.

364. Over the next few months, our client suffered from unusual and heavy menstrual cycles, fatigue, forgetfulness, severe cramps, and pain during intercourse.

365. On or about September 12, 2014, Plaintiff presented to Dr. Jeffrey D. Lovinger at Eagles Landing OBGYN in Stockbridge, Georgia, complaining of severe vaginal bleeding.

366. On or about September 18, 2014, a sonogram taken of the Plaintiff's reproductive system at Eagles Landing OBGYN in Stockbridge, Georgia, revealed the Plaintiff's endometrium had thickened and cervical polyp had developed.

367. On or about October 8, 2014, Plaintiff underwent a polypectomy, dilation and curettage to remove the cervical polyp at Piedmont Henry Hospital in Stockbridge, Georgia by Dr. Jeffrey David Lovinger.

368. Plaintiff's symptoms continued to be so severe and problematic that Plaintiff underwent hysterectomy to remove the Essure® device on December 13, 2014, at Piedmont Henry Hospital in Stockbridge, Georgia by Dr. Jeffrey David Lovinger.

5. James York

369. James York is a resident of McDonough, Georgia.

370. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

371. Plaintiff's wife experienced suffered from unusual and heavy menstrual cycles, fatigue, forgetfulness, severe cramping, and pain during intercourse.

372. Plaintiff had to care for his wife after she underwent a polypectomy, dilation and curettage on October 8, 2014, and a hysterectomy on December 13, 2014.

373. During that time, Plaintiff became primarily responsible for completing household chores when his wife was incapacitated due to pain.

374. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from painful intercourse.

375. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

6. Takai Hose

376. Takai Hose is a resident of Moultrie, Georgia.

377. In or around January 2013, Plaintiff underwent the Essure® procedure at Colquitt Regional Medical Center in Moultrie, Georgia by Dr. Danny Kouskis.

378. Shortly after undergoing the procedure, Plaintiff has suffered from irregular and prolonged menstruation, heavy bleeding, severe menstruation pain, painful intercourse, and hormonal changes, including but not limited to, an increase in body temperature.

379. After undergoing the Essure® procedure Plaintiff suffered from severe migraines —for which she had no history of suffering prior to undergoing the implantation of Essure®.

380. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have to undergo a hysterectomy to remove the Essure® device. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

H. ILLINOIS

1. Elizabeth Bertelsman

381. Elizabeth Bertelsman is a resident of Ashkum, Illinois.

382. In or about October of 2010, Plaintiff underwent Essure® procedure at Congressional OBGYN in Rockland, Maryland.

383. After undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain, ovarian cysts, and fibromyalgia.

384. On October 20, 2017, a hysterectomy was performed to remove the Essure® device at Riverside Medical Center, in Kankakee, Illinois.

385. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Latronica Smith

386. Latronica Smith is a resident of Chicago, Illinois.

387. In or around February 2013, Plaintiff underwent the Essure® procedure at the McCammon-Chase Total Wellness Center in Oak Park, Illinois with by Dr. Nathalie McCammon-Chase.

388. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

389. Shortly after the procedure, Plaintiff began suffering from hormonal fluctuations, irregular bleeding, painful intercourse, cramping and bloating.

390. Additionally, Plaintiff suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

391. On or about March 23, 2017, Plaintiff presented to West Suburban Medical Center's Emergency Department in Oak Park, Illinois suffering from an ectopic pregnancy.

392. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff may have no choice but to undergo a hysterectomy to remove the Essure® device. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. Jody Kemp

393. Jody Kemp is a resident of Crystal Lake, Illinois.

394. In or about June of 2011, Plaintiff underwent the Essure® procedure at Advocate Good Shepherd Hospital in Barrington, Illinois by Dr. Heather Beall.

395. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

396. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from abdominal pain and cramping, shortness of breath, irregular periods, bloating, numbness throughout her body, painful intercourse, and fevers.

397. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

398. Plaintiff also suffered from excessive vaginal bleeding, extreme fatigue, shortness of breath, and was subsequently diagnosed with fibromyalgia.

399. Plaintiff's symptoms became so problematic that she underwent a hysterectomy on October 18, 2015, to remove the Essure® device at Advocate Good Shepherd in Barrington, Illinois by Dr. Heather Beall.

400. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

5. Jeremy Kemp

401. Jeremy Kemp is a resident of Crystal Lake, Illinois.

402. Jeremy Kemp is married to Plaintiff Jody Kemp and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

403. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

404. Plaintiff's wife experienced abdominal pain and cramping, shortness of breath, fatigue, irregular periods, bloating, excessive vaginal bleeding, numbness throughout her body, and fevers on a daily basis.

405. The couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from frequent abdominal pain and painful intercourse.

406. Plaintiff had to care for his wife after she underwent a hysterectomy on October 18, 2015, to remove the Essure® device at Advocate Good Shepherd in Barrington, Illinois by Dr. Heather Beall.

407. During that time, Plaintiff became primarily responsible for completing household chores when his wife was incapacitated due to pain.

408. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

6. Fran Leach

409. Fran Leach is a resident of Steger, Illinois.

410. On or about December 9, 2010, Plaintiff underwent the Essure® procedure at Scott-Terry Female Health Associates in Frankfort, Illinois with Dr. Toni Scott-Terry.

411. Shortly after undergoing the Essure® procedure, Plaintiff began suffering from irregular and prolonged menstruation, painful intercourse, severe cramps, pain throughout her body, dizziness, and excessive bleeding.

412. Since undergoing the Essure® procedure, Plaintiff has been diagnosed with fibromyalgia and rheumatoid arthritis.

413. On or about October 11, 2012 and August 8, 2017, Plaintiff presented to Scott Terry Female Frankfort Associates in Frankfort, Illinois complaining of excessive bleeding, irregular periods, fatigue, and dizziness.

414. On August 8, 2017, Dr. Scott-Terry diagnosed Plaintiff with secondary dysmenorrhea, menorrhagia, and recommended Plaintiff undergo a hysterectomy to remove the Essure® device.

415. On or about August 23, 2017, Plaintiff underwent a hysterectomy to remove the Essure® device at Franciscan St. James Hospital in Olympia Fields, Illinois by Dr. Tony Scott-Terry.

7. Robert Leach

416. Robert Leach is a resident of Steger, Illinois.

417. Robert Leach is married to Plaintiff Fran Leach and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

418. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

419. Plaintiff's wife began suffering from irregular and prolonged menstruation, painful intercourse, severe cramps, pain throughout her body, dizziness, excessive bleeding, nausea, rheumatoid arthritis, and fibromyalgia.

420. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from frequent abdominal pain and painful intercourse. The couple nearly divorced due to intimacy issues.

421. Additionally, Plaintiff had to care for his wife after she underwent a hysterectomy to remove the Essure® device at Franciscan St. James Hospital in Olympia Fields, Illinois by Dr. Tony Scott-Terry.

422. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

8. Ericka Collier

423. Erika Collier is a resident of Justice, Illinois.

424. On or about May 2012, Plaintiff underwent the Essure® procedure at Amita Health Adventist Medical Center La Grange in La Grange, Illinois.

425. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

426. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, cramping, unusual periods and painful intercourse.

427. Plaintiff also suffered from pain from device migration.

428. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

9. Denorvelle Collier

429. Denorvelle Collier is a resident of Justice, Illinois.

430. Denorvelle Collier is married to Plaintiff Ericka Collier and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

431. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

432. Plaintiff's wife experienced unusual bleeding, pain from migrated implants, cramping, unusual periods, and painful intercourse.

433. The couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from painful intercourse.

434. Additionally, Plaintiff has become primarily responsible for completing household chores when his wife is incapacitated due to pain.

435. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

I. INDIANA

1. Beth Carr

436. Beth Carr is a resident of Columbus, Indiana.

437. In or about January 2011, Plaintiff underwent the Essure® procedure at Presbyterian Hospital of Dallas in Dallas, Texas by Dr. Kavitha Blewett.

438. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

439. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain and cramping, unusual periods, painful intercourse, hot flashes, insomnia, restless legs, and anxiety.

440. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

441. Plaintiff's symptoms became so severe and problematic that on or about March 22, 2015, she underwent a hysterectomy at Comanche County Memorial Hospital in Lawton, Oklahoma by Dr. Janice Lepp.

2. Jessie Carr, Jr.

442. Jessie Carr, Jr. is a resident of Columbus, Indiana.

443. Jessie Carr, Jr. is married to Plaintiff Beth Carr and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

444. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

445. Plaintiff's wife experienced unusual bleeding, pain and cramping, unusual periods and painful intercourse.

446. Additionally, since undergoing the Essure® procedure Plaintiff's wife suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

447. The couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from painful intercourse.

448. Plaintiff had to also care for his wife after she underwent a hysterectomy on or about March 22, 2015, at Comanche County Memorial Hospital in Lawton, Oklahoma by Dr. Janice Lepp.

449. During that time, Plaintiff became primarily responsible for completing household chores when his wife was incapacitated due to pain.

450. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

J. KENTUCKY

1. Michelle Hornsby

451. Michelle Hornsby is a resident of Independence, Kentucky.

452. On or about March 2011, Plaintiff underwent the Essure® procedure at The Christ Hospital in Cincinnati, Ohio by Dr. Parag Patel.

453. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

454. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from cramping, unusual periods, kidney and bladder infections, depression, and anxiety.

455. After undergoing the Essure® procedure Plaintiff suffered from severe migraines —for which she had no history of suffering prior to undergoing the implantation of Essure®.

456. Additionally, Plaintiff was diagnosed with Sjogren's syndrome and Fibromyalgia.

457. Plaintiff's symptoms became so severe and problematic that she underwent a removal of the implants at The Christ Hospital in Cincinnati, Ohio by Dr. Parag Patel in or about January 2013.

458. On March 21, 2014, Plaintiff went on to have a complete hysterectomy at Jewish Hospital Outpatient Clinic in Cincinnati, Ohio by Dr. Joel Paranikoff.

459. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

K. LOUISIANA

1. Aimee Morrison

460. Aimee Morrison is a resident of Sulphur, Louisiana.

461. In or around January 2012, Plaintiff underwent the Essure® procedure at Affinity Medical Associates in Tomball, Texas by Dr. Laura Davidson.

462. Shortly after Essure® implantation, Plaintiff began experiencing severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, abdominal pain, cramping and bloating, hair loss, depression, and anemia.

463. Plaintiff was unable to continuously work because she was often times incapacitated due to pain.

464. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device on March 18, 2013 at Memorial Hermann Hospital in Woodlands, Texas by Dr. Gregory Eads.

L. MAINE

1. Tracy Hammond

465. Tracy Hammond is a resident of Bangor, Maine.

466. In or about March 2007, Plaintiff underwent the Essure® procedure at Bangor Women's HealthCare in Bangor, Maine by Dr. Robert Grover.

467. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

468. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe menstruation pain, excessive bleeding, abdominal pain, cramping, and unusual periods.

469. Additionally, Plaintiff developed fibroids in her uterus.

470. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device and ablation in or about August 2013 at Eastern Maine Medical Center in Jeffersonville, Indiana.

M. MASSACHUSETTS

1. Maxine Bell

471. Maxine Bell is a resident of Mattapan, Massachusetts.

472. In or around February 2008, Plaintiff underwent the Essure® procedure at Harvard Vanguard Medical Associates in Somerville, Massachusetts.

473. In or around May 2008, Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

474. Shortly after Essure® implantation, Plaintiff began experiencing severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, abdominal pain, cramping and bloating, hormonal fluctuations, migraines, device migration, and painful intercourse.

475. After undergoing the Essure® procedure Plaintiff suffered from severe migraines —for which she had no history of suffering prior to undergoing the implantation of Essure®.

476. In or around August 2008, approximately six months after the Plaintiff underwent the Essure® implant, the Plaintiff suffered an unintended pregnancy. An ultrasound revealed the Essure® device had failed in at least one of Plaintiff's fallopian tubes.

477. Plaintiff's physicians have recommended Plaintiff undergo a hysterectomy in the near future to remove the Essure® device.

2. <u>Keith Bell</u>

478. Keith Bell is a resident of Mattapan, Massachusetts.

479. Keith Bell is married to Plaintiff Maxine Bell and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

480. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

481. Plaintiff's wife experienced severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, pain during intercourse, abdominal pain, cramping and bloating, hormonal fluctuations, migraines, device migration, and an unintended pregnancy just months after Essure® implantation.

482. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from frequent abdominal pain and bleeding; causing the couple to separate for a time.

483. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

484. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Cristie Lajoie

485. Cristie Lajoie is a resident of New Salem, Massachusetts.

486. In or around January 2014, Plaintiff was implanted with Essure® at Haywood Health Center for Women in Gardner, Massachusetts with Dr. Jeffrey Blake.

487. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

488. Shortly after undergoing Essure® implantation, Plaintiff began to suffer a heavy menstruation cycle, extreme anemia, uterine cysts and fibroids, and constant pain throughout her body.

489. On or about October 2, 2017, Plaintiff underwent a total hysterectomy at Haywood Hospital in Gardner, Massachusetts.

490. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

N. MICHIGAN

1. Lillie Croft

491. Lillie Croft is a resident of Grand Rapids, Michigan.

492. On or about September 15, 2009, Plaintiff was implanted with an Essure® device by Dr. Charles Newton at Grand Rapids Women's Health in Grand Rapids, Michigan.

493. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

494. Over the next few months, our client suffered severe pain and cramping, unusual periods, painful intercourse, excessive vaginal bleeding, hormonal fluctuations, and developed fibroids.

495. On or about September 14, 2017, Ms. Croft underwent a polypectomy at Mercy Health Hospital in Grand Rapids, Michigan. Plaintiff experienced complications consisting of a serious infection resulting in prolonged hospitalization.

496. Plaintiff's physicians have recommended Plaintiff undergo a hysterectomy in the near future to remove the Essure® device.

2. Shawn Foster

497. Shawn Foster is a resident of Durand, Michigan.

498. In or about June 2005, Plaintiff underwent the Essure® procedure at St. Joseph Mercy Livingston Hospital in Howell, Michigan by Dr. William Bradfield.

499. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

500. Shortly after undergoing the Essure® procedure, Plaintiff was diagnosed with Lupus and Sjogren's syndrome.

501. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at St. Joseph Mercy Livingston Hospital in Howell, Michigan by Dr. Adam Ziff.

3. Cheryl Root

502. Cheryl Root is a resident of Pontiac, Michigan.

503. On January 22, 2009 Plaintiff underwent the Essure® procedure at North Oakland Medical Center in Pontiac, Michigan by Dr. Jennifer Holan.

504. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, abdominal uterine bleeding, pelvic pain, cramping and unusual menstruation.

505. On or about December 5, 2016, Plaintiff presented to Hurley Medical Center in Flint, Michigan complaining of severe pelvic cramping, irregular periods, excessive bleeding. She reported to Dr. Vickie Mello that she began to experience these symptoms post Essure® implantation.

506. Dr. Vickie Mello at Hurley Medical Center recommended the Plaintiff undergo a hysterectomy in the near future to remove the Essure® device.

4. Katherine Kelley

507. Katherine Kelley is a resident of Reed City, Michigan.

508. On April 3, 2008, Plaintiff underwent the Essure® procedure at Trinity Health Hospital in Minot, North Dakota by Dr. David Billings.

509. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

510. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from skin rashes, urinary tract infections, vaginosis and vaginal discharge, kidney infections, sharp abdominal pains, unexplained bruising, weight gain, back pain, unusual bleeding, painful intercourse, unusual periods, abdominal pain, dizziness, anemia, hair loss, loss of concentration, and depression.

511. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Additionally, Plaintiff may have no choice but to undergo a hysterectomy to have her Essure® removed. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

5. Todd Kelley

512. Todd Kelley is a resident of Reed City, Michigan.

513. Todd Kelley is married to Plaintiff Katherine Kelley and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

514. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff's wife experienced skin rashes, urinary tract infections, vaginosis and vaginal discharge, kidney infections, sharp abdominal pains, unexplained bruising, weight gain, back pain, unusual bleeding, painful intercourse, unusual periods, abdominal pain, dizziness, anemia, hair loss, loss of concentration, and depression.

515. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from painful intercourse.

516. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

517. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

O. MISSISSIPPI

1. Michelle Nouisser

518. Michelle Nouisser is a resident of Natchez, Mississippi.

519. In or about February 2009, Plaintiff underwent the Essure® procedure at Kaiser Permanente in Aurora, Colorado by Dr. Dave Kronbach.

520. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

521. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual periods, unusual bleeding, pain, and cramping.

522. On or about June 16, 2014, Plaintiff underwent an ablation in an attempt to control her excessive vaginal bleeding, and irregular periods.

523. Plaintiff's symptoms became so severe and problematic that on or about November 15, 2014, Plaintiff underwent a hysterectomy at Natchez Women's Center in Natchez, Mississippi by Dr. Melissa Jones.

524. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

P. NEBRASKA

1. Ashley Naranjo

525. Plaintiff Ashley Naranjo is a resident of North Platte, Nebraska.

526. On May 25, 2010, Plaintiff underwent the Essure® procedure at McKee Medical Center in Loveland, Colorado by Dr. Kenneth Slack.

527. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain and cramping, unusual menstruation, hormonal changes, and painful intercourse.

528. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

529. On November 24, 2014, Plaintiff was admitted to Ogallala Community Hospital where it was confirmed that her Essure® device was malpositioned.

530. Dr. Amy C. Short at North Platte OB/GYN, PC has informed Plaintiff that she will no choice but to undergo a hysterectomy to have the Essure® device removed.

Q. NEW MEXICO

1. Ona Garcia

531. Plaintiff Ona Garcia is a resident of Raton, New Mexico.

532. On or about September 2012, Plaintiff underwent the Essure® procedure at Spanish Peaks Outreach & Women's Clinic in Walsenburg, Colorado.

533. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain and cramping, unusual menstruation, hormonal fluctuations, mood swings, forgetfulness, and blood clots.

534. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

535. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device on October 18, 2017, at Miner's Colfax Medical Center in Raton, New Mexico by Dr. Mary L. VanSickle.

536. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

R. NEVADA

1. Angelique Frances

537. Angelique Frances is a resident of Las Vegas, Nevada.

538. In or about February 2012, Plaintiff underwent the Essure® procedure at Las Vegas Obstetrics Gynecology: The Ob-Gyn Center in Las Vegas, Nevada by Dr. Henry Luh.

539. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were not properly occluded. An HSG re-test was performed approximately three months later and revealed the nickel coil(s) placed in the Plaintiff's fallopian tubes had migrated. Specifically, one nickel coil had migrated to the top of Plaintiff's uterus.

540. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from pain and cramping and unusual periods.

541. Plaintiff's symptoms became so severe and problematic that in or about September 2013, Plaintiff underwent a right salpingo-oophorectomy to remove the Essure® device at Centennial Hills Hospital in Las Vegas, Nevada with Dr. Henry Luh.

542. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. <u>David Frances</u>

543. David Frances is a resident of Las Vegas, Nevada.

544. David Frances is married to Plaintiff Angelique Frances and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

545. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

546. Plaintiff's wife experienced pain and cramping, and unusual menstruation, regularly, interrupting their day-to-day living.

547. Plaintiff had to also care for his wife after she underwent a hysterectomy in or about September 2013 to remove the Essure® device at Centennial Hills Hospital in Las Vegas, Nevada with Dr. Henry Luh.

548. During that time, Plaintiff also became primarily responsible for completing household chores, and tending to the couple's children when his wife was incapacitated due to pain.

549. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from frequent abdominal pain and painful intercourse.

550. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. Kristi Byers

551. Kristi Byers is a resident of Las Vegas, Nevada. In or about January 2007, Plaintiff underwent the Essure® procedure at Bronson Methodist Hospital in Kalamazoo, Michigan by Dr. Berkowitz.

552. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

553. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from severe urinary tract infections, bloating, cramping, unusual periods and painful intercourse.

554. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device in Las Vegas, Nevada by Dr. Henry Luh in or around September 2012.

S. NEW YORK

1. Rachel Sweatt

555. Rachel Sweatt is a resident of East Syracuse, New York.

556. In or about December 2010, Plaintiff underwent the Essure® procedure at Women's Place in Liverpool, New York by Dr. Michael Cummings.

557. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

558. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding and weight extreme weight gain.

559. Plaintiff also suffered device migration.

560. Plaintiff's symptoms became so severe and problematic that on or about June 2011, she underwent a partial hysterectomy at Women's Place in Liverpool, New York by Dr. Cummings to remove the Essure® device. Dr. Cummings informed the Plaintiff that one of her fallopian tubes that contained a migrated nickel coil had to remain inside of the Plaintiff because it was too dangerous to remove.

561. Plaintiff is unable to work as a result of the pain she still experiences post Essure® implantation.

562. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. <u>Leon Sweatt</u>

563. Leon Sweatt is a resident of East Syracuse, New York.

564. Leon Sweatt is married to Plaintiff Rachel Sweatt and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

565. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

566. Plaintiff had to also care for his wife after she underwent a partial hysterectomy to remove the Essure® device in or about June 2011 at Women's Place in Liverpool, New York by Dr. Cummings.

567. Plaintiff has since become primarily responsible for completing household chores when his wife is on disability and incapacitated due to pain.

568. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. <u>Brenda Whipple</u>

569. Brenda Whipple is a resident of Mallory, New York.

570. In or about March 2002, Plaintiff underwent the Essure® procedure at Harrison Outpatient Center in Syracuse, New York by Dr. Douglas Powell.

571. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

572. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, ovary pain, cramping, depression, anxiety, and forgetfulness.

573. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

574. On October 7, 2017, Plaintiff's symptoms became so problematic that she underwent a hysterectomy at St. Joseph Hospital Health Center in Syracuse, New York by Dr. Christopher Larissa.

575. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. <u>John Whipple</u>

576. John Whipple is a resident of Mallory, New York.

577. John Whipple is married to Plaintiff Brenda Whipple and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

578. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

579. Plaintiff's wife began to suffer from unusual bleeding, ovary pain, cramping, anxiety, depression, and forgetfulness.

580. Additionally, Plaintiff's wife suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

581. Plaintiff had to also care for his wife after she underwent a hysterectomy on or about October 7, 2017, at St. Joseph Hospital Health Center in Syracuse, New York by Dr. Christopher Larissa.

582. During that time, Plaintiff also became primarily responsible for completing household chores, and tending to the couple's children when his wife was incapacitated due to pain.

583. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. Keisha McNaughton

584. Keisha McNaughton is a resident of Wyandanch, New York.

585. On or about January 25, 2013, Plaintiff underwent Essure® procedure at Southside Hospital in New York by Dr. Mark Pillateri.

586. Over the next few years, Plaintiff suffered pain from migrated implants, unusual bleeding, painful intercourse, cramping and bloating, unusual periods, severe abdominal pain, and hormonal fluctuations.

587. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

588. Plaintiff's symptoms became so problematic that in or about November 2016, Plaintiff underwent a hysterectomy at Southside Hospital in New York by Dr. Mark Pillateri.

6. Rushik McNaughton

589. Rushik McNaughton is a resident of Wyandanch, New York.

590. Rushik McNaughton is married to Plaintiff Keisha McNaughton and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

591. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

592. Plaintiff's wife began to suffer from severe menstrual pain, irregular and prolonged menstruation, heavy and abnormal bleeding, pain during intercourse, abdominal pain, cramping and bloating, hormonal fluctuations, and migraines.

593. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device because she suffered from painful intercourse.

594. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

595. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

7. <u>Rachel Lewis</u>

596. Rachel Lewis is a resident of Brooklyn, New York.

597. On or about June 3, 2010, Plaintiff underwent the Essure® procedure at Englewood Hospital & Medical Center in Englewood, New Jersey.

598. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place.

599. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from heavy, abnormal, and irregular menstruation, severe pelvic pain, painful intercourse, hormonal changes, hot flashes, night sweats, and unexplained rashes.

600. Plaintiff also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

601. Additionally, on or about February 17, 2014, Plaintiff experienced an unintended pregnancy which she was forced to terminate.

602. Plaintiff's physicians have recommended a total hysterectomy to remove the Essure® devices due to the amount of scar tissue that has formed over the nickel coils.

8. Nathan Deliotte

603. Nathan Deliotte is a resident of Brooklyn, New York.

604. Nathan Deliotte is married to Plaintiff Rachel Lewis and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

605. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

606. Plaintiff's wife began to suffer from heavy, abnormal, and irregular menstruation, severe pelvic pain, painful intercourse, hormonal changes, hot flashes, night sweats, unexplained rashes, and an unintended pregnancy.

607. Since undergoing the Essure® procedure, Plaintiff's wife has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

608. Plaintiff became primarily responsible for tending to the household chores when his wife was incapacitated due to with pain.

609. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device because she suffered from painful intercourse.

610. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

T. NORTH CAROLINA

1. Mayaanne Mays

611. Mayaanne Mays is a resident of Charlotte, North Carolina.

612. In or around October 2010, Plaintiff was implanted with the Essure® device at Novant Health Carmel OB/GYN - Blakeney in Charlotte, North Carolina by Dr. Rina Roginsky.

613. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

614. Shortly after undergoing Essure® implantation, Plaintiff began to suffer hair loss, loss of libido, abnormal vaginal bleeding, muscle fatigue, joint pain, and abdominal pain and has been diagnosed with lupus, Sjogren's Syndrome, and Fibromyalgia.

615. Additionally, since undergoing the Essure® procedure, Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

616. Due to the severity of her symptoms, Plaintiff's Essure® coils were removed via total hysterectomy on or around September 20, 2017 at Carolina Medical Center in Charlotte, North Carolina, by Dr. Wendell Naumann.

U. OHIO

1. Melanie Dubaj

617. Melanie Dubaj is a resident of Alliance, Ohio.

618. In or about May 2008, Plaintiff underwent the Essure® procedure at Atrium OBGYN, Inc. in Canton, Ohio by Dr. David Brandau.

619. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

620. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from pain and cramping, unusual periods, fatigue, vision deterioration, uterine prolapse, and Celiac disease.

621. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

622. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at Mercy Health – St. Elizabeth Boardman Hospital in Boardman, Ohio by Dr. Priya Patel.

2. James Dubaj

623. James Dubaj is a resident of Alliance, Ohio.

624. James Dubaj is married to Plaintiff Melanie Dubaj and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

625. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

626. Plaintiff's wife began to suffer from wife experienced pain and cramping, unusual periods, fatigue, vision deterioration, uterine prolapse, and Celiac disease.

627. Since undergoing the Essure® procedure, Plaintiff's wife has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

628. Plaintiff became primarily responsible for tending to the household chores when his wife was incapacitated due to with pain.

629. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

630. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. <u>Brandy Graves</u>

631. Brandy Graves is a resident of Columbus, Ohio.

632. On or about February 18, 2009, Plaintiff underwent the Essure® procedure at Firelands Regional Medical in Sandusky, Ohio by Dr. Brian J. Printy.

633. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place.

634. Shortly after undergoing the Essure® procedure, Plaintiff began experiencing severe abdominal pain, painful intercourse, cramping and bloating, fibromyalgia, and myasthenia gravis.

635. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®, and has been unable to consistently work because she is often incapacitated with pain.

636. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff may have no choice but to undergo a hysterectomy to remove the Essure® device. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. <u>Damian Coleman</u>

637. Damian Coleman is a resident of Columbus, Ohio.

638. Plaintiff Damian Coleman is married to Plaintiff Brandy Graves and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

639. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

640. Plaintiff's wife began to suffer from severe abdominal pain, painful intercourse, cramping and bloating, fibromyalgia, and myasthenia gravis.

641. Additionally, since undergoing the Essure® procedure Plaintiff's wife has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®, and has been unable to work as she often incapacitated with pain.

642. The Plaintiff has become the primary breadwinner and is responsible for performing many of the household chores.

643. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device.

644. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

645. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. <u>Stephanie Dorsey</u>

646. Stephanie Dorsey is a resident of Wintersville, Ohio.

647. On or about October 2011, Plaintiff underwent the Essure® procedure at Edgeworth Medical Commons in Sewickley, Pennsylvania by Dr. Bryan Labuda.

648. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

649. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from severe bloating, acne, abdominal pain, and irregular periods.

650. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

651. Plaintiff's symptoms became so severe and problematic that she underwent a partial hysterectomy to remove the Essure® device on or about July 26, 2012, at Heritage Valley Beaver Medical Center in Beaver, Pennsylvania by Dr. John Wright.

652. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

6. <u>Michele McGovern</u>

653. Michele McGovern is a resident of Massillon, Ohio.

654. On October 21, 2008, Plaintiff underwent the Essure® procedure at Aultman West Hospital in Massillon, Ohio by Dr. Melissa Vassas.

655. Plaintiff underwent an HSG test on or about January 2009 at Aultman West Hospital in Massillon, Ohio, during which it was confirmed that Plaintiff's Essure® coils were not properly in place or occluded. The scan revealed that at least one Essure® coil had fractured and migrated.

656. Plaintiff has suffered from painful intercourse.

657. Plaintiff may be forced to undergo a hysterectomy to remove the Essure® device in the future.

7. Kevin McGovern

658. Kevin McGovern is a resident of Massolin, Ohio.

659. Kevin McGovern is married to Plaintiff Michele McGovern and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

660. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

661. Plaintiff became primarily responsible for performing household chores when his wife was incapacitated due to pain.

662. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device.

663. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

664. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

V. OKLAHOMA

1. Clarissa Mimms

665. Clarissa Mimms is a resident of Fairfax, Oklahoma.

666. In or about November 2003, Plaintiff underwent the Essure® procedure at Hillcrest Medical Center in Tulsa, Oklahoma.

667. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, pain, cramping and unusual periods.

668. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

669. Plaintiff also suffered from pain as a result of device fracture.

670. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at St. John Medical Center in Tulsa, Oklahoma in or about May of 2009.

2. <u>Leonard Mimms</u>

671. Leonard Mimms is a resident of Fairfax, Oklahoma.

672. Leonard Mimms is married to Plaintiff Clarissa Mimms and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

673. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

674. Plaintiff had to care for his wife after she underwent a partial hysterectomy to remove the Essure® device in or about May of 2009 at St. John Medical Center in Tulsa, Oklahoma.

675. Plaintiff became primarily responsible for performing household chores when his wife was incapacitated due to pain.

676. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

W. PENNSYLVANIA

1. Julia Mikotowicz

677. Julia Mikotowicz is a resident of Harbor Creek, Pennsylvania.

678. In or about September 2008, Plaintiff underwent the Essure® procedure at UPMC Hamot Surgery Center in Erie, Pennsylvania by Dr. Timothy Weibel.

679. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

680. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual bleeding, irregular and prolonged menstruation, hormonal fluctuations, fatigue, acne, and psoriasis.

681. Since undergoing the Essure® procedure Plaintiff has also suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

682. Plaintiff's symptoms became so severe and problematic that she underwent a partial hysterectomy to remove the Essure® device on in or about August 2017 at Saint Vincent Health System in Erie, Pennsylvania by Dr. Michael Scutella.

2. Michael Mikotowicz

683. Michael Mikotowicz is a resident of Harbor Creek, Pennsylvania.

684. Michael Mikotowicz is married to Plaintiff Julia Mikotowicz and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

685. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

686. Plaintiff had to care for his wife after she underwent a partial hysterectomy to remove the Essure® device on in or about August 2017 at Saint Vincent Health System in Erie, Pennsylvania by Dr. Michael Scutell.

687. Plaintiff became primarily responsible for caring for his wife and children, and performing household chores when his wife was incapacitated due to pain.

688. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. <u>Sharon Hood</u>

689. Sharon Hood is a resident of Mifflintown, Pennsylvania.

690. In or about July 2014, Plaintiff underwent the Essure® procedure at Altoona Hospital in Altoona, Pennsylvania by Dr. Debra Pike.

691. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

692. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from excessive bleeding, abdominal pain, weight fluctuations, hair loss, painful intercourse, fatigue, memory problems and severe cramps.

693. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device at Lewistown Hospital in Lewistown, Pennsylvania by Dr. Stephen Solomon.

694. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

4. <u>Joshua Hood</u>

695. Joshua Hood is a resident of Mifflintown, Pennsylvania.

696. Joshua Hood is married to Plaintiff Sharon Hood and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

697. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

698. Plaintiff's wife began to suffer from excessive bleeding, abdominal pain, weight issues, hair loss, painful intercourse, fatigue, memory problems and severe cramps.

699. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device.

700. Plaintiff had to care for his wife after she underwent a hysterectomy to remove the Essure® device at Lewistown Hospital in Lewistown, Pennsylvania by Dr. Stephen Solomon.

701. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

702. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

X. TENNESSEE

1. Reagan Burgenheim

703. Reagan Burgenheim is a resident of Gallatin, Tennessee.

704. In or about May 2013, Plaintiff underwent the Essure® procedure at TriStar Hendersonville Medical Center in Hendersonville, Tennessee by Dr. Brent Nason.

705. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were not properly in place. Her right fallopian tube had not occluded.

706. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from severe pelvic pain. Plaintiff also suffered from pain due to device migration.

707. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device at TriStar Hendersonville Medical Center in Hendersonville, Tennessee by Dr. Brandon Riggan in or about September 2016.

Y. TEXAS

1. Angela Owens

708. Angela Owens is a resident of Baytown, Texas.

709. In or about 2008, Plaintiff underwent the Essure® procedure at Kelsey Seybold Clinic in Pasadena, Texas.

710. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

711. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from unusual vaginal bleeding, severe abdominal pain and cramping, painful intercourse, and dizziness.

712. On or about October 20, 2015, Plaintiff presented to Houston Methodist San Jacinto Hospital in Baytown, Texas with complaints of severe pelvic pain, and very heavy menstrual cycles.

713. On or about October 20, 2015, Dr. Patricia A. Frey attributed the etiology of the Plaintiff's symptoms to the Essure® device, and recommended the Plaintiff undergo a hysterectomy and bilateral salpingectomy to remove the Essure® device.

714. An ultrasound also performed in or about October 2015 by Dr. Patricia A. Frey revealed the Plaintiff had developed a cyst on her right ovary.

715. Plaintiff underwent a hysterectomy and bilateral salpingectomy to remove the Essure® device at Houston Methodist San Jacinto Hospital in Baytown, Texas by Dr. Patricia Frey on October 23, 2015.

2. Jason Owens

716. Jason Owens is a resident of Baytown, Texas.

717. Jason Owens is married to Plaintiff Angela Owens and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

718. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

719. Plaintiff's wife began to suffer from unusual vaginal bleeding, severe abdominal pain and cramping, painful intercourse, and dizziness.

720. The couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device because his wife experienced painful intercourse.

721. Plaintiff became primarily responsible for tending to the household chores when his wife was incapacitated due to pain.

722. Additionally, Plaintiff had to care for his wife after she underwent a hysterectomy and bilateral salpingectomy to remove the Essure® device at Houston Methodist San Jacinto Hospital in Baytown, Texas by Dr. Patricia Frey on October 23, 2015.

723. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

724. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

3. <u>Tametria Nash</u>

725. Tametria Nash is a resident of Fort Worth, Texas.

726. On January 29, 2013, Plaintiff underwent the Essure® procedure at UNT Health Science Center in Fort Worth, Texas by Dr. Shanna Marie Combs.

727. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer pelvic pain, cramping and bloating, severe menstruation pain, heavy and abnormal bleeding, and painful intercourse.

728. On or about February 6, 2013, Plaintiff underwent a diagnostic hysteroscopy at Texas Health Methodist Hospital in Fort Worth, Texas by Dr. Shanna Marie Combs, during

which it was confirmed that an Essure® coil which had been placed in the Plaintiff's left fallopian tube had migrated to the endometrium.

729. On February 6, 2012, Plaintiff underwent a second Essure® procedure at Texas Health Methodist Hospital in Fort Worth, Texas by Dr. Shanna Marie Combs, wherein the Essure® coil that had migrated was removed and another was deployed in its place.

730. Plaintiff continues to experience pelvic pain, cramping and bloating, severe menstruation pain, heavy and abnormal bleeding, painful intercourse, and may have no choice but to undergo a hysterectomy in the near future to remove the Essure® device.

4. Christopher Nash

731. Christopher Nash is a resident of Fort Worth, Texas.

732. Christopher Nash is married to Plaintiff Tametria Nash and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

733. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

734. Plaintiff's wife began to experience pelvic pain, cramping and bloating, severe menstruation pain, heavy and abnormal bleeding, painful intercourse, and pain from device migration.

735. Plaintiff had to care for his wife after she underwent an Essure® implant and removal procedure, and also became primarily responsible for completing household chores when his wife was incapacitated due to pain.

736. Additionally, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device because his wife experienced painful intercourse.

737. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

5. <u>The Estate of Holly Williams</u>

738. Holly Williams, Decedent, was a resident of Joshua, Texas.

739. Decedent passed away on May 18, 2016 of a deep vein thrombosis, and is represented herein by the Estate of Holly Williams, by and through, Gregory Williams, her Personal Representative (hereinafter "Plaintiff").

740. Plaintiff, incurring medical bills, funeral expenses, and enduring the pain and suffering that follows a loved one's passing, hereby brings a survival action for the untimely death of Decedent, Holly Williams.

741. On or about June 23, 2011, Decedent Holly Williams underwent the Essure® procedure by Dr. Ralph T. Wiegman at his personal office in Grand Prairie, Texas.

742. Decedent underwent an HSG test, during which it was confirmed that Decedent's Essure® coils were properly in place and that her fallopian tubes were occluded.

743. Shortly after undergoing the Essure® procedure, Decedent began to suffer severe abdominal pain, painful intercourse, and hair loss.

744. Additionally, Decedent suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

745. On or about July 3, 2011, approximately ten (10) days after the Essure® procedure, Decedent suffered from device migration, experienced her first deep vein thrombosis, and was hospitalized for an extended period of time at University of Texas Southwestern Medical Center.

746. Decedent developed a blood clotting disorder following the Essure® procedure and continued to suffer from excessive bleeding for several months until February 29, 2012, when Decedent underwent a bilateral salpingectomy at University of Texas Southwestern Medical Center by Dr. Xercerla Littles to remove the Essure® device.

747. Decedent reviewed a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Decedent relied on Defendants' misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Decedent would not have chosen to undergo the implantation of Essure® had she not relied on Defendants' misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Decedent relied to her detriment on Defendants' misrepresentations concerning Essure®.

6. Gregory Williams

748. Plaintiff Gregory Williams is a resident of Joshua, Texas. Plaintiff Gregory Williams was married to Decedent, Holly Williams and hereby brings a wrongful death and loss of consortium cause of action as a result of his wife's Essure®-related injuries, and for her untimely death on May 18, 2016.

749. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

750. Decedent began to suffer severe abdominal pain, painful intercourse, hair loss, migraines, and developed a blood clotting disorder—for which she had no history of suffering prior to undergoing the implantation of Essure®.

751. Plaintiff became primarily responsible for caring for his wife and tending to household chores when she was incapacitated due to pain on almost a daily basis.

752. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her well-being as she recovered from a hysterectomy.

753. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

754. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

755. He has suffered damages for his mental anguish, emotional pain and suffering, loss of his wife's care, comfort, companionship, society, love, and friendship, and he continues to suffer damages.

7. Michelle Bartell

756. Michelle Bartell is a resident of Leander, Texas.

757. On or about May 8, 2009, Plaintiff Michelle Bartell underwent the Essure® procedure, at Bryan Medical Center in Lincoln, Nebraska by Dr. Nicolle Mahoney.

758. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

759. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer severe abdominal pain, irregular menstrual cycles, cramping, bloating, and hormonal changes.

760. Plaintiff also suffered from device migration and severe organ perforation.

761. On or about February 2013, Plaintiff underwent an unsuccessful surgery at Lakeshore Surgical Center in Gainesville, Georgia to remove the Essure® device and repair one of her fallopian tubes which had been perforated by the device.

762. Plaintiff's symptoms are so severe and problematic that Plaintiff is discussing with her doctor the possibility of undergoing a hysterectomy in the near future to remove the Essure® device.

8. Michael Bartell

763. Plaintiff Michael Bartell is a resident of Leander, Texas.

764. Plaintiff Michael Bartell is married to Plaintiff Michelle Bartell and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

765. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

766. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

767. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her well-being when she was incapacitated due to pain.

768. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

769. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

770. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

9. Maria Ouellette

771. Maria Ouellette is a resident of Houston, Texas.

772. In or about December 2008, Plaintiff underwent the Essure® procedure at St. Joseph Professional Building in Houston Texas by Dr. Willie Tjoa.

773. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

774. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from excessive vaginal bleeding, weight fluctuations, bloating and cramping, unusual periods, and anemia.

775. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at Methodist Hospital in Houston, Texas by Dr. Joshua Kilgore on September 7, 2017. During the surgery Dr. Joshua Kilgore discovered the Plaintiff had developed an ovarian mass.

776. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and,

based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

10. Michael Anthony

777. Michael Anthony is a resident of Houston, Texas.

778. Michael Anthony is married to Plaintiff Maria Ouellette and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

779. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

780. Plaintiff's wife began to suffer from excessive vaginal bleeding, weight fluctuations, bloating and cramping, unusual periods, and anemia.

781. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her well-being while she recuperated from a hysterectomy.

782. Additionally, after Plaintiff's wife was implanted with Essure®, he was primarily responsible for tending to all household chores.

783. Further, the couple's level of sexual intimacy sharply declined after Plaintiff's wife was implanted with the Essure® device as she suffered from pain during intercourse.

784. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

785. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

Z. UTAH

1. Cara Ramey

786. Cara Ramey is a resident of Saratoga Springs, Utah.

787. In or about October 2012, Plaintiff underwent the Essure® procedure at Arrowhead OBGYN in Glendale, Arizona by Dr. Bradley Folkestad.

788. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

789. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from pain and cramping, unusual bleeding and unusual periods.

790. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy at American Fork Hospital in American Fork, Utah by Dr. Clark Sheffield.

791. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. Bryce Ramey

792. Bryce Ramey is a resident of Saratoga Springs, Utah.

793. Bryce Ramey is married to Plaintiff Cara Ramey and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

794. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

795. Plaintiff's wife began to suffer from pain and cramping, unusual bleeding and unusual periods.

796. Plaintiff took his wife to and from doctor's appointments on several occasions, and tended to her well-being while she recuperated from a hysterectomy.

797. Additionally, after Plaintiff's wife was implanted with Essure®, he became primarily responsible for completing to all household chores, and caring for the couple's children while his wife was incapacitated due to pain.

798. As such, Plaintiff's relationship with his wife was adversely affected after she underwent the Essure® procedure.

799. He has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

AA. VIRGINIA

1. Yolanda Lambert

800. Yolanda Lambert is a resident of Bristol, Virginia.

801. On or about January 7, 2006, Plaintiff underwent the Essure® procedure at Inova Fairfax Hospital in Falls Church, Virginia with Dr. Regina Burton.

802. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

803. Shortly after undergoing the Essure® procedure, Plaintiff began experiencing irregular and prolonged menstruation, severe menstrual pain, cramping and bloating, painful intercourse, and severe back pain.

804. Additionally, Plaintiff has suffered tissue scarring and abdominal pain due to device migration.

805. Plaintiff recalls meeting with a team from Bayer on the day of her Essure® procedure, who described minimal risks associated with device implantation, such as diminished menstrual cycles, weight gain, and depression. Plaintiff would not have undergone the procedure had she known the true risks.

806. Plaintiff's physicians have recommended and Plaintiff will undergo a hysterectomy in the near future to remove the Essure® device.

2. <u>Kristin Purdy</u>

807. Kristin Purdy is a resident of Manassas, Virginia.

808. On or about January 2012, Plaintiff underwent the Essure® procedure at OB/GYN Consultants of Fairfax with Dr. Rutland in Fairfax, Virginia.

809. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

810. Shortly after undergoing the Essure® procedure, Plaintiff began experiencing irregular and prolonged menstruation, severe menstrual pain, cramping and bloating, and device migration.

811. Since undergoing the Essure® procedure, Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

812. Additionally, the Plaintiff has experienced one miscarriage and one full term pregnancy post Essure® implantation.

813. Plaintiff has experienced the turmoil and unexpected financial hardship that accompanies a miscarriage and a full-term pregnancy.

814. Plaintiff underwent a CT scan in late 2017 that determined that the device migrated to under her bowel.

815. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff may have to undergo a hysterectomy to remove the Essure® device. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. <u>Jessie Purdy</u>

816. Jessie Purdy is a resident of Manassas, Virginia.

817. Jessie Purdy is married to Plaintiff Kristin Purdy and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

818. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

819. Plaintiff's wife experienced irregular and prolonged menstruation, severe menstrual pain, cramping and bloating, and device migration.

820. Additionally, since undergoing the Essure® procedure, Plaintiff's wife has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

821. Plaintiff experiences the turmoil and unexpected financial hardship that accompanies a miscarriage and a full-term pregnancy.

822. The migrating of the Essure® device and subsequent second unintended pregnancy caused Plaintiff to undergo a vasectomy.

823. Plaintiff has had to tend to the majority of household chores, cleaning, cooking and tending to the couple's children.

824. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

4. <u>Brianne Meadows</u>

825. Brianne Meadows is a resident of Chesapeake, Virginia.

826. On or about March 23, 2012, Plaintiff underwent the Essure® procedure at Monarch Women's Wellness in Chesapeake, Virginia by Dr. Rachel D. Lee.

827. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

828. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer unusual and excessive, bleeding, pain and cramping, unusual periods, and painful intercourse.

829. Additionally, Plaintiff developed a Nabothian cyst and was diagnosed with chronic cervicitis.

830. Plaintiff's symptoms became so problematic that on or about October 16, 2012, Plaintiff underwent a hysterectomy at Monarch Women's Wellness, PC in Chesapeake, Virginia, by Dr. Rebecca B. Thibodeau.

831. Plaintiff recalls reviewing a brochure and video for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

5. <u>Ian Meadows</u>

832. Ian Meadows is a resident of Chesapeake, Virginia.

833. Ian Meadows is married to Plaintiff Brianne Meadows and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

834. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

835. Plaintiff's wife began to suffer from unusual and excessive, bleeding, pain and cramping, unusual periods, painful intercourse, chronic cervicitis, and cysts.

836. Plaintiff had to care for his wife after she underwent a hysterectomy at Monarch Women's Wellness, PC in Chesapeake, Virginia, by Dr. Rebecca B. Thibodeau on or about October 16, 2012.

837. Further, Plaintiff became primarily responsible for performing the majority of household chores when his wife was incapacitated due to pain.

838. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

BB. WASHINGTON

1. Sharon Harris

839. Sharon Harris is a resident of Federal Way, Washington.

840. On or about August 25, 2014, Plaintiff was implanted with an Essure® device at MultiCare Auburn Medical Center in Auburn, Washington.

841. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from intense abdominal pain, later revealed to be caused by device migration.

842. On or about December 12, 2016, a histopathology report showed an Essure® coil had migrated, and was protruding from Plaintiff's uterus.

843. Dr. Yao and Dr. Elizabeth K. Boswell at Tacoma General Hospital in Tacoma, Washington have recommended, and Plaintiff will undergo a hysterectomy in the near future to remove the Essure® device.

2. Melanie Mesker

844. Melanie Mesker is a resident of Maple Valley, Washington.

845. In or around November 2011, Plaintiff was implanted with Essure® at MultiCare Women's Healthcare in Covington, Washington with Dr. Catherine Hunter.

846. Shortly after Essure® implantation, Plaintiff began to suffer from extreme fatigue, brain fog, decreased vision, chemical sensitivity, heavy menstrual bleeding, abdominal pain, bloating, depression, and painful intercourse.

847. Plaintiff's symptoms were so severe that she underwent a total hysterectomy to remove the Essure® device in or around October 2016 at Valley Medical Center in Renton, Washington by Dr. Mandeep Kingra.

848. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

3. Brittney Bird

849. Brittney Bird is a resident of Kelso, Washington.

850. On or about October 30, 2015, Plaintiff was implanted with Essure® at the Office of Dr. Adam V. Levy in Las Vegas, Nevada, by Dr. Adam V. Levy.

851. Shortly after Essure® implantation, Plaintiff began to suffer from heavy and frequent menstrual bleeding, large blood clots, severe abdominal pain and cramping, back pain, bloating, painful intercourse, frequent and severe urinary tract infections, hair loss, mood swings and forgetfulness.

852. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

853. Plaintiff's symptoms are so severe that she has discussed with her physician undergoing a total hysterectomy to remove the Essure® device.

854. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

CC. WEST VIRGINIA

1. Amy Bruce

855. Amy Bruce is a resident of Charleston, West Virginia.

856. In or about May 2014, Plaintiff underwent the Essure® procedure at Thomas Memorial Hospital in South Charleston, West Virginia by Dr. Kimberly Bush.

857. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

858. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer from severe pain and cramping, and fatigue.

859. Additionally, since undergoing the Essure® procedure Plaintiff has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

860. Plaintiff's symptoms became so severe and problematic that she underwent a partial hysterectomy to remove the Essure® device at Thomas Memorial Hospital in South Charleston, West Virginia by Dr. Kimberly Bush in or about May 2016.

861. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

2. <u>Ivan Bruce</u>

862. Ivan Bruce is a resident of Charleston, West Virginia.

863. Ivan Bruce is married to Plaintiff Amy Bruce and has suffered a loss of consortium as a result of his wife's Essure®-related injuries.

864. Shortly after Plaintiff's wife was implanted with Essure®, Plaintiff noticed a change in his wife's demeanor as she was no longer as happy and energetic as she once was prior to undergoing the implantation of Essure®.

865. Plaintiff's wife began to suffer from severe pain and cramping, and fatigue.

866. Additionally, since undergoing the Essure® procedure, Plaintiff's wife has suffered from severe migraines—for which she had no history of suffering prior to undergoing the implantation of Essure®.

867. Plaintiff had to care for his wife after she underwent a partial hysterectomy to remove the Essure® device at Thomas Memorial Hospital in South Charleston, West Virginia by Dr. Kimberly Bush in or about May 2016.

868. Plaintiff became primarily responsible for the majority of household chores, cleaning, cooking, and tending to the couple's children when his wife was incapacitated due to pain.

869. Plaintiff has suffered damages for the loss of his wife's care, comfort, society, love, and friendship, and he continues to suffer damages.

DD. WISCONSIN

1. Abby Noyes

870. Abby Noyes is a resident of Milwaukee, Wisconsin.

871. On or about November 12, 2012, Plaintiff underwent the Essure® procedure at University Community Hospital in Tampa, Florida by Dr. Barreiro.

872. Plaintiff underwent an HSG test, during which it was confirmed that Plaintiff's Essure® coils were properly in place and that her fallopian tubes were occluded.

873. Shortly after undergoing the Essure® procedure, Plaintiff began to suffer excessive vaginal bleeding, prolonged menstruation, unusual periods, severe and constant abdominal pain, and cramping.

874. Plaintiff's symptoms became so severe and problematic that she underwent a hysterectomy to remove the Essure® device at St. Joseph's Hospital in Tampa, Texas by Dr. Barreiro on or about October 24, 2013.

875. Plaintiff recalls reviewing a brochure for Essure® that promoted the device as a safe and effective form of permanent birth control. Plaintiff relied on Defendant's misrepresentations in the Essure® brochure as to the safety and effectiveness of Essure® and, based thereon, decided to undergo the implantation of Essure®. Plaintiff would not have chosen to undergo the implantation of Essure® had she not relied on Defendant's misrepresentations as to the safety and effectiveness of Essure® as a permanent birth control device. Plaintiff relied to her detriment on Defendant's misrepresentations concerning Essure®.

XI.

FRAUDULENT CONCEALMENT/DISCOVERY RULE/EQUITABLE TOLLING/EQUITABLE ESTOPPEL

A. SUMMARY OF ACTIVE CONCEALMENT

876. Defendant's fraudulent acts and/or omissions prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injuries or causes thereof as alleged in this complaint until February 29, 2016.

877. Defendant's failure to report, document, or follow up on the known adverse event complaints, and concealment and altering of adverse events, serious increased risks, dangers, and complications, constitutes fraudulent concealment that tolls Plaintiffs' statutes of limitations.

878. Defendant also is estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure®, actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure®, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiffs. As a result of Defendant's concealment of the true character, quality, history, and nature of their product, it is estopped from relying on any statute of limitations defense.

879. Defendant furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in Essure® and/or arising out of the use of Essure® and a continued and intentional, systematic failure to disclose and/or conceal such information from/to Plaintiffs, Plaintiffs' physicians, and the FDA.

880. In short, Defendant:

a. Actively and intentionally concealed from Plaintiffs that their physicians were not trained pursuant to FDA-approved training.

b. Actively and intentionally concealed the defects and adverse events, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure®, and failed to disclose known dangerous defects and serious increased risks and complications to the FDA, physicians and Plaintiffs.

c. Actively and intentionally concealed from Plaintiffs and Plaintiffs' physicians' risks by making the misrepresentations/warranties discussed

herein knowing they were false. In short, Defendant knew the misrepresentations were false because they had studies and reports which showed the opposite, yet altered and concealed the same from Plaintiffs, the FDA and Plaintiffs' physicians. Defendant made the misrepresentations with the intent of misleading Plaintiffs into relying on them because they had studies and reports which showed the opposite, yet decided to conceal the same (collectively "the acts and omissions").

881. If Defendant had met their duties under the applicable federal and parallel state laws, the FDA would have had the information necessary to warn the public, including Plaintiffs and Plaintiffs' physicians, of the increased risks and serious dangers associated with Essure® in time to have lessened or prevented Plaintiffs' injuries, which is evidenced by the fact that the FDA is now mandating a new clinical trial, a "black box" warning, and a "patient decision checklist" which discusses and warns in detail about the risks of the very same injuries Plaintiffs suffered. Had Defendant satisfied their obligations, these FDA mandates would have been implemented prior to Plaintiffs' implantations. However, Defendant continued to misrepresent the safety and efficacy of Essure® at the FDA Hearings.

882. In short, Defendant manipulated their reports to the FDA and presented false and misleading information, which, in turn, resulted in Plaintiffs' consent to implant not being informed because critical facts regarding the nature and quality of side effects from Essure® were concealed from Plaintiffs and their physicians.

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

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

B. FDA CALLS ESSURE® MEETING

885. The FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and plan recommendations for Essure®.

886. On February 29, 2016, the FDA first announced that it will force a major change to the Essure® warning label and also require all women considering receiving Essure®, to fill out a "Patient Decision Checklist" to ensure that they are fully informed of the true risks.[3]

887. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.[4].

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

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

890. Finally, women considering Essure® will have the chance to be fully informed of its true risks.

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

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

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3 *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm.

4 *Id.*

893. The checklist specifically warns of device migration, perforation of organs, and new side effects that Defendant had been cited for hiding from the FDA, Plaintiffs, and Plaintiffs' physicians and/or enhances prior inadequate warnings.

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

895. The checklist has a major impact on the risk/benefit profile of the device, and Plaintiffs would not have had the device implanted if they were aware of the true risks of Essure®.

896. On February 29, 2016, the FDA also announced that it would require a detailed boxed warning for the Essure® device. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events. Boxed warnings indicate the highest level of risk.

897. The FDA suggested the following warning:

> **WARNING: Some patients implanted with the Essure® System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure® device during discussion of the benefits and risks of the device.**[5]

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

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

C. DISCOVERY RULE – TOLLING

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

900. Plaintiffs did not possess the sufficient critical facts to put them on notice that the wrongs and the acts and omissions discussed herein had been committed until such date. This is because it was not until the FDA hearing that Essure®'s safety and Defendant's acts and omissions were publicly called into question by the FDA and the medical community and the FDA required the "black box warning," "patient decision checklist," and "new clinical trials."

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

902. Plaintiffs did not have the opportunity to discover the harm inflicted because Defendant was and are continuing to conceal the acts and omissions noted above.

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

904. Regardless of the exercise of reasonable diligence, Plaintiffs did not know, or reasonably should not have known, that they suffered injuries and that their injuries were caused by Defendant's conduct until February 29, 2016.

905. Plaintiffs neither suspected nor knew of Defendant's wrongdoings as alleged herein until February 29, 2016.

906. In sum, Plaintiffs were reasonably unaware, and had no reasonable way of knowing, that their injuries described above were caused by Defendant's conduct until February 29, 2016.

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

D. FRAUDULENT CONCEALMENT – EQUITABLE TOLLING

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

909. These acts and omissions misled Plaintiffs in regard to their causes of action and prevented them from asserting such rights because the facts which would support their causes of action as alleged in this amended complaint were not apparent to a reasonably prudent person until February 29, 2016.

910. Defendant also prevented Plaintiffs from asserting their rights by committing affirmative independent acts of concealment as noted above upon which Plaintiffs relied.

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

912. As such, Plaintiffs' statutes of limitations were tolled in light of Defendant's fraudulent concealment and their statutes began to run starting from the date that facts supporting

their causes of action in this amended complaint became apparent, which was on or after February 29, 2016.

913. Defendant's misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs and their physicians of vital information essential to the pursuit of the claims in this amended complaint, without any fault or lack of diligence on their part. Plaintiffs relied on Defendant's misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable, prudent person to make an inquiry to discover Defendant's tortious conduct.

E. EQUITABLE ESTOPPEL

914. In the alternative, Defendant is estopped and may not invoke the statute of limitations as a defense because, through the fraud or concealment noted above, specifically the acts and omissions, Defendant caused Plaintiffs to relax their vigilance and/or deviate from their right of inquiry into the facts as alleged in this amended complaint.

915. Defendant affirmatively induced Plaintiffs to delay bringing this amended complaint by and through its acts and omissions.

916. In addition to the acts and omissions noted above, Defendant consistently represented to Plaintiffs and/or Plaintiffs' physicians that Essure® was not the cause of any of Plaintiffs' injuries to delay their bringing a claim against Defendant.

917. Defendant is and was under a continuing duty to monitor and disclose the true character, quality, and nature of Essure®. Because of Defendant's misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendant is estopped from relying on any statute of limitations defense.

XII.

FACTS AND WARRANTIES

918. Defendant failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians on how to use Essure® and the necessary hysteroscopic equipment.

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

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

921. Defendant failed to abide by FDA approved training guidelines when training Plaintiffs' implanting physicians and provided hysteroscopic equipment to the implanting physicians who were not qualified to use such complicated equipment.

922. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, but not for successful placement, pain, and complication rates, evidencing that Defendant's training methods were failing[6].

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

923. Defendant provided hysteroscopic equipment to the implanting physicians who were not competent to use such equipment. Defendant knew the implanting physicians were not competent to use such sophisticated equipment, yet provided the equipment regardless in order to sell its product.

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

925. Defendant's distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and federal law; (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 perforations which occurred as a result of Essure®; (4) erroneously using non-conforming material in the manufacturing of Essure® and failing to keep track of the non-conforming material; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure® at an unlicensed facility and (7) manufacturing Essure® for three (3) years without a license to do so.

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

XIII.

COUNTS

A. NEGLIGENT TRAINING – COUNT I

927. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

928. First, Defendant undertook an independent duty to train physicians on how to properly use Essure® and place the micro-inserts which failed to abide by FDA training guidelines.

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

930. As part of Defendant's training, Defendant had a duty to abide by the FDA training guidelines for the implanting physicians on how to place Essure® using its own delivery system, certify the implanting physicians, and oversee this particular procedure. Defendant also had a duty to disclose adverse events to the physicians so that they, in turn, could properly advise their patients of the actual risks.

931. Specifically, pursuant to the FDA approved training regulations and guidelines, Defendant had a duty to comply with the following federal requirements so that implanting physicians performed "competent procedures" and would be able to "manage possible technical issues":

(a) Ensure that the implanting physicians completed the required preceptoring (generally five [5] cases) in Essure® placement until competency;

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

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

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

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

(b) Ensure that the implanting physicians were appropriately counseling Plaintiffs on the known risks; and

(c) Ensure the implanting physicians were qualified and competent to perform the Essure® procedure to ensure proper placement to preclude migration, perforation and fracturing of coils.

933. Defendant breached this duty and parallel state laws, thereby departing from the FDA approved guidelines by:

(a) Not ensuring that the implanting physicians completed the required preceptoring in Essure® placement until competency. The implanting physicians did not complete the required preceptoring until competency;

(b) Not ensuring that the implanting physicians had read and understood the Physician Training Manual. The Implanting Physicians did not understand the Physician Training Manual.

(c) Not ensuring that the implanting physicians had "successful completion of Essure® Simulator Training". The implanting physicians did not successfully complete the Essure® Simulator Training.

934. This departure from the training guidelines caused the Essure® coils to migrate/fracture and/or perforate organs because:

(a) The Essure® Training Program ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(b) The required preceptoring ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above;

(c) The requirement to read and understand the Physician Training Manual ensured proper placement and without it, the Implanting Physicians' technique caused the coils to migrate, perforate, fracture, and/or cause other injury, producing the damages noted above.

936. This breach caused Plaintiffs' damages as noted above.

937. As a result of Defendant's negligence individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

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

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

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

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

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

B. NEGLIGENCE – RISK MANAGEMENT – COUNT II

942. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

943. In short, Defendant had a duty, under both state and federal law, to have in place a reasonable risk management procedure to ensure that, *inter alia*, (1) adverse events were being reported to the FDA so that it could be relayed to the implanting physicians and/or Plaintiffs; (2) adverse reports were considered in its risk analysis and that the risk analysis was updated to reflect the same so that it could be relayed to the implanting physicians and/or Plaintiffs; (3) Defendant investigated information about the risks Essure® posed so that it could be relayed to the implanting physicians and/or Plaintiffs; (4) the continued sale of Essure® was appropriate and reasonable despite information being withheld from the public by Defendant; (5) Defendant monitored the product after pre-market approval to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.; (6) Defendant had internal procedures for reviewing complaints and event reports, 21 CFR §§ 820.198, §§ 820.100 et seq., and §§ 820.20 et seq.; and (7) Defendant maintained the labeling of Essure® by filing a "Special PMA Supplement – Changes Being Effected" ("CBE") which

allowed Defendant to unilaterally update the labeling of Essure® to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d).

944. Specifically, Defendant had a duty to comply with the following federal regulations, but breached its duties promulgated by these regulations by the subsequent violations noted directly below (which Defendant was cited for by the FDA):

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

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians. This failure to disclose and include the information in their risk management analysis was a a breach of a condition of approval in its CPMA.)

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

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose

coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(c) 21 C.F.R. 803.10 – (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us. (2) Submit annual reports (described in 803.33) to us. (b) If you are an importer, you must submit reports (described in subpart D of this part), as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event: (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or (ii) Submit reports of device-related malfunctions to the manufacturer. (2) [Reserved]. (c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows: (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction. (2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of: (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or (ii) A reportable event for which we made a written request. (3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(d) 21 C.F.R. 803.50(a) – (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a

death or serious injury, if the malfunction were to recur. (b) What information does FDA consider "reasonably known" to me? (1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you: (i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter; (ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device. (2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

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

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(f) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device, which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven-digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation “C” or “R”. For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven-digit registration number will be assigned a seven-digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4)

Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c) (13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not

necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(g) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

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

(Defendant breached this federal standard by failing to establish and maintain procedures for identification of each Essure® unit which in turn precluded proper corrective actions and led to the failure to disclose and include in their risk management analysis thousands of adverse events and complaints for migrations, perforations, pregnancies, and device failures and malfunctions, which in turn were never disclosed to Plaintiffs and Implanting Physicians. This failure to disclose and include in their risk management analysis was a condition of approval in its CPMA).

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

(Defendant was cited for and breached this federal standard by failing to comply with post-market surveillance plans. Specifically, by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians. Defendant further breached this federal standard by not withdrawing its product from the market.)

(j) 21 C.F.R. 820.180 – All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those notes stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(k) 21 C.F.R. 820.198 – (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated,

and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

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

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

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

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

(n) Monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

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

(Defendant was cited for and breached this federal standard by failing to disclose, consider, and include in their risk management plans thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, and the safety of loose coils, which in turn were never disclosed to Plaintiffs and Implanting Physicians.)

945. Due to these breaches, Defendant was cited by the FDA as Defendant "did not consider these complaints in their risk analysis" and "for their risk analysis of Essure® being incomplete".

946. This was an unreasonably dangerous and negligent risk analysis plan which was required by federal law as it put Plaintiffs at unnecessary risk of injury due to Defendant's failure to report adverse reports to the FDA, to track non-conforming product, update its labeling of Essure®, and to consider adverse reports in its risk analysis.

947. This breach caused Plaintiffs' damages because but for Defendant's failure to comply with federal law and disclose, consider, and include in their risk management plans and/or labeling the thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions, Plaintiffs would not have been implanted with Essure® and therefore would also not have been injured by Essure®. Instead, Defendant failed to have a complete Risk Management Plan in place, thereby precluding Plaintiffs and their implanting physicians from knowing of the thousands of migrations, perforations, pregnancies, device failures and malfunctions. This was actively concealed by Defendant.

948. This breach caused Plaintiffs' injuries and damages noted above.

949. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

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

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

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

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

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

C. BREACH OF EXPRESS WARRANTY – COUNT III

954. Plaintiffs re-allege and re-incorporate the preceding paragraphs and plead in the alternative to Counts IV.

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

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

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

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

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

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

b. However, this warranty was false as there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiffs. "There were Zero pregnancies in the clinical trials."

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

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

   iii. However, this warranty was false as there were actually four pregnancies during the clinical trials and five (5) pregnancies during the first year of commercial experience. Defendant concealed this information from Plaintiffs.

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

c. "Physicians must be signed-off to perform Essure® procedures"

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

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

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

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

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

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

vii. However, this warranty was false as several pregnancies have been reported subsequent to confirmation. Defendant concealed this information from Plaintiffs. Between 1997 and 2005, sixty-four (64) pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three (3) month Confirmation Test was performed. Defendant concealed this information from Plaintiffs. There have been over thirty (30) pregnancies after "doctors confirmed the tubes were blocked." Women who have Essure® have a ten (10) times greater risk of pregnancy after one year than those who use laparoscopic

sterilization. At ten (10) years, the risk of pregnancy is almost four (4) times greater.[8] Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."

d. "Essure® is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy."

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

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

iii. However, this warranty was false as Defendant's SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendant. Defendant stated, "We did not conduct a clinical trial to compare the Essure® procedure to laparoscopic tubal ligation." Defendant concealed this information from Plaintiffs. In fact, women who have Essure® have a ten (10) times greater risk of pregnancy after one (1) year than those who use laparoscopic sterilization. At ten (10) years, the risk of pregnancy is almost four (4) times greater[9].

e. "Correct placement…is performed easily because of the design of the micro-insert."

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

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

9 *Id.*

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

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

f. "Essure® is a surgery-free permanent birth control."

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

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

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

g. "Zero pregnancies" in its clinical or pivotal trials.

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

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

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

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

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

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

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

h. You will never have to worry about unplanned pregnancy again.

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

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

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

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

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

on an advertisement entitled "When your family is complete, choose Essure®." The circumstances under which Plaintiffs encountered this representation were via a brochure when they were researching options of birth control.

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

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

j. "Worry free."

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

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

iii. However, Defendant actively concealed and failed to report eight (8) perforations which occurred as a result of Essure® to the FDA as evidenced in a Form 483 issued by the FDA to Defendant. Defendant actively concealed this from Plaintiffs. Defendant was issued another Form 483 when it "erroneously used non-conforming material". Defendant actively concealed this and was issued an additional Form 483 for "failing to adequately document the situation." Defendant actively concealed this from Plaintiffs. Defendant's facility was also issued a notice of violation as it "no longer uses pre-sterile and post-sterile cages". Defendant actively concealed this from Plaintiffs. Defendant also was issued a notice of violation when they "failed to obtain a valid license…prior to manufacturing medical devices". Defendant was manufacturing devices for three years without a license. Defendant actively

concealed this from Plaintiffs. Defendant was also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. Defendant actively concealed this from Plaintiffs. Defendant failed to notice the FDA of their internal excel file containing 16,047 entries of complaints. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%". Defendant was issued Form 483s for not disclosing MDRs 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.

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

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

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

iii. However, this warranty was false as the micro-inserts do not remain secure but migrate and are expelled by the body. Defendant actively concealed this information from Plaintiffs. Defendant actively concealed and failed to report eight (8) perforations which occurred as a result of Essure® to the FDA as evidenced in a Form 483 issued to Defendant by the FDA. Defendant was issued Form 483s for not disclosing MDRs 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.

l. "The Essure® inserts are made from the same trusted, silicone free material used in heart stents."

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

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

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

m. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

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

encountered this representation were via a brochure when they were researching options of birth control.

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

iii. However, this warranty was false as Defendant also stated that it is only after "The Confirmation" test that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was performed. Between 1997 and 2005, sixty-four (64) pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. There have been over thirty (30) pregnancies after "doctors confirmed the tubes were blocked". There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test.[10]

n. "Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures."

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

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure® is not "surgery-free"; rather, surgery is not required. Defendant's SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described by Defendant as "painful and is also known to be highly inaccurate, with false-positive results in as many as 40%".

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o. Essure® is a …permanent birth control procedure-without … the risks of getting your tubes tied.

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

ii. This warranty created the basis of the bargain as Plaintiffs read and saw the warranty and wanted a reliable type of birth control that eliminated the risks and discomfort associated with other types of birth control.

iii. However, this warranty was false as Essure® does not eliminate the risks associated with other surgeries, such as tubal ligation, but actually includes more risks which were not known to Plaintiffs.

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

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

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

iii. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, Defendant refers to Essure® and classify it as a "drug."

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

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

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

iii. However, this warranty was false because Essure® does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendant concealed this information from Plaintiffs. Defendant actively concealed and failed to report 8 perforations which occurred as a result of Essure® to the FDA as evidenced in a Form 483. Defendant was issued Form 483s for not disclosing MDRs 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.

r. "There was no cutting, no pain, no scars…"

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

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

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

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

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

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

961. As a result of Defendant's warranties and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure® device did not perform as warranted and instead migrated, perforated, broke, and/or caused other injuries noted above.

962. As a result of Defendant's breaches individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

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

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

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

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

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

D. NEGLIGENT MISREPRESENTATION – COUNT IV

967. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

968. Defendant made the following misrepresentations:

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

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

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

iii. However, this warranty was false as Defendant "signed off" on "Essure® physicians" who did not perform the procedure every six (6) to eight (8) weeks, including the implanting physicians. Defendant concealed this information from Plaintiffs.

b. Step Two: "pregnancy cannot occur"; Step Three: The Confirmation.

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

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

iii. However, this warranty was false as Defendant also state that it is only after "The Confirmation" that pregnancy cannot occur, i.e., the complete opposite of what is warranted in the brochure. Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed. Between 1997 and 2005, sixty-four (64) pregnancies were reported to Defendant. Defendant concealed this information from Plaintiffs. There have been over thirty (30) pregnancies after "doctors confirmed the tubes were blocked." There have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test[11].

iv. This representation was via a brochure when they were researching options of birth control.

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

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vi. However, this warranty was false as the inserts are not made of safe, trusted material as they migrate, corrode, break, cause injuries, and contain drugs. In fact, Defendant refers to Essure® and classifies it as a "drug."

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

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

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

iii. However, this warranty was false as Essure® does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. Defendant concealed this information from Plaintiffs. Defendant actively concealed and failed to report eight (8) perforations which occurred as a result of Essure® to the FDA as evidenced in Form 483. Defendant was issued Form 483s for not disclosing MDRs 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.

d. "There was no cutting, no pain, no scars…"

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

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

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

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

969. Plaintiffs justifiably relied on the misrepresentations. Specifically, Plaintiffs would have never had Essure® implanted had they been aware of the falsity of the representations specifically delineated in the preceding paragraphs which violate both federal law and the CPMA.

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

971. As a result of Defendant's misrepresentations and Plaintiffs' reliance on same, Plaintiffs have suffered damages. Specifically, the Essure® device did not perform as represented and instead migrated, perforated, broke and/or caused other injuries, all to Plaintiffs' damage.

972. As a result of Defendant's negligence individually, jointly, and severally, Plaintiffs sustained the injuries and damages noted above.

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

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

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

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

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

E. NEGLIGENCE – FAILURE TO WARN – COUNT V

977. Plaintiffs re-allege and re-incorporate the preceding paragraphs.

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

979. Defendant had a duty to warn Plaintiffs and/or their implanting physicians consistent with federal law and its CMPA which included:

(a) 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

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

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

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

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

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

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

(g) 21 C.F.R. 803.53 – You must submit a five (5) day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than five (5) work

days after the day that you become aware that: (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or (b) We have made a written request for the submission of a five (5) day report. If you receive such a written request from us, you must submit, without further requests, a five (5) day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

(h) 21 C.F.R. 806.10 – (a) Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated: (1) To reduce a risk to health posed by the device; or (2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b). (b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within ten (10) working days of initiating such correction or removal. (c) The manufacturer or importer shall include the following information in the report: (1) The seven (7) digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation “C” or “R”. For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven-digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven (7) digit registration number will be assigned a seven (7) digit central file number by the district office reviewing the reports. (2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible

for conducting the device correction or removal. (3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device. (4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a pre-amendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA. (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number. (6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report. (7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken. (8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers. (9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal. (10) The date of manufacture or distribution and the device's expiration date or expected life. (11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee. (12) A copy of all communications regarding the correction or removal and the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section. (13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted. (d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within ten (10) working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available. (e) A report submitted by a manufacturer or importer under this section (and any release by

FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury. (f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter. [62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013].

(i) 21 C.F.R. 814.84 – (a) The holder of an approved PMA shall comply with the requirements of part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device. (b) Unless FDA specifies otherwise, any periodic report shall: (1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b). (2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA: (i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant. (ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted. (3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter. (4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

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

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

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

(m) 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are

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

(n) 21 C.F.R. 820.90 – (a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented. (b) *Nonconformity review and disposition.* (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications.

Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

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

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

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

separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used; (4) The name, address, and phone number of the complainant; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action taken; and (8) Any reply to the complainant. (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment. (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor.

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

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

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

(u) 21 U.S.C. 352 (q) (r) – Restricted devices using false or misleading advertising or used in violation of regulations. In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

(v) FDA requirement in CPMA order – "Within ten (10) days after [Defendant] receives knowledge of any adverse reaction to report the matter to the FDA."

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

(x) FDA requirement in CPMA order – Report Due Dates – six month, one year, eighteenth month, and two (2) year reports.

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

(z) FDA requirement in CPMA order – Warranties are truthful, accurate, and not misleading…Warranties are consistent with applicable federal and state law.

980. Defendant breached these duties by not complying with the CPMA or federal law:

(a) Defendant failed to timely provide the FDA with reports after twelve (12) months, eighteen (18) months and then a final report for one (1) schedule. Defendant also failed to timely submit post approval reports for its six (6) month, one (1) year, eighteenth (18th) month and two (2) year reports. All reports failed to meet the respective deadlines.

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

(c) Defendant failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant failed to report eight (8) perforations which occurred as a result of Essure® and was cited for the same by the FDA via Form 483.

(d) Defendant failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendant failed to report eight (8) perforations as adverse events which occurred as a result of Essure® to the FDA as evidenced in Form 483.

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

(f) Defendant excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendant had violated the FDCA.

(g) Erroneously using non-conforming material in the manufacturing of Essure®.

(h) Failing to use pre-sterile and post-sterile cages.

(i) Manufacturing Essure® at an unlicensed facility.

(j) Manufacturing Essure® for three (3) years without a license to do so.

(k) Not reporting … complaints in which their product migrated.

(l) Not considering these complaints in their risk analysis for the design of Essure®.

(m) Failing to document CAPA activities for a supplier corrective action.

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

(o) Defendant had notice of one hundred and sixty-eight (168) perforations but only disclosed twenty-two (22) to the FDA.

(p) On January 6, 2011, Defendant was cited for their risk analysis of Essure® being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure® did not include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

(q) On January 6, 2011, Defendant was cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendant's Design. The FDA also found that Defendant's CAPA did not mention the non-conformity of materials used in Essure® or certain detachment failures. The FDA found that Defendant's engineers learned of this and it was not documented.

(r) On July 7, 2003, Defendant was 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).

(s) On July 7, 2003, Defendant was cited for not following procedures used to control products which did not confirm to specifications.

(t) Defendant failed to disclose to Plaintiffs and their implanting physicians the fact that Defendant's altered medical records to reflect less pain then was being reported during the clinical studies for Essure® and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.

981. Had Defendant disclosed such information as was required by the CPMA and federal law to Plaintiffs or the Implanting Physicians, Plaintiffs would never have had Essure® implanted and would have avoided their injuries.

982. At all times referenced herein, Defendant and each of them were acting as agents and employees of each of the other Defendant 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.

983. As a result of Defendant's negligence, individually, jointly, and severally, Plaintiffs sustained the injuries noted above.

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

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

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

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

WHEREFORE, for the above reasons, Plaintiffs demand judgment in their favor and against Defendant for an amount in excess of $75,000.00 each, including compensatory

damages, punitive damages, incidental expenses, consequential damages, including pain and suffering which was a foreseeable consequential damage, delayed damages, attorney's fees and costs of suit in an amount to be determined upon the trial of this matter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;

2. Past and future economic and special damages according to proof at trial;

3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Equitable relief as the Court deems just and proper;

6. Declaratory judgment that Defendant is liable to Plaintiffs for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendant's wrongdoing;

7. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

8. Punitive or exemplary damages according to proof at the time of trial;

9. Costs of suit incurred herein;

10. Pre-judgment interest as provided by law; and

11. Such other and further relief as the Court may deem just and proper.

Dated: January 8, 2018 By: */s/ C. Moze Cowper*

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JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: January 8, 2018 By: */s/ C. Moze Cowper*

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