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Attorneys for Defendants and Specially Appearing Defendants Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc. and Bayer HealthCare Pharmaceuticals Inc.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

COORDINATION PROCEEDING SPECIAL TITLE [Rule 3.550], ESSURE PRODUCTS CASES	JCCP No. 4887 ASSIGNED FOR ALL PURPOSES TO: Judge Winifred Y. Smith, Dept. 21
THIS DOCUMENT RELATES TO: *Martinez et al. v. Bayer Corp. et al*, Los Angeles Superior Court, Case No. BC662859 (regarding Plaintiff Valerie George only)	**DECLARATION OF ALYCIA A. DEGEN IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, OR, IN THE ALTERNATIVE, FOR SUMMARY ADJUDICATION (VALERIE GEORGE)** [Filed concurrently with: Notice of Motion and Motion; Memorandum of Points and Authorities; Separate Statement of Undisputed Facts; Declaration of Alicia Lowery; Request for Judicial Notice] Reservation ID: R-2137240

Date: January 15, 2020
Time: 9:00 a.m.
Place: Administrative Building
1221 Oak Street, Dept. 21
Oakland, California 94612
Judge: Winifred Y. Smith

DECLARATION OF ALYCIA A. DEGEN

I, Alycia A. Degen, hereby declare as follows:

I am an attorney licensed to practice law in all the courts of the State of California. I am a partner with the law firm of Sidley Austin LLP, counsel of record for defendants and specially appearing defendants Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals Inc., and Bayer Essure Inc. (collectively, "Bayer") in these coordinated proceedings, JCCP No. 4887, including the case listed in the caption to this declaration. This declaration is submitted in support of Defendants' Motion for Summary Judgment or, in the Alternative, Summary Adjudication (Valerie George). The facts set forth in this declaration are within my personal knowledge. If called as a witness, I could and would competently testify as follows.

1. Attached hereto as **Exhibit 124** is a true and correct copy of Plaintiff Valerie George's Short Form Complaint, served via Case Anywhere on April 9, 2019.

2. Attached hereto as **Exhibit 125** is a true and correct copy of the Master Complaint filed in this JCCP as Exhibit A to CMO No. 10 on August 28, 2018.

3. Attached hereto as **Exhibit 126** is a true and correct copy of this Court's Order (1) Overruling Demurrer to Affirmative Defenses in Answer, (2) Granting In Part Motion on Choice of Law, and (3) Addressing Case Management, filed in this JCCP on May 20, 2019.

4. Attached hereto as **Exhibit 127** is a true and correct copy of the Court's Order (1) Sustaining Without Leave to Amend Demurrer to Claim For Negligent Risk Management in Short Form Complaint of Katie Elder (2) Sustaining Without Leave to Amend Demurrer to Claim for Direct Failure to Warn in Short Form Complaint of Summer Frost and (3) Granting Motion to Strike Allegations In Complaints in *Elder v. Bayer Corp.*, Case No. RIC1717556 (Riverside Super. Ct.) and *Frost v. Bayer Corp.*, Case No. CIVDS1716459 (San Bernardino Super Ct.), filed in this JCCP on October 2, 2019.

5. Attached hereto as **Exhibit 128** is a true and correct copy of the Court's Order on Preemption Demurrer, filed on August 2, 2016 in the following included actions: *Lance v. Bayer Corp. et al.*, Case No. RG16809860, *Migliaccio v. Bayer Corp. et al.*, Case No. RG16809292, *Bianchi*

v. Bayer Corp. et al, Case No. RG16813262, *Brown v. Bayer Corp. et al.*, Case No. RG16813616, *Birruete v. Bayer Corp. et al.*, Case no. RG16809875, *Hyde et al. v. Bayer Corp. et al.*, Case No. RG16812313, *Journey v. Bayer Corp. et al.*, RG16810409, *Mattern v. Bayer Corp. et al.*, RG16809878, *Parades et al. v. Bayer Corp. et al.*, Case No. RG16804887, *Ripperger v. Bayer Corp. et al.*, Case No. RG16804878, and *Webb v. Bayer Corp. et al.*, Case No. RG16809876.

6. Attached hereto as **Exhibit 129** is a true and correct copy of the Arkansas Supreme Court's slip opinion in *Despain v. Bradburn*, No. 07-714 (Ark. Feb. 7, 2008), *superseded on reh'g* 282 S.W.3d 814, retrieved by the Arkansas Reporter of Decisions on September 12, 2019.

7. Attached hereto as **Exhibit 130** is a true and correct copy of certain excerpts from the certified transcript of the deposition of Cem Sarinoglu, M.D., taken in Forrest City, Arkansas on April 12, 2019.

8. Attached hereto as **Exhibit 131** is a true and correct copy of certain medical records produced by Plaintiff Valerie George via MDL Centrality on or about February 25, 2018.

9. Attached hereto as **Exhibit 132** is a true and correct copy of certain excerpts from the certified transcript of the deposition of Plaintiff Valerie George, taken in Memphis, Tennessee on March 6, 2019.

10. Attached hereto as **Exhibit 133** is a true and correct copy of Plaintiff Valerie George's verified Third Amended Plaintiff Fact Sheet, served via MDL Centrality on or about March 1, 2019.

11. Attached hereto as **Exhibit 134** is a true and correct copy of Plaintiff Valerie George's Further Responses In Response to Defendants' First Set of Contention Interrogatories Nos. 1, 13, 35, 36, 37, 41, and 42, served via email on July 22, 2019.

12. Attached hereto as **Exhibit 135** is a true and correct copy of Plaintiff Valerie George's Further Responses to Bayer's First Set of Contention Interrogatories Per Referee's Recommended Order No. 20, served via email on September 19, 2019.

13. Attached hereto as **Exhibit 136** is a true and correct copy of the expert report of Denise Willers, M.D., served via encrypted ShareFile on October 4, 2019.

14. Attached hereto as **Exhibit 137** is a true and correct copy of the expert report of Steven M. Grover, M.D., served via encrypted ShareFile on October 4, 2019.

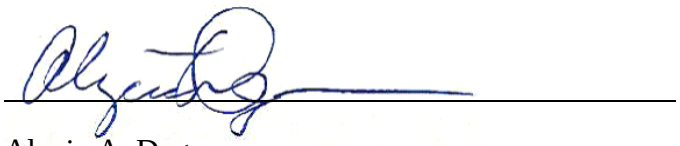
15. Attached hereto as **Exhibit 138** is a true and correct copy of certain excerpts from the certified transcript of the deposition of Amitasrigowri Murthy, M.D., taken in New York, New York on October 23, 2019.

16. Attached hereto as **Exhibit 139** is a true and correct copy of certain excerpts from the certified transcript of the deposition of Denise Willers, M.D., taken in St. Louis, Missouri on November 2, 2019.

17. Attached hereto as **Exhibit 140** is a true and correct copy of certain excerpts from the certified transcript of the deposition of Steven M. Grover, M.D., taken in Salt Lake City, Utah on November 18, 2019.

18. Attached hereto as **Exhibit 141** is a true and correct copy of the Superior Court of New Jersey, Middlesex County's opinion in *Sandobal v. Bayer Corp.*, No. MID-L-4930-17 (Aug. 31, 2018).

Executed on this 22nd day of November 2019, at Los Angeles, California.



Alycia A. Degen

EXHIBIT 124

Michael S. Goetz (*Pro Hac Vice*)
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Attorney for Plaintiff

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA - UNLIMITED JURISDICTION

COORDINATION PROCEEDING SPECIAL TITLE [Rule 1550(b)] IN RE: ESSURE PRODUCT CASES THIS DOCUMENT RELATES TO: *Iveth Martinez, et al. v. Bayer Corp., et al.*, Los Angeles Superior Court, Case No. BC662859 (regarding Plaintiff Valerie George only)	**CASE NO. JCCP** **SHORT FORM COMPLAINT PURSUANT TO ORDER TO SEVER FOR PURPOSES OF TRIAL ASSIGNMENT**

COME NOW the Plaintiff, VALERIE GEORGE, and files this Complaint seeking judgment against Defendants BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 10, inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Plaintiff being implanted with the permanent birth control device Essure®.

Plaintiff incorporates by reference relevant portions of the *Master Long Form Complaint and Demand for Jury Trial* (and any and all amendments thereto approved by this Court) in Judicial Council Coordinated Proceeding No. 4887, *In re Essure Product Cases* ("JCCP 4887"), in Superior Court of California, County of Alameda, before the Honorable Winifred Y. Smith. Pursuant to Case Management Order No. 10, ordered August 28, 2018, this *Short Form Complaint* is utilized in the above-captioned

action. Plaintiff selects and indicates by checking off the appropriate spaces, those claims that are specific to her case. Where certain claims require additional pleading or case specific facts and individual information, Plaintiff shall add and include them herein.

INDIVIDUAL PLAINTIFF ALLEGATIONS
VALERIE GEORGE

1. Plaintiff VALERIE GEORGE is a citizen and resident of Madison, St. Francis County, Arkansas.

2. Venue is proper in this county in accordance with §395(a) of the California Code of Civil Procedure because:

☐ At all relevant times Plaintiff(s) NAME resided in this county and the injuries alleged herein arose from conduct that occurred in this county.

☒ At all relevant times Defendants resided in California and the injuries alleged herein arose from conduct that occurred in California.

3. Plaintiff brings this action:

☒ On behalf of herself;

☐ As a representative of NAME;

☐ As administrator of the estate of NAME who died on *[date]* DATE in the state of STATE.

4. Plaintiff claims damages as a result of:

☒ injury to herself

☐ injury to the person represented

☐ wrongful death

☐ survivorship action

☒economic loss

☐ loss of services

5. Plaintiff's action is:

☐ a new case

☒ a case previously filed and ordered coordinated into JCCP No. 4887.

☐ a case previously filed and pending coordination into JCCP No. 4887. Plaintiff's add-on petition and supporting documents were filed on DATE.

6. Plaintiff was implanted with the Essure® permanent birth control device on or about July 13, 2011, in the state of Arkansas.

7. At the time of implantation, Plaintiff was a resident of Arkansas.

8. Plaintiff has suffered injuries and complications as a result of implantation of the Essure® permanent birth control device manufactured by Defendants, as described in the forthcoming Plaintiff Fact Sheet.

9. The following claims asserted in the Amended Master Complaint and the allegations with regard thereto in the Amended Master Complaint are herein adopted by reference:

☒ Count I: Negligence

☒ Count II: Strict Product Liability

☒ Count III: Concealment

☐ Count IV: Intentional Misrepresentation

☐ Count V: Negligent Misrepresentation

☐ Count VI: Breach of Express Warranty

☐ Count VII: Manufacturing Defect

☐ Count VIII: Loss of Consortium

i. Plaintiff NAME (hereinafter "Spouse Plaintiff") was married to SPOUSE,

Injured, from DATE to DATE, and is a citizen and resident of CITY, Name of County County, *STATE*.

ii. As a direct and proximate result of the injuries sustained by Injured and caused by Defendants, Spouse Plaintiff suffered, and will continue to suffer the loss of his/her spouses' consortium, companionship, society, affection, services and support.

10. Plaintiff asserts the following additional facts or theory of recovery against Defendants: Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiff and her physicians of vital information essential to the pursuit of these claims, without any fault or lack of due diligence on their part. Plaintiff relied on Defendants' misrepresentations and omission 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 Defendants' tortious conduct. Plaintiff diligently filed suit once she discovered the actual facts. Defendants' misconduct and fraudulent concealment of the relevant facts, as described *infra*, tolls any relevant statute of limitations. Plaintiff's suit is filed well within the applicable statutory limitations period.

11. As a result of the injuries Plaintiff sustained, she is entitled to recover compensatory damages for past, present and future: pain and suffering, emotional distress, economic loss, as well as punitive damages and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff, VALERIE GEORGE, prays for relief and judgment against Defendants as set forth in the *Master Long Form Complaint and Demand for Jury Trial* as appropriate.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: April 4, 2019

MORGAN & MORGAN

By: _____

Michael Goetz
201 North Franklin Ave, 7th Floor
Tampa, FL 33602
Ph. (813) 223-5505
Fax: (813) 222.4737

MGoetz@ForThePeople.com

Attorney for Plaintiff

EXHIBIT 125

M. Elizabeth Graham (SBN 143085)
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egraham@gelaw.com

Plaintiffs' Co-Liaison Counsel

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY ALAMEDA

COORDINATION PROCEEDING SPECIAL TITLE [Rule 1550(b)] ESSURE PRODUCT CASES THIS DOCUMENT RELATES TO: ALL CASES	Case No. JCCP 4887 ASSIGNED FOR ALL PURPOSES TO: Judge Winifred Y. Smith Dept. 21 **NOTICE OF ENTRY OF CASE MANAGEMENT ORDER NO. 10: MASTER AND SHORT FORM COMPLAINT**

TO THE CLERK OF THE COURT AND ALL COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on August 28, 2018, the Court entered Case Management Order No. 10: Master and Short Form Complaint. A copy of the order is attached hereto as ***Exhibit A.***

Dated: September 12, 2018

Respectfully submitted,

By: _____

M. Elizabeth Graham, CA 143085
Jay W. Eisenhofer
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Plaintifffs' Co-Liaison Counsel

EXHIBIT A

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA - UNLIMITED JURISDICTION

COORDINATION PROCEEDING SPECIAL TITLE [Rule 1550(b)] ESSURE PRODUCT CASES	Case No.: JCCP 4887 ASSIGNED FOR ALL PURPOSES TO: Hon. Winifred Y. Smith Dept. 21
THIS DOCUMENT RELATES TO: **ALL CASES**	**[PROPOSED] CASE MANAGEMENT ORDER NO. 10: MASTER AND SHORT FORM COMPLAINT**

Pursuant to Rules 3.540 and 3.541 of the California Rules of Court, having considered the submissions of the parties, and good cause appearing,

IT IS HEREBY ORDERED:

1. THIS ORDER shall govern all cases being litigated as part of Judicial Council Coordinated Proceeding No. 4887, *In re Essure Product Cases* ("JCCP 4887"), whether by an original filing, coordination, or transfer to this Court.

2. Pursuant to the Court's request for a master complaint in this JCCP 4887, Plaintiffs' Executive Committee prepared a Master Long Form Complaint in *In re Essure Product Cases* attached hereto as Exhibit A ("Master Complaint"). The Master Long Form Complaint, attached as Exhibit A, is deemed filed with the entry of this Case Management Order. The Master Long Form Complaint and the Master Short Form Complaint attached hereto as Exhibit B shall be used henceforth for all Complaints filed with the intention of coordination in this JCCP 4887 in accordance with the provisions of this Case Management Order No. 10 and all subsequent Case Management Orders in this JCCP 4887.

3. With the entry of this Order, all cases currently coordinated in JCCP 4887 as of the date of this Order are deemed to have adopted all general allegations and Counts 1, 2, 3, and 8 (where applicable) of the Master Long Form Complaint. The allegations, named defendants, and causes of action 1, 2, 3, and 8 (where applicable) of the Master Long Form Complaint amend, supersede, and replace in their entirety: (i) all previously pleaded causes of action in all complaints; (ii) all defendants previously named in all complaints; and (iii) all previously pleaded general allegations in all complaints.

4. Any Plaintiff whose case is currently coordinated in JCCP 4887, and who wishes to adopt Counts 4, 5, 6, or 7 of the Master Long Form Complaint and/or wishes to plead any allegations or claims not set forth in the Master Long Form Complaint, must file a Short Form Complaint within (30) days from the entry of this Order, in the form attached hereto as Exhibit B, which alleges the specific facts supporting those allegations, pled in accordance with California Rules of Civil Procedure.

5. If a Plaintiff whose case is currently coordinated in JCCP 4887 does not wish to plead any additional allegations, claims, or counts other than 1, 2, 3, or 8 (where applicable), she does not need to file a Short Form Complaint.

6. Any Plaintiff with a currently filed Essure case, whose Essure case is coordinated in this JCCP 4887 after the date of this Order, shall file an Individual Short Form Complaint, in the form attached hereto as Exhibit B, within thirty (30) days of the date of the order granting coordination. Upon filing, the Short Form Complaint adopts the Master Long Form Complaint. The allegations, named defendants, and selected causes of action of the Master Long Form Complaint amend, supersede, and replace in their entirety: (i) all previously pleaded causes of action in all complaints; (ii) all defendants previously named in all complaints; and (iii) all previously pleaded allegations in all complaints. For any Plaintiff who fails to file an Individual Short Form Complaint within the time limits set forth in this paragraph, any defendant may file a motion to enforce compliance with this paragraph after providing 14 days written notice to counsel for such Plaintiff, with a copy to Plaintiffs' Co-Liaison Counsel. The moving defendant may request monetary sanctions or other appropriate relief upon a showing of good cause.

7. The Master Short Form Complaint attached hereto as Exhibit B shall be used henceforth for all Complaints filed with the intention of coordination in this JCCP 4887. If a Plaintiff fails to use the Short Form Complaint in connection with her original filing, she shall be subject to the requirements of Paragraph 6 of this Order. Plaintiffs using the Short Form Complaint in connection with an original filing shall comply with Case Management Order No. 1 and California Rules of Civil Procedure pertaining to service and add-on processes.

8. In the event a Plaintiff files a Short Form Complaint, the Master Long Form Complaint combined with the Plaintiff's Short Form Complaint shall be deemed to be the controlling pleading in the Plaintiff's individual action.

9. Plaintiffs have the option to disavow any allegations and causes of action from the Master Long Form Complaint that they believe do not apply to the prosecution of their purported claims. In the event a Plaintiff chooses to disavow any such allegations or causes of action, he or she shall file the Judicial Council Form CIV-110 and specify in Section 1(b)(6) the causes of action and/or allegations that he or she disavows and dismisses.

10. The filing of the Master Long Form Complaint does not toll nor in any way affect any applicable statute of limitations or repose in individual cases. For cases filed, coordinated, or pending

coordination in the JCCP as of the date of entry of this order, the date of filing of the Plaintiffs' complaint shall be deemed to be the date of the original filing.

11. Defendants' stipulation to the filing of a Master Long Form Complaint and to this Case Management Order is not an agreement that the Master Long Form Complaint, or any Short Form Complaint, states any valid causes of action, and this stipulation shall not be deemed to waive any such arguments or any other defenses. To the extent that a defendant has any procedural or substantive challenges to the Master Long Form Complaint, the parties shall meet and confer and discuss with the Court at the next case management conference a procedure and schedule for hearing any such challenge.

12. The parties contemplate that Defendants will file and serve a Master Answer to the Master Long Form Complaint for use in these coordinated proceedings. The Master Answer shall be filed and served by a date to be determined by the parties or the Court at a later date. Defendants' Master Answer is an answer in all included actions as to the claims asserted in the Master Long Form Complaint and does not waive any applicable defenses. Once a defendant has filed its Master Answer, and upon any new case being coordinated with this JCCP 4887, it will be deemed that the Master Answer has been filed and served in that action without any further action by the defendant. No default may be taken against a defendant where such defendant has filed a Master Answer.

13. Defendants may respond to individual complaints, including Short Form Complaints, by way of motions permissible under the California Rules of Civil Procedure. To allow for orderly administration of such motions or other responses to Short Form Complaints, a Plaintiff's filing of a Short Form Complaint, including a Short Form Complaint asserting claims or allegations in addition to those set forth in the Master Long Form Complaint, does not trigger any responsive pleading deadline on the part of any Defendant at this time. All responsive pleading obligations for Defendants shall remain stayed until further Order of the Court. The parties will meet and confer, and a deadline will be set at a later date for Defendants to file motions and/or supplemental responsive pleadings, if warranted. Defendants expressly retain the right to challenge all claims and allegations in any Short Form Complaint separately at a later date. Challenges to claims or allegation in any Short Form Complaint(s) shall be limited to the specific Short Form Complaint(s) at issue. Defendants shall give notice to Plaintiffs' Executive Committee of their request to meet and confer on any such challenge, and

Plaintiffs' Executive Committee shall have the right to participate in any meet and confer, briefing or argument on any demurrer to or motion to strike a Short Form Complaint, or dispositive motion, and Defendants' Liaison Counsel shall advise Plaintiffs' Co-Liaison Counsel in the event any such motions are contemplated. No default shall be taken against a defendant where such defendant has filed a Master Answer.

14. Any pre-trial motions filed by any Party to the Master Long Form Complaint or the Master Long Form Answer (including but not limited to demurrers, motions to strike, motions for judgment on the pleadings, motions for summary judgment or summary adjudication) shall be deemed to be made in, and apply to, all cases that are part of these coordinated proceedings, unless otherwise specified in the motions or by order of the Court. Any orders by the Court on any such motions shall apply to all cases that are part of the coordinated proceedings, unless otherwise specified in the orders.

15. Nothing in this Order is intended to resolve any matter relating to personal jurisdiction, venue, choice of substantive law, or any applicable defense.

IT IS SO STIPULATED.

Dated: July , 2018

GRANT & EISENHOFER, P.A.
M. Elizabeth Graham

KERSHAW, COOK & TALLEY
William A. Kershaw
Plaintiffs' Co-Liaison Counsel

MOTLEY RICE LLC
Fidelma L. Fitzpatrick
Plaintiffs' Lead Counsel

By: _____
M. Elizabeth Graham
Plaintiffs' Co-Liaison Counsel

Dated: July , 2018

SIDLEY AUSTIN LLP

By: _____
Alycia A. Degen
Defendants' Lead and Liaison Counsel

IT IS SO ORDERED.

Dated: 8/24/16

HONORABLE WINIFRED Y. SMITH

Superior Court of California, County of Alameda
Department 21, Administration Building

Case Number: JCCP004887
Case Name: Essure Product Cases

RE: CASE MANAGEMENT ORDER NO. 10

DECLARATION OF ELECTRONIC SERVICE

I certify that I am not a party to these cases and that a true and correct copy of the foregoing document was served electronically pursuant to Case Management Order No. 2, entered in these coordinated proceedings on January 23, 2017, via the CASE ANYWHERE system. Execution of this certificate occurred at 1221 Oak Street, Oakland, California.

Executed on August 28, 2018

Executive Officer/Clerk of the Superior Court

By *Christopher Wright*
Deputy Clerk

Kershaw, Cook & Talley
William A. Kershaw
401 Watt Ave.
Sacramento, CA 95846

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M. Elizabeth Graham
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San Francisco, CA 94111

EXHIBIT A

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA - UNLIMITED JURISDICTION

COORDINATION PROCEEDING SPECIAL TITLE [Rule 1550(b)]	CASE NO. JCCP 4887
	ASSIGNED FOR ALL PURPOSES TO: Judge Winifred Y. Smith Dept. 21
IN RE: ESSURE PRODUCT CASES	**MASTER LONG FORM COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**
THIS DOCUMENT RELATES TO ALL CASES	(1) Negligence (2) Strict Products Liability (3) Concealment (4) Intentional Misrepresentation (5) Negligent Misrepresentation (6) Breach of Express Warranty (7) Manufacturing Defect (8) Loss of Consortium

COME NOW the Plaintiffs, and file this Complaint seeking judgment against Defendants BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 10, inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Plaintiffs being implanted with the defective and unreasonably dangerous product, Essure®. At all times relevant hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

I. INTRODUCTION

1. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

2. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably

available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the U.S. Food and Drug Administration ("FDA"), and thereby to the healthcare community and to consumers. The manufacturer also must carefully monitor its own quality controls post-market to ensure that the device uniformly conforms with its representations and warranties and with specifications of approval.

3. When monitoring and reporting the post-market experience with its product, including any adverse events as required by both federal regulations and state law, including California law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could mean that researchers, regulatory bodies, and the medical community are years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report post-market experience, but it must also report the data to the FDA as soon as it is received, take appropriate actions to identify the root cause of product failures, and take corrective and preventative actions as appropriate.

4. This action arises from Defendants' failure to uphold their post-market responsibilities to warn about serious health risks that became apparent to the manufacturer after their permanent birth control device, Essure®, was marketed in the United States. In 2002, the FDA approved the device for sale in the United States based on clinical studies of only 745 women presented by the device manufacturer.

5. After the FDA approved the Essure device for sale and it began to be implanted in patients in a real world setting, Defendants became aware of serious issues and adverse events that should have led Defendants to, among other things, report the adverse events to the FDA pursuant to 21 C.F.R. §803, et seq. For example, Defendants failed to disclose to health care providers and consumers that they had received thousands of complaints of serious injuries associated with Essure® after the device was approved for sale. The FDA was not made aware that the device could cause serious health risks, such as perforation of the uterus or fallopian tubes, device migration or fracture, chronic pain, prolonged bleeding, and unintended pregnancies. The FDA was also not made aware that the frequency and

severity of complications was greater than expected, and ultimately the device must be removed requiring major surgery.

6. Defendants failed to timely report this new information to the FDA. When the FDA later became aware of this information, it made Essure a restricted device and required additional warnings, including a black box warning and Patient Decision Checklist, to reflect serious health risks that were ultimately suffered by Plaintiffs. If the Defendants had timely and adequately disclosed this information and had reported serious adverse events to the FDA, Plaintiffs' injuries would have been avoided.

7. Despite their actual knowledge about the frequency, severity, and permanence of the clinical complications associated with Essure®, Defendants persisted in conducting a nationwide false and misleading marketing campaign. In Defendants' own words, their marketing strategy aimed to capitalize on a physicians' position of trust with patients.

8. The conduct of Defendants violated their obligations under relevant federal and state law, including California law, governing the post-market conduct of Class III medical device manufacturers.

II. PARTIES, JURISDICTION AND VENUE

9. The Court has personal jurisdiction over Defendants. Defendant Bayer Essure® Inc. (f/k/a Conceptus, Inc.) and Bayer HealthCare LLC have at all relevant times maintained their corporate headquarters in, and purposefully availed themselves of the benefits, profits and privileges deriving from their business activities in this state. At the time of each Plaintiff's implant, all Defendants centralized Essure®'s research and development, labeling, regulatory, manufacturing, and marketing strategy in California, and each Defendant participated in that joint effort. The Essure® devices sold to California and non-California residents were part of a common course of distribution from California; the Essure device was conceived of, tested, manufactured, packaged, approved, marketed, distributed, and sold directly from California to the 50 states and overseas. Clinical trials which formed the basis of the approval of this device were conducted from California, including facilities in Santa Clara County. Neither the product design nor the deceptive representations and omissions made about the devices differed from state to state.

10. Defendant BAYER CORP. is a for-profit corporation incorporated in the state of Indiana with its principal place of business in Pennsylvania. Bayer Corp. indirectly owns both Bayer Essure, Inc.,

which is one of the members of Bayer Healthcare, LLC, and Bayer Healthcare Pharmaceuticals, Inc.. Bayer Corp. presently and in the past has simultaneously shared officers, agents, and/or employees with Bayer Healthcare, LLC, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Essure, Inc. (f/k/a Conceptus). Bayer Corp. also provided support for Bayer's acquisition of Bayer Essure, Inc. (f/k/a Conceptus) and it is the custodian of documents related to the acquisition. Bayer Corp. maintains offices in Commerce, San Ramon, Fresno, Chula Vista, Mission Viejo, and Long Beach, California. Bayer Corp.'s U.S. Innovation Center, a 48-acre Multipurpose Biotechnology Plant, is located in Berkeley, California. At all relevant times, Bayer Corp. engaged in conduct in California, together with Bayer Healthcare Pharmaceuticals, Bayer Healthcare, LLC, and Bayer Essure, Inc., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States, including the Essure® devices implanted in Plaintiffs.

11. Defendant BAYER HEALTHCARE LLC is a for-profit limited liability company organized under the laws of the state of Delaware with its principal place of business in Pennsylvania. It is a wholly owned subsidiary of Bayer A.G. Bayer Healthcare, LLC's sole member is Defendant Bayer Corp. Bayer Healthcare, LLC is authorized to and does business throughout the state of California and during the time period relevant to this litigation had manufacturing operations located in Berkeley, Alameda County, California and research and development operations in San Francisco, San Francisco County, California. At all relevant times, Bayer Healthcare, LLC's principle place of business for its Essure® operations, including, but not limited to, Quality Assurance through which technical and medical complaints were processed, was in a plant in Milpitas, California, which is the same plant from which Conceptus performed Essure® functions. At present, Bayer Healthcare, LLC maintains facilities in Berkeley, California and corresponds with the FDA regarding Essure® from this location. At all relevant times, Bayer Healthcare, LLC engaged in conduct in California, in concert with Bayer Healthcare Pharmaceuticals, Bayer Corp., and Bayer Essure, Inc., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States, including the Essure® devices implanted in Plaintiffs. At all times relevant to this action, Bayer Essure, Inc. and Bayer Healthcare

LLC, both California entities, acted as agents for Bayer Corp. in the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States.

12. Defendant BAYER ESSURE® INC. (F/K/A CONCEPTUS, INC.) is a for-profit corporation incorporated in the state of Delaware and is a wholly owned by subsidiary of Bayer A.G. and/or Bayer Healthcare, LLC. Conceptus, Inc. ("Conceptus") was a Silicon Valley "start up", founded in 1992 by Julian Nikolchev, a self-described "medical technology developer and serial entrepreneur." On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly owned subsidiary of Bayer HealthCare LLC and, thereafter was renamed "Bayer Essure Inc." For purposes of this Complaint, Conceptus, Inc. and Bayer Essure Inc. are one and the same. Bayer Essure Inc.'s headquarters were located at 1021 Howard Avenue, San Carlos, California 94070, until 2005 when they relocated to 331 East Evelyn Avenue, Mountain View, California 94041. In July of 2013, Bayer Essure Inc. moved its headquarters to 1011 McCarthy Boulevard, Milpitas, Santa Clara County, California 95035. On or about July 1, 2013, Bayer Healthcare LLC and Conceptus entered into an Asset Sale Agreement, whereby Conceptus agreed to transfer substantially all of its operating tangible assets and certain liabilities to Bayer Healthcare LLC. That same day, Conceptus assigned its lease of the Milpitas facility, from which it was conducting substantially all of its Essure® functions, to Bayer Healthcare LLC. Thereafter, Bayer Healthcare LLC was the lessee and occupant of the premises and performed its Essure functions from the premises at least until March 2016 or later. In July 2015, Bayer Essure, Inc. transferred its remaining assets and liabilities (except certain tax assets and liabilities) to Bayer Healthcare LLC in exchange for common membership units in Bayer Healthcare LLC. Upon information and belief, as of May 20, 2016, Bayer Essure Inc. surrendered its right to conduct intra-state business in the state of California. In its 2017 Annual Report, Bayer AG listed Bayer Essure, Inc. as a fully consolidated subsidiary with a place of business in Milpitas, California. Bayer Essure, Inc. played a primary role in Essure®-related operations, such as manufacturing, marketing, promotion, product labeling, and regulatory affairs. At all times relevant hereto, Bayer Essure engaged in conduct in California, in concert with Bayer Healthcare

Pharmaceuticals, Bayer Healthcare, LLC, and Bayer Corp., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure throughout the United States, including the Essure® devices implanted in Plaintiffs. At all times relevant to this action, Bayer Essure, Inc. and Bayer Healthcare LLC, both California entities, acted as agents for Bayer Corp. in the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. Bayer Healthcare Pharmaceuticals. It is authorized to and does business throughout the state of California. Bayer Healthcare Pharmaceuticals, played a role in the marketing, promotion, product labeling, and post-market surveillance for Essure®. Bayer Healthcare Pharmaceuticals, Inc. maintains offices in San Pablo, Emeryville, and San Diego and employs roughly 500 employees in California. At all relevant times, Bayer Healthcare Pharmaceuticals, Inc. engaged in conduct in California, together with Bayer Corp., Bayer Healthcare, LLC, and Bayer Essure, Inc., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States, including the Essure® devices implanted in Plaintiffs.

14. In as early as 2004, the Defendants began sub-contracting the manufacture and sterilization of the device to several other companies, including Accellent Corp., f/k/a Venusa, Ltd., Accellent Inc. d/b/a Lake Region Medical Inc., FlexMedical, formerly named Avail Medical, and Sterigenics International. Defendants are liable for the actions and inactions of these sub-contractors.

15. At all times herein mentioned, there existed a unity of interest, and activity in furtherance of that interest, among Defendants such that any individuality and separateness among them has ceased, and these Defendants are the alter egos of each other with respect to Essure® operations.

16. Defendants acted jointly and in combination with one another to take advantage of each Defendants' resources, personnel, services, and sales, marketing and promotional networks. This includes the Defendants transacting, soliciting and conducting business in California through their

offices, employees, agents and/or sales representatives, from which they derived substantial revenue in California.

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

18. The true names and capacities of those defendants designated as DOES 1-10, whether individual, corporate, association or otherwise, are unknown to Plaintiffs at the time of filing this Complaint and Plaintiffs, therefore, sue said defendants by such fictitious names and will ask leave of Court to amend this Complaint to show their true names or capacities when the same have been ascertained. Plaintiffs are informed and believe, and thereon allege, that each of the DOE defendants is, in some manner, responsible for the events and happenings herein set forth and proximately and/or directly caused injury and damages to Plaintiffs as herein alleged.

III. DESCRIPTION OF ESSURE®

19. Essure® is a medical device manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

20. Essure® was first manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Conceptus, Inc. and initially developed under the name Selective Tubal Occlusion Procedure or "STOP™" Permanent Contraception device.

21. Essure® is touted as a form of permanent female birth control (female sterilization) with a 99.3% effectiveness rate of preventing pregnancy. Defendants intended the device to be implanted "permanently," *i.e.*, to remain securely in place for each patient's lifetime.

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

23. The micro-inserts are composed of two metal coils: one coil made of nitinol (nickel and titanium) and the other made of steel with polyethylene terephthalate ("PET") fibers wound in and around the coil. The micro-inserts are inserted through the vagina, cervix, and uterus and then implanted into a woman's fallopian tubes via Defendants' disposable delivery system.

24. Defendants' disposable delivery system consists of a single handle that contains a nitinol core 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 monitor this process through hysteroscopic equipment, including a hysteroscope, a lightbox, and a monitor, collectively known as a "tower."

25. The hysteroscopic equipment is not part of the Essure® device or its pre-market approval process, but the equipment is necessary for proper implantation of the Essure® device.

26. After implantation of the coils in the fallopian tubes, the micro-inserts are intended to expand and cause a chronic inflammatory and fibrotic response to the PET fibers which elicits tissue growth that blocks the fallopian tubes and prevents pregnancy.

27. The Instructions for Use ("IFU") accompanying the Essure® device provide that patients should be counseled to receive a confirmation test three months post-implant to determine that there is complete occlusion in each fallopian tube. The Confirmation Test is performed using a hysterosalpingogram ("HSG Test") and, as of July 2015, a transvaginal ultrasound ("TVU").

28. Since Essure®'s market entry in 2002, the device has undergone several design changes. The Selective Tubal Occlusion Product ("STOP") device was the original model used in the two clinical trials (STOP 10 and STOP2000) submitted in an effort to obtain FDA approval of the device. The first U.S. launched device was the ESS205 model, which was comprised of the same coil insert as the STOP device, but incorporated a different delivery system (i.e., support catheter). The original support catheter was discontinued in 2003 to address continued reports of difficulty/failure to disengage or detach the delivery wire from the Essure micro-insert during implantation. Additional changes were later made to the delivery system. In 2007, Defendants changed the shape of the inserts by removing the

tapered "pigtail" at the proximal end of the outer coil and renamed the device the ESS305 model.

IV. PRE-MARKET APPROVAL AND POST MARKET OBLIGATIONS

29. In April 2002, Conceptus submitted its Premarket Approval Application to the FDA for the Essure® device.

30. Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices based on the information available at the time. *See* 21 U.S.C. § 360(e); 21 C.F.R. § 814.3(e).

31. On November 4, 2002, the FDA conditionally approved the Essure® PMA application to market the device in the United States.

32. FDA approval in 2002 was based on studies of only 745 clinical trial patients for a short period of time; the majority of the clinical trial data regarding the coils and PET in the fallopian tube was based on only 12–24 months of implantation. Beyond 24 months, therefore, the nature of the body's cellular and fibrotic response to the inserts and the ability of the devices to maintain occlusion were unknown. The FDA advised Conceptus of these facts and emphasized their special significance with respect to the risk of ectopic pregnancies, putting Conceptus on clear notice that the company's duty to vigilantly monitor and report the real world clinical experience with the device was paramount. Thus, the importance of maintaining the integrity of post-marketing data collection and reporting was known to Defendants from the outset.

33. Approval of a device through the PMA process signals the beginning, not the end, of a device manufacturer's duties to patients under both federal regulations and established state law, including California law. The FDA's initial approval of a device label amounts to a finding by the FDA that the label is adequate for purposes of gaining initial approval to market the device. It does not represent a finding by the FDA that the label can never be deemed inadequate after approval as new safety information from the real world experience with the device becomes available to the manufacturer. Sound reasons support these principles: there are products, such as Essure®, for which evidence of the device's defects comes to light only after the device is used in a real world setting.

34. The FDA's Conditional Premarket Approval ("CPMA") Order for Essure® outlined several requirements for the manufacturer, and the CPMA expressly made non-compliance with any of these

requirements a violation of federal law. For example, the Order required that the manufacturer:

a. conduct a post-approval study in order to gather long-term safety and effectiveness data on Essure®;

b. conduct a post-approval study in the U.S. to "document the bilateral placement rate [of Essure®] for newly trained physicians";

c. annually report on the patients who participated in the post-approval studies;

d. ensure that any warranty statements are truthful, accurate, not misleading and are consistent with applicable federal and state laws;

e. 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;

f. submit pursuant to 21 CFR §814.84 a post-approval Annual Report that includes 1) a bibliography and summary of information from unpublished reports of data from any clinical investigations or non-clinical laboratory studies involving Essure® as well as reports in the scientific literature concerning Essure®, 2) identification of changes made pursuant to §814.39(a) or (b) that effect the safety or effectiveness of the device, and 3) any failures of the device to meet the specifications established in the approved PMA that were correctable by procedures described in the approved labeling;

g. submit pursuant to 21 CFR §814.82(a)(9) a "Device Defect Report" or "Adverse Reaction Report" to the FDA within 10 days after Defendants receive or have knowledge or information of any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that has either not been addressed by the device's labeling, or has been addressed by the device's labeling but is occurring with unexpected severity or frequency. The express purpose of this requirement is to provide continued reasonable assurance of the safety and effectiveness of the device;

h. submit pursuant to 21 CFR §814.82(a)(9) a "Device Defect Report" or "Adverse Reaction Report" to the FDA within 10 days after Defendants receive or have knowledge or information of any significant change or deterioration of the device, or any failure of

the device to meet specifications established in the approved PMA, that could not cause or contribute to death or serious injury, but is not correctable by adjustments or other procedures described in the approved labeling. The express purpose of this requirement is to provide continued reasonable assurance of the safety and effectiveness of the device;

35. The CPMA Order for Essure® further outlined reporting requirements that Defendants were required to follow under the Medical Device Reporting regulations ("MDR"). Under these requirements, pursuant to 21 CFR §803.50, et seq. Defendants were required to:

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. *See* 21 CFR 803.50(a)(1);

b. 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 has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur. *See* 21 CFR 803.50(a)(2);

c. Report to the FDA within 5 days after Defendants received or became aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. *See* 21 C.F.R. § 803.52; and,

d. Report to the FDA within 30 days after Defendants received any supplemental information that was not provided in the initial report. *See* 21 C.F.R. §803.56.

36. The CPMA Order acknowledged the Defendants' obligation and ability to update safety warnings for Essure® without prior FDA approval by utilizing the "Changes Being Effected" provision in 21 C.F.R. § 814.39(d)(2).

37. The FDA made clear in the CPMA order that "[f]ailure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Act."

38. In order to comply with its reporting obligations under the Essure® CPMA and federal law, Defendants were required to conduct an investigation of each adverse event and evaluate the cause of the event. *See* 21 C.F.R. §§ 803.50(a); 803.50(b)(3)

39. To competently investigate whether a complaint represents an adverse event required to be reported under §803.50 et seq., Defendants were required to establish and maintain procedures for receiving, reviewing, and evaluating complaints of adverse events by a formally designated unit to ensure that 1) all complaints were processed in a uniform and timely manner; 2) oral complaints were documented upon receipt; and 3) complaints were evaluated to determine whether the complaint represents an adverse event which is required to be reported to the FDA. *See* 21 CFR §§803.17; 820.198(a).

40. Any complaint involving the possible failure of a device to meet any of its specifications must be reviewed, evaluated, and investigated; and records of these complaints must be maintained separately. 21 CFR §820.198(d). If a manufacturer decides not to investigate a complaint, they must maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. *See* 21 CFR §820.198(b).

41. Whether or not the manufacturer determines the event is an MDR reportable event, they must maintain a MDR file that contains all information and documentation in their possession related to the adverse event, a record of any investigation and the results of any evaluation of an adverse event, any information a qualified person used to determine whether or not a device-related event was reportable, copies of all reports submitted to the FDA related to the adverse event, and copies of all electronic acknowledgements the FDA sends in response to an MDR submission. *See* 21 CFR §§803.18(a); 803.18(e); 803.20(c)(2); 803.22(b)(1); 820.198(e) et seq.

42. If a manufacturer fails to adequately and timely evaluate and investigate reports of adverse events pursuant to the FDCA, it is impossible for the manufacturer to comply with its reporting requirements under the same.

43. The FDCA states, "If you are a manufacturer...you must report deaths and serious injuries that your device has or may have caused or contributed to, and 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."

44. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulations as described above. The FDA publishes the adverse events

and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

45. Upon information and belief, Defendants failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints of adverse events, they failed to timely and adequately evaluate and investigate complaints of adverse events, and failed to timely report complaints of adverse events to the FDA. These failures violated regulations outlined above under federal law and subsequently violated state law.

46. Had Defendants fulfilled their post-market reporting obligations in a timely fashion, which federal and state law required them to do, Plaintiffs' injuries would not have occurred.

47. Pursuant to 21 U.S. Code § 352 (m), a medical device is rendered misbranded if its advertising is false or misleading in any particular.

48. Additionally, in the case of any restricted device distributed or offered for sale in any State, such a device is rendered misbranded 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, a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

49. Pursuant to 21 U.S. Code § 321 (n), if an article is alleged to be misbranded because the advertising is misleading, then in determining whether the advertising is misleading, there shall be taken into account (among other things), not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the advertising relates under the conditions of use prescribed in the advertising thereof or under such conditions of use as are customary or usual.

50. Defendants' concealment of adverse events, health hazards, and risks associated with Essure®

rendered the Essure® device misbranded.

51. Even if Defendants disclosed some information regarding adverse events, their failure to correct inaccuracies and fully disclose material information left any previous disclosure deceptive.

52. By failing to ensure representations regarding Essure® were truthful, accurate, and not misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

V. DEFENDANTS BREACHED THEIR OBLIGATION TO UPDATE WARNINGS AND REPORT ADVERSE EVENTS

53. The claims in this case concern Defendants' duties that arose after premarket approval of Essure®, when Defendants learned of new information bearing on the safety of its device. Defendants' systemic noncompliance with federal regulations can be seen throughout the company's history as they continuously failed to acknowledge, report, correct, and warn about known problems with the Essure® device. This neglect contributed to thousands of adverse events in women implanted with Essure®. Defendants' subsequent failure to report these adverse events and update warnings is part and parcel of Defendants' indifferent attitude toward federal regulations and their CPMA.

54. Under state law, including California law, Defendants had a duty to exercise reasonable care in adequately warning about the dangers of Essure® that were known or knowable to Defendants at the time of distribution. Under both federal and state law, Defendants have a post-market duty to report adverse events and risks associated with the device.

55. Despite having knowledge and possession of evidence that showed the use of Essure® was dangerous and likely to place users' health at serious risk, Defendants failed to disclose the known or knowable health hazards and risks associated with Essure®. Defendants' conduct here failed to meet their federal obligations and violated state law, including California law.

56. Throughout its existence, Conceptus accumulated hundreds of millions of dollars of debt and never achieved profitability.

57. By 2007, Essure® was the only product sold by Conceptus, and Defendants had greatly increased production and sales of the device.

58. Upon information and belief, as their sales volume grew, Defendants were not adequately staffed or equipped to comply with federal regulations regarding the investigation and reporting of adverse

events that were continuously brought to their attention.

59. To protect the Essure® brand within the permanent birth control market, Defendants made a decision to hide their knowledge of serious safety risks from the FDA and to misrepresent the safety and efficacy of the device in its marketing materials.

60. Conceptus was aware of thousands of unreported adverse events stemming from the Essure® device. Defendants failed to take any action to correct the device failures, failed to report its knowledge of known device failures to the FDA, and failed to disclose to the medical community the increased risk of adverse events related to Essure®.

61. Some of these adverse events included perforations of the fallopian tubes, uterus, and other organs. The FDA previously advised Defendants as early as 2004 that FDA considers tubal perforations to be MDR-reportable events under 21 CFR 803 and all cases should be reported to the FDA.

62. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all field activities, including inspections and enforcement. During an inspection, if ORA investigators observe conditions they deem to be objectionable, these observations are required to be listed on an FDA Form 483 when they indicate that an FDA-regulated product may be in violation of FDA requirements.

63. FDA Form 483s typically are discussed with a company's management team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of every possible deviation from law and regulation. There may be other objectionable conditions that exist that are not cited on the FDA Form 483. Companies must take corrective action to address the cited objectionable conditions and any related, non-cited objectionable conditions that exist.

64. From December, 8 2010 through January, 6, 2011, the FDA conducted a fifteen-day "For Cause" inspection. During the fifteen-day "For Cause" inspection, the FDA noted conditions that it found objectionable and/or constituted violations of the FDCA and related Acts.

65. The objectionable conditions were communicated to Conceptus by the FDA via a Form 483 dated January 6, 2011, and included the:

a. failure to submit MDR Reports to the FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to death or serious injury. This included injuries that occurred

during the Essure placement procedure involving the use of equipment indicated in the PMA for use during the procedure. Examples given included failure to submit MDR reports for: 1) two reports of bowel perforation, 2) one report of pain and the Essure® device breaking into pieces immediately following implant, 3) 41 complaints that involved perforation of the uterus or fallopian tubes;

b. failure to submit MDR's to the FDA within 30 days for reports of the device failing to function as specified in the PMA when it would be likely to cause or contribute to serious injury. Examples given included failure to submit MDR reports for five reports of the Essure® coils perforating the fallopian tubes and penetrating the abdominal or peritoneal cavity;

c. failure to include perforation of the Essure® micro-coil insert into the peritoneal cavity in its Design Failure Mode Effects Analysis (DFMEA) for Essure®, despite having documented at least 508 complaints of perforation involving the Essure® device;

d. and failure to adequately document in a Corrective Action and Preventative Actions ("CAPA") an incident involving Conceptus's contract manufacturer using uncertified material in a validation protocol and failing to follow their own Standard Operating Procedure for control of non-conforming material.

66. The FDA inspector specifically advised Defendants that any instances of the device migrating to, perforating, or penetrating areas in the body outside of the fallopian tubes constituted a malfunction and should be reported. In response, the Quality Manager at Conceptus told the inspector that he did not consider an Essure® device migrating out of the fallopian tube because of a perforation to be a device malfunction.

67. In their response to the FDA regarding the form 483 on January 20, 2011, Defendants "acknowledged that the Essure® device 'malfunctioned' in these cases, since the device failed to 'meet its performance specifications or otherwise perform as intended,' namely, to cause permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes."

68. The FDA Establishment Inspection Report for this inspection was issued on May 18, 2011, and stated the following:

a. All firm personnel identified Mr. Sieczkarek as the person most responsible for the company's response to the FDA investigation, which included an investigation of consumer complaint reporting violations.

b. "My inspection of the complaint system of Conceptus Inc. found that the firm was not reporting complaints of loose micro-insert coils in the peritoneal or abdomino-pelvic cavity (*See* FDA483 Observation #2). Some placement procedures have a perforation of the fallopian tubes. In some of these cases the micro-insert coil will migrate through the perforation in the tube and will be found on x-ray to be outside the female reproductive tract in the peritoneal cavity. Such cases will be reported as MDR by the firm if the patient is complaining of pain and a second procedure is required to remove the coil. However, the firm will not report such complaints if an abdominal located coil is removed during a laparoscopic tubal ligation performed because of failure of the Essure® procedure."

c. During this inspection, Conceptus gave the FDA inspector "an Excel spreadsheet with all of the complaints opened since Jan. 1, 2008 [and] there were 16,581 complaint[s] from 1/1/08 until 12/6/10 listed. There were 182 MDRs reported in the same time period."

d. Conceptus also gave the FDA inspector a more detailed complaint spreadsheet "that starts at 7/20/2010 and goes to 12/10/2010. That spreadsheet [had] a total of 2,752 complaints."

e. The FDA inspector looked at the complaints for perforation and noted that a review of these databases showed that in the previous two years there were no less than 177 complaints for perforation with migration, however "that figure may not be exact because complaints could have multiple failure modes with only one listed on the less detailed database."

f. A review of the Risk Analysis Design Failure Mode Effects Analysis showed that there is no failure mode for perforation itself or inserts migrating into the peritoneal cavity. The inspector asked if the firm had any safety data for an intraperitoneal location of the coil inserts. He could only provide anecdotal information for the Phase II clinical trials.

g. The FDA inspector told Defendants that the reason for considering complaints in which

the micro-insert was found in the peritoneal cavity to be likely to lead into an injury was based on the number of MDR's in the firm's database in which such a situation led to a complication. Defendants stated that they "did not consider a micro-insert falling out of the fallopian tube because of a perforation to be a 'malfunction' because it does not involve a malfunction of the micro-insert itself." The inspector reiterated that the coil migrating to a different location represented the device not functioning as it was designed and was the condition that led to an intra-abdominal coil becoming symptomatic in all cases in which an intra-abdominal coil had to be removed surgically.

69. Defendants failed to report incidences of device malfunction and serious injury in accordance with FDA regulations. The FDA's review of Defendants' complaint databases showed that there was an inherent flaw in the way reports of adverse events were categorized and stored.

70. On May 11, 2011, at the first quarter 2011 earnings call, Mr. Sieczkarek discussed their plan to continue to promote Essure® as safe and effective despite the thousands of adverse event reports they had received. During that call, Mr. Sieczkarek stated, "We intend to increase productivity, grow our physician pipeline, expand Essure® utilization, and drive greater patient adoption through integrated marketing." He again described Essure®'s "superior efficacy, reduced patient trauma, risk and recovery, and lower cost versus tubal ligation" to investors. He did not discuss how Conceptus had been put on notice of their violations of FDA regulations and failed to report serious adverse events to the FDA.

71. On August 4, 2011 at the second quarter earnings call, Mr. Sieczkarek stated they had a "comprehensive publication plan to keep physicians up to date on information that may impact their use of Essure®." Despite these statements, Defendants continued to underreport adverse events associated with Essure® to the FDA and medical community.

72. Defendants intentionally, willfully, and maliciously concealed and/or suppressed material safety information regarding Essure® in order to increase sales of Essure®, protect the Essure® brand, and increase market share.

73. From May 30, 2013 through June 26, 2013, the FDA conducted another inspection that included an evaluation of Defendants' complaint handling and adverse event reporting practices. As part of the inspection process, the FDA requested a complete list of complaints since January 2011. Defendants

provided the FDA inspector with a spreadsheet containing 16,047 complaints Conceptus received on the Essure® device between January 2011 and the date of the inspection, only 183 of which were reported by Defendants to the FDA as MDRs.

74. The inspector reviewed 29 random complaint forms received by Defendants. None of the randomly reviewed complaints in which one or more coils were imaged outside of the fallopian tubes were reported to the FDA as MDRs.

75. Upon information and belief, from January 1, 2008 through May 2013, Defendants were receiving on average over 15 complaints per day about their product and thousands of complaints each year. Defendants timely reported only a tiny fraction of these complaints to the FDA.

76. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA Regulations.

77. Defendants had unique knowledge concerning the frequency, severity, and permanence of the complications and risks associated with the Essure® device. Despite this unique knowledge, Defendants failed to take necessary action —such as timely submitting MDRs—to advise users of Essure® of the defects and risks described above, violating state law, including California law.

78. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA Regulations related to complaint handling, investigation, and reporting to the FDA, including, but not limited to, 21 C.F.R. § 803.10; 21 C.F.R. §803.17; 21 C.F.R. §803.18; 21 C.F.R. §803.20; 21 C.F.R. §803.22; 21 C.F.R. § 803.3; 21 C.F.R. §803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21 C.F.R. §803.22(b)(1); 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; and 21 C.F.R. §820.198.

79. Defendants' failure to adequately investigate complaints and to timely file MDR's 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 violated the CPMA, FDA post-marketing regulations, and parallel state law. Defendants' violations prevented Plaintiffs, their physicians, and the public from understanding the true nature of Essure®'s adverse events, risks, and ineffectiveness.

80. Defendants' actions violated duties under state law, including California law, governing their

post-marketing conduct.

81. The medical community, prescribing and implanting physicians, healthcare providers, and patients, including Plaintiffs and their healthcare providers, neither knew, nor had reason to know at the time of their use of Essure®, of the existence of the aforementioned adverse events and defects. Ordinary consumers would not have recognized the potential risks or side effects that Defendants concealed and misrepresented through their promotion of Essure®.

82. Only after the FDA directed Defendants to disclose the withheld information did the medical community become aware of the frequency, severity, and permanence of complications associated with the prescription and implementation of the Essure® device.

83. Between Essure®'s inception in 2002 until 2015, the FDA received approximately 9,900 medical device reports (MDRs) related to safety problems with the device. Of those 9,900 MDRs, 8,950 reports were received by the FDA between October 26, 2013 and December 31, 2015.

84. Since that time, a consulting firm specializing in medical device post-marketing surveillance, Device Events, recently analyzed data provided to the FDA by a Congressman. The analysis uncovered raw data that revealed discrepancies in Defendants' reporting practices. These inconsistencies made it difficult to assess the true frequency of occurrences of the adverse events that Defendants did report.

85. For example, previously the FDA was aware of only five fetal deaths among women who had the Essure® device, but acknowledged 299 additional fetal deaths after reviewing the Device Events reports.

86. The analysis showed that the manufacturers' reports were falsely marked as mere injury or malfunction reports. However, they described instances of miscarriage, abortion or fetal death, and should have been categorized as "death" reports.

87. Defendants' conduct violated the Essure® CPMA, parallel state laws regarding post-marketing conduct, and the FDA post-marketing regulations, which ultimately prevented Plaintiff, physicians, and the public from understanding the true nature of Essure®'s adverse events, risks, and ineffectiveness.

VI. FDA REQUIRES BLACK BOX WARNING FOR ESSURE®

88. In response to continued public complaints, on September 24 and 25, 2015, the FDA convened a public hearing concerning the safety and efficacy of the Essure® device.

89. On February 29, 2016, the FDA first 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. These actions included implementing a Black Box Warning and unprecedented Patient Decision Checklist.

90. On October 31, 2016, the FDA announced its Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, stating:

> "FDA believes that some women are not receiving or understanding information regarding the risks and benefits of permanent, hysteroscopically-placed tubal implants that are intended for sterilization. This guidance addresses these concerns by identifying labeling components, namely a boxed warning and patient decision checklist, which FDA intends to require as part of the labeling for these devices. FDA believes this will help to ensure a woman receives and understands the benefits and risks associated with her contraceptive options so that she can make an informed decision…"

91. The FDA advised that "[a]ccurate product labeling and effective messaging of that labeling is important to make device users and patients aware of the risks associated with permanent, hysteroscopically-placed tubal implants intended for sterilization. FDA believes that a boxed warning and a patient decision checklist as described in this guidance should be included."

92. The FDA took the following actions in its announcement:

a. 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, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions." The FDA draft guidance black box warning for Essure® also warns: "If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device."

b. Requiring Defendants 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 recommended Patient Decision Checklist is a three-page single spaced 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 "unintended pregnancy," "the risks of Essure on a developing fetus," and increased risk for…ectopic pregnancy…may result in serious and even life-threatening complications;" "continued pain or new pain;" "some women may develop allergic reactions…and have signs or symptoms such as rash and itching…may occur even if there is no prior history of sensitivity" and "there is no reliable test to predict ahead of time who may develop a reaction to the device;" "a sign of an Essure-related problem…might require further evaluation and treatment, including possibly the need to have the device removed by surgery;" "headaches, fatigue, weight changes, hair loss and mood changes such as depression;" "the device could poke through the wall of the uterus or fallopian tubes ("perforation") and/or move to other locations in the abdomen and pelvis ("migration");" "the device may become ineffective in preventing pregnancy and may lead to serious adverse events such as bleeding or bowel damage which may require surgery to address;" for removal "a surgical procedure will be required," including "hysterectomy (removal of the entire uterus);" and "device removal may not be covered by…insurance company.

c. Requiring Defendants "to conduct a new postmarket 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."

93. On September 2, 2016 the FDA approved the post-market surveillance study plan which required a sample size of 2,800 women of childbearing age who chose to undergo either hysteroscopic

sterilization with Essure® or laparoscopic tubal sterilization. The main safety endpoints of the study include evaluating; 1) chronic lower abdominal and/or pelvic pain, 2) abnormal uterine bleeding (new onset or worsening), 3) hypersensitivity and allergic reactions including autoimmune disorders or autoimmune-like reactions, and 4) invasive gynecologic surgery including Essure® insert removal. Secondary safety endpoints include other adverse events and effectiveness. This open-label, non-randomized, prospective observational cohort study will be the first clinical study to directly compare Essure® with tubal ligation.

94. On November 22, 2016, the FDA approved final labeling with Defendants' changes in response to the FDA's guidance. The Essure® patient information booklet was updated to include:

a. A black box warning that outlined reported adverse events such as perforations of the uterus and/or fallopian tubes, migration into the abdominal cavity, and persistent pain. The black box warning also warns that if the device needs to be removed, a surgical procedure will be required.

b. A patient decision checklist.

c. Additional warnings about long-term risks including Pain (acute or persistent) of varying intensity and length of time; warnings regarding hypersensitivity to Essure® components; that removal of the device will require surgery which may include removal of fallopian tubes and/or hysterectomy; that there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, neonatal complications, and genetic and developmental abnormalities in pregnancies with Essure®; and that other symptoms have been reported such as headache, fatigue, weight changes, hair loss, and mood changes.

95. On March 8, 2018, FDA Commissioner Scott Gottlieb issued a statement regarding the FDA's ongoing post-market review of Essure®. He stated, "While the FDA continues to believe that Essure® may be appropriate for some women based on our current information, the agency also recognizes that serious problems have been associated with its use. We're continuing to monitor adverse events reported to our database, as well as other data sources, such as the post-marketing (522) study, and will communicate publicly on any new findings or concerns."

96. On April 9, 2018, the FDA issued an order further restricting sales of the Essure® device to only doctors and healthcare facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement." Sale and distribution of Essure® is limited to healthcare providers who agree to review this checklist with patients, and give them the opportunity to sign it, before Essure® implantation. The Physician must also sign the document to verify that the warnings were given. The FDA issued this order after becoming aware that women were not being adequately informed of Essure's® risks prior to implantation. The FDA approved this new safety measure to ensure that the device meets standards for a reasonable assurance of safety and effectiveness. Additionally, the FDA announced plans to require Defendants to increase the number of participating study sites for their post-market surveillance study to account for declining sales volume of Essure®.

97. Unfortunately, these new warnings, labeling, and patient decision checklist came too late to warn Plaintiffs of the true risks of Essure®.

98. On July 20, 2018 Bayer notified the FDA that the Essure Permanent Birth Control Device will no longer be sold or distributed in the United States after December 31, 2018. The same day, FDA Commissioner Scott Gottlieb issued a statement regarding Bayer's decision to halt sales of Essure. He stated, "The device has been associated with serious risks including persistent pain, perforation of the uterus and fallopian tubes, and migration of the coils into the pelvis or abdomen. As the FDA learned more from patients about the serious adverse events associated with this device, we took a series of important actions to better understand the benefits and risks, and to address patient safety concerns."

99. He stated that, "When we [FDA] first became aware of an increase in adverse events submitted to our database concerning this device, we launched an ongoing effort to review these reports to better understand concerns." Commissioner Gottlieb outlined the FDA's efforts regarding Essure, described above, and further stated, "Since the FDA ordered Bayer to conduct the post-market study and then to add a boxed warning and a Patient Decision Checklist to the labeling, there has been an approximate 70 percent decline in sales of Essure in the U.S. The company stated its decision to halt sales and distribution of the device was due to commercial reasons."

100. Notwithstanding Bayer's decision to remove Essure from the market, they must still meet their postmarket obligations regarding the device, including timely reporting adverse events in those who

have had Essure implanted, and proceeding with the 522 post market study. "Each study participant will be followed for a total of three years and the company will continue to submit reports to the FDA on the study's progress and results."

101. Had Defendants complied with their federal regulatory duties and their duties under California law by warning about and reporting the known risks and complications in a timely fashion, Plaintiffs and their physicians would have had this relevant, critical information available to them before the implantation of the Essure® device. Plaintiffs would not have chosen to have the Essure® device implanted had they been warned by Defendants of the risks and complications associated with the device.

IX. CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE

102. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

103. Defendants formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, Essure®, including the Essure® devices that were implanted into Plaintiffs.

104. Defendants had a duty under parallel state law, including California law, to exercise reasonable care to provide adequate warning about the risks and dangers of Essure® that were known or knowable to Defendants at the time of distribution.

105. Defendants breached their duty in that they failed to comply with federal regulations by not adequately investigating and/or handling the complaints that they had received related to Essure which led to a failure to properly or timely report adverse events to the FDA.

106. Defendants breached their duty in that they failed to warn Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Essure® prior to the time of Plaintiffs' implantation.

107. Specifically, Defendants breached these duties and violated federal and state law by, *inter alia*: receiving and failing to warn of or report many of the approximately 32,000 complaints about Essure®

to the FDA or the public and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Essure®, including but not limited to:

a. instances of perforation and/or penetration of the fallopian tubes;

b. instances of perforation and/or penetration of the uterus;

c. instances of perforation and/or penetration of the bowel;

d. instances of perforation and/or penetration of the abdominal cavity;

e. instances of perforation and/or penetration of the peritoneal cavity;

f. instances of migration;

g. instances of chronic/persistent abdominal and pelvic pain/cramping;

h. instances of chronic/persistent irregular vaginal bleeding;

i. instances of the device internally separating or breaking into pieces; and

j. instances of adverse events/reactions requiring surgical device removal.

108. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Essure®, in violation of state law, including California law, the Essure® CPMA and FDA regulations.

109. In addition, the Essure® CPMA set forth specific reporting requirements - as described above - that obligated Defendants to report:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;

b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;

c. any knowledge or information of Essure®'s failure to meet any device specifications established in the approved CPMA;

d. any changes to the performance of the device;

e. any information from any source that reasonably suggests a device may have caused or contributed to serious injury; and

f. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

110. Defendants negligently failed to comply with the above requirements and failed to take necessary action to timely advise users of Essure® of the defects and risks described above. By failing to comply with federal regulations, Defendants failed to properly meet the applicable standard of care under state law, including California law.

111. Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded.

112. Defendants were cited in 2002, 2003, 2008, 2011 and 2013 by the FDA and CDHP for: failure to report complications it knew were associated with Essure®. These violations were not isolated events, but represented ongoing, systematic, and widespread conduct by Defendants that signified problems with the device starting before Plaintiffs received their Essure® implants and continuing through at least August 2015.

113. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physicians, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' physicians, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

114. In this case, once the medical community and the FDA became aware of the true frequency of adverse events associated with Essure, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiffs have experienced due to Essure®.

115. Defendants' delay in timely reporting their known complications prevented the Plaintiff and her physicians from having timely information concerning the real-life risks associated with the Essure® device. Had Plaintiffs received timely and adequate information of these serious risks and adverse events, they would not have consented to the Essure® implant.

116. Once the medical community and the FDA became aware of the undisclosed adverse events,

physicians began to study Essure® adverse events further and published articles in well-respected medical journals. This information would have been available for review by Plaintiffs and Plaintiffs' physicians.

117. Indeed, if Plaintiffs and Plaintiffs' physicians had been adequately warned of these serious risks and adverse events, they would not have agreed to or used the Essure® implant. As a proximate and legal result of Defendants' failure to comply with its CPMA and FDA post-marketing regulations, Defendants breached their duty of care to Plaintiffs under parallel state law and caused Plaintiffs' past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

118. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their CPMA and the FDCA. Violations of the following federal regulations also constitute violations of Defendants' parallel state law duties and give rise to negligence *per se*: 21 C.F.R. § 803.10; 21 C.F.R. §803.17; 21 C.F.R. §803.18; 21 C.F.R. §803.20; 21 C.F.R. §803.22; 21 C.F.R. §803.3; 21 C.F.R. §803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21 C.F.R. §803.22; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. §820.198.

119. Plaintiffs are within the class of persons the statutes and regulations protect, and Plaintiffs' injuries are of the type of harm these statutes and regulations are designed to prevent.

120. Defendants' violations of these statutes and regulations proximately caused Plaintiffs' injuries alleged herein.

121. The conditions of the Essure® CPMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the CPMA. *See* 21 C.F.R. § 814.82(c).

122. As a proximate and legal result of Defendants' failure to exercise reasonable, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

123. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

124. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

125. Defendants failed to warn Plaintiffs and their physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

126. Specifically, Defendants failed to:

a. report more than 32,000 complaints about Essure® to the FDA or the public;

b. report Essure®'s nonconformity with its performance specifications; and

c. update Essure®'s labeling or report to the FDA and the medical community their post-market information regarding complaints about Essure®.

127. Plaintiffs' Essure® devices were defective at the time of sale and distribution and at the time it left the possession of Defendants in that Defendants failed to adequately warn of the risks of migration, perforation, penetration, device breakage, removal, chronic abnormal bleeding and pain, autoimmune response, and other injuries involved in the use of Essure®. The accurate rate of occurrence for these and other injuries associated with the use of Essure® were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' physicians.

128. The Essure® devices were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the products created a serious risk of migration, perforation, penetration, autoimmune response, and other harm to consumers, and Defendants failed to adequately warn consumers of said risks - including Plaintiffs and/or their healthcare providers - in accordance with state law, including California law.

129. The Essure® devices manufactured and sold by Defendants were defective and unreasonably dangerous due to inadequate warnings and instructions because Defendants knew or should have known that Essure® created, among other things, a higher than expected risk for adverse events, and Defendants failed to adequately warn of those risks, to monitor those risks, report them, and update its labeling regarding such risks when the information became available.

130. At all relevant times, Plaintiffs' Essure® devices were prescribed and used as intended by

Defendants and in a manner reasonably foreseeable to Defendants.

131. The Essure® devices manufactured, marketed, promoted, and sold by Defendants were expected to, and did, reach Plaintiffs without substantial change in the condition in which they were sold.

132. Despite the fact that Defendants knew or should have known that the use of Essure® was unreasonably dangerous and likely to place users at serious risks to their health, Defendants failed to monitor and warn of the defects, health hazards, and risks associated with Essure®.

133. At the time of sale and distribution, and at the time the devices left the possession of Defendants, Plaintiffs' Essure® devices differed from Defendants' intended result and design specifications.

134. The failures inherent in the Essure® devices were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' physicians.

135. At all relevant times, Plaintiffs' Essure® devices were prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

136. The Essure® devices manufactured, designed, promoted, marketed, and sold by Defendants were expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

137. Defendants knew that the Essure® devices would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

138. At all times relevant to this action, the dangerous propensities of Essure® were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to prescribe and implant Essure® for their patients.

139. Defendants knew that physicians and other healthcare providers began prescribing this product as a safe and effective contraceptive device despite its potential for serious, severe, and permanent side effects.

140. Defendants were required to provide adequate warnings to consumers and the medical community under federal and state law, including California law, but failed to do so in a timely and responsible manner.

141. Had Defendants timely and adequately reported the adverse events to the FDA, there would have been effective warnings to physicians, including Plaintiffs' physicians, of those adverse events both

directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' physicians, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

142. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiffs have experienced due to Essure®.

143. Defendants' delay in timely reporting their known complications prevented Plaintiffs and their physicians from having updated information concerning the real-life risks associated with the Essure® device. Had Plaintiffs and their physicians received timely and adequate information of these serious risks and adverse events, they would not have agreed to the Essure® implant, nor would their physicians have recommended use of this product.

144. Essure®, which was manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendants, was a substantial contributing factor in bringing about Plaintiffs' injuries, which would not have occurred but for the use of Essure®.

145. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiffs that would not have occurred but for the use of Essure®.

146. As a proximate result and/or substantial factor of the Essure®'s defective condition at the time it was sold, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

147. By reason of the foregoing, Plaintiffs have been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

148. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION

CONCEALMENT

149. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

150. At all times mentioned in this Complaint, Defendants had the duty and obligation to truthfully represent the facts concerning Essure® to Plaintiffs and/or their healthcare providers pursuant to federal and state law outlined herein.

151. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk is liable for any damages which she thereby suffers.

152. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the suppression of fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact.

153. Defendants willfully deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by concealing material information concerning Essure®- which Defendants had a duty to disclose, thus misrepresenting the true nature of the device.

154. As described in the forgoing sections, Defendants concealed material facts concerning Essure® from Plaintiffs, their physicians, and other healthcare providers.

155. Specifically, Defendants received and concealed many of the approximately 32,000 complaints about Essure® to the FDA or the public and concealed their knowledge and information regarding complaints about Essure®, including but not limited to:

a. instances of perforation and/or penetration of the fallopian tubes;

b. instances of perforation and/or penetration of the uterus;

c. instances of perforation and/or penetration of the bowel;

d. instances of perforation and/or penetration of the abdominal cavity;

e. instances of perforation and/or penetration of the peritoneal cavity;

f. instances of migration;

g. instances of chronic/persistent abdominal and pelvic pain/cramping;

h. instances of chronic/persistent irregular vaginal bleeding;

i. instances of the device internally separating or breaking into pieces; and

j. instances of adverse events/reactions requiring surgical device removal.

156. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants concealed the health hazards and increased risks associated with Essure®, in violation of state law, including California law, the Essure® CPMA and FDA regulations.

157. In addition, in violation of their CPMA, federal law and state law including California law, Defendants concealed:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;

b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;

c. any knowledge or information of Essure®'s failure to meet any device specifications established in the approved CPMA;

d. any changes to the performance of the device;

e. any information from any source that reasonably suggests a device may have caused or contributed to serious injury; and

f. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

158. As described above in the foregoing section, Defendants made affirmative representations to Plaintiffs and/or their physicians before Essure® was implanted in Plaintiffs, while concealing and omitting the material facts including but not limited to those set forth herein. Defendants intended that Plaintiffs, their physicians, and the healthcare industry would rely on their representations, leading to the use of Essure® by Plaintiffs.

159. Defendants intentionally, willfully, and maliciously concealed and/or suppressed material information from Plaintiffs and their physicians with the intent to defraud as alleged herein.

160. Even if Defendants disclosed some information regarding adverse events, their failure to correct inaccuracies and fully disclose material information left any previous disclosure deceptive.

161. By failing to ensure representations regarding Essure® were truthful, accurate, and not misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

162. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiffs and their physicians.

163. After the concealed information became known, the FDA mandated the addition of the black box warning and other dramatic changes to the FDA-approved label, including but not limited to an unprecedented patient-decision checklist.

164. Neither Plaintiffs nor their healthcare providers were aware, nor could have been aware, of the concealed and/or suppressed facts. Had Plaintiffs and/or their healthcare providers been aware of those facts, they would not have purchased and used Essure®, and Plaintiffs would not have been injured as a result.

165. Plaintiffs and her physicians justifiably relied on and/or were induced by Defendants' misrepresentations and/or concealment. Specifically, Plaintiffs would never have had the Essure® device implanted had they been aware that there were multiple reports of device migration and perforations of human cavities or that there had been over 32,000 complaints regarding Essure®.

166. It is reasonable that Plaintiffs, their physicians, and the healthcare industry would rely on the statements of Defendants regarding whether Essure® was safe and effective because, as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

167. Defendants had a duty to warn Plaintiffs, their physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiffs and their healthcare providers reasonably relied on Defendants' deception and, Plaintiffs were implanted with Essure® and subsequently sustained injuries and damages as described herein. Defendants' concealment was a substantial contributing factor in causing Plaintiffs' injuries.

168. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs seek punitive damages according to proof.

169. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be

proven at trial.

170. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

171. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

172. At all times mentioned in this Complaint, Defendants had the duty and obligation to truthfully represent the facts concerning Essure® to Plaintiff and/or her healthcare providers.

173. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk is liable for any damages which she thereby suffers.

174. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true.

175. Defendants negligently deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by suggesting untrue facts about their product that they had no reasonable ground for believing to be true.

176. Conceptus' marketing plan not only involved the creation and dissemination of advertisements and marketing materials to the patient; Conceptus also invested heavily in a specialized sales force designed to teach physicians how to market Essure®, generate a referral network, and grow their practice using Essure®. Conceptus' marketing campaigns to physicians included the following:

a. Conceptus' concierge development team and practice program provided all of the necessary Essure® marketing materials to the physician; including posters, pamphlets, promotional letter templates, in-office videos, web-based materials, interactive patient education tools, and phone hold message templates.

b. Conceptus advised both physicians and their staff on Essure® public relations, patient counseling techniques, and how to answer patient questions about Essure®. This included role-

playing how to introduce Essure® information to all patients and telephone patient counseling conversation training.

c. Conceptus advised physician staff on reimbursement and other administrative issues related to Essure® with their Essure® Office Management Program.

d. Conceptus helped physicians design their procedure room infrastructure.

e. Conceptus advised physicians how to use external marketing campaigns to draw Essure® patients via radio, TV, DTC, or print.

f. Conceptus advised physicians how to create an extensive public relations plan to include local corporations, plastic surgeons, and other non OB/GYNs into their referral network for Essure®.

g. Conceptus not only used monetary incentive compensation plans in their own salesforce, they also advised physicians how to integrate staff incentive/motivation plans for increased Essure® sales into their practice.

h. The development team also utilized Conceptus e-newsletters, conference presentations, and multi-day intensive Essure® Summit seminars.

177. Defendants authorized and pioneered a sales plan aimed at physicians that placed profits above patient care. The marketing materials, marketing plans, and sales tactics described above incorporated misrepresentations about the efficacy, risks, and complications of Essure®. These and other misrepresentations also permeated Defendants' DTC marketing and advertising. Whether it was in an advertisement in a magazine, or from counseling received in her doctor's office, the Essure® patient received Defendants' deceptive message about the superiority of Essure®.

178. Defendants directed their willful dissemination of false and misleading information at a time when there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in Defendants' possession.

179. The specific misrepresentations and coinciding facts are identified in Plaintiffs' short form complaints. These statements were false and/or misleading, violating federal law and state law,

including California law.

180. Pursuant to 21 U.S. Code § 352 (m), a medical device is rendered misbranded if its advertising is false or misleading in any particular.

181. Additionally, in the case of any restricted device distributed or offered for sale in any State, such a device is rendered misbranded 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, a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

182. Pursuant to 21 U.S. Code § 321 (n), if an article is alleged to be misbranded because the advertising is misleading, then in determining whether the advertising is misleading, there shall be taken into account (among other things), not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the advertising relates under the conditions of use prescribed in the advertising thereof or under such conditions of use as are customary or usual.

183. Defendants' concealment of adverse events, health hazards, and risks associated with Essure® rendered the Essure® device misbranded.

184. Even if Defendants disclosed some information regarding adverse events, their failure to correct inaccuracies and fully disclose material information left any previous disclosure deceptive.

185. By failing to ensure representations regarding Essure® were truthful, accurate, and not misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

186. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiff and her physicians.

187. Neither Plaintiff nor her healthcare providers were aware of the true risks and complications

associated with Essure®. Had Plaintiff and/or her healthcare providers been aware of those facts, she would not have purchased and used Essure®, and Plaintiff would not have been injured as a result.

188. Plaintiff and her physicians justifiably relied on and/or were induced by Defendants' negligent misrepresentations. Specifically, Plaintiff would never have had the Essure® device implanted had she been aware that there were multiple reports of device migration and perforations of human cavities, or that there had been more than 32,000 complaints regarding Essure®.

189. It is reasonable that Plaintiff, her physicians, and the healthcare industry would rely on the statements of Defendants regarding whether Essure® was safe and effective because, as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

190. Defendants had a duty to warn Plaintiff, her physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. As a proximate result of the negligent misrepresentations set forth above, Plaintiff and her healthcare providers reasonably relied on Defendants' deception, were implanted with Essure®, and subsequently sustained injuries and damages as described herein. Defendants' negligent misrepresentations were a substantial contributing factor in causing Plaintiff's injuries.

191. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she entitled to compensatory and other damages in an amount to be proven at trial.

192. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff seeks punitive damages according to proof.

193. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION

FRAUD/ INTENTIONAL MISREPRESENTATION

194. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

195. Defendants violated the Essure® CPMA and §§ 502(q) and (r) of the FDCA and parallel state laws by engaging in false and misleading advertising of Essure®.

196. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants concealed health hazards and risks associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to warn or otherwise ensure the safety of its users in violation of state law, including California law, the Essure® CPMA and FDA regulations.

197. Conceptus' marketing plan not only involved the creation and dissemination of advertisements and marketing materials to the patient; Conceptus also invested heavily in a specialized sales force designed to teach physicians how to market Essure®, generate a referral network, and grow their practice using Essure®. Conceptus' marketing campaigns to physicians included the following:

a. Conceptus' concierge development team and practice program provided all of the necessary Essure® marketing materials to the physician; including posters, pamphlets, promotional letter templates, in-office videos, web-based materials, interactive patient education tools, and phone hold message templates.

b. Conceptus advised both physicians and their staff on Essure® public relations, patient counseling techniques, and how to answer patient questions about Essure®. This included role-playing how to introduce Essure® information to all patients and telephone patient counseling conversation training.

c. Conceptus advised physician staff on reimbursement and other administrative issues related to Essure® with their Essure® Office Management Program.

d. Conceptus helped physicians design their procedure room infrastructure.

e. Conceptus advised physicians how to use external marketing campaigns to draw Essure® patients via radio, TV, DTC, or print.

f. Conceptus advised physicians how to create an extensive public relations plan to include local corporations, plastic surgeons, and other non OB/GYNs into their referral network for Essure®.

g. Conceptus not only used monetary incentive compensation plans in their own salesforce, they also advised physicians how to integrate staff incentive/motivation plans for increased Essure® sales into their practice.

h. The development team also utilized Conceptus e-newsletters, conference presentations, and multi-day intensive Essure® Summit seminars.

198. Defendants authorized and pioneered a sales plan aimed at physicians that placed profits above patient care. The marketing materials, marketing plans, and sales tactics described above incorporated misrepresentations about the efficacy, risks, and complications of Essure®. These and other misrepresentations also permeated Defendants' DTC marketing and advertising. Whether it was in an advertisement in a magazine, or from counseling received in her doctor's office, the Essure® patient received Defendants' deceptive message about the superiority of Essure®.

199. Defendants directed their willful dissemination of false and misleading information at a time when there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in Defendants' possession.

200. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, including California law, but also failed to provide information that was necessary for the medical and scientific community to protect each patient's interest. Because the Defendants failed to timely, completely, or accurately disclose their knowledge of the risks and complications associated with the Essure® device, the public's knowledge of the risks associated with the Essure® device were seriously hampered and delayed. This delay of information endangered patient safety, including Plaintiff's safety.

201. At all times mentioned in this Complaint, Defendants had the duty and obligation to disclose to Plaintiff and/or her healthcare providers, the true facts concerning Essure®.

202. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk is liable for any damages which she thereby suffers.

203. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the suggestion, as a fact, of that which is not true, by one who does not believe it to be true.

204. Defendants willfully deceived Plaintiffs, their healthcare providers, the medical community, and

the public in general, by suggesting untrue facts about their product that they knew to be false.

205. The specific misrepresentations and coinciding facts are identified in Plaintiffs' short form complaints. These statements were false and/or misleading, violating federal law and state law, including California law.

206. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiffs and their physicians.

207. Neither Plaintiffs nor their healthcare providers were aware of the true risks and complications associated with Essure®. Had Plaintiffs and/or their healthcare providers been aware of those facts, they would not have purchased and used Essure®, and Plaintiff would not have been injured as a result.

208. Plaintiffs and their physicians justifiably relied on and/or were induced by Defendants' intentional misrepresentations. Specifically, Plaintiffs would never have had the Essure® device implanted had they been aware that there were multiple reports of device migration and perforations of human cavities or that there had been more than 32,000 complaints regarding Essure®.

209. It is reasonable that Plaintiffs, their physicians, and the healthcare industry would rely on the statements of Defendants because, as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

210. Defendants had a duty to warn Plaintiffs, their physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff and her healthcare providers reasonably relied on Defendants' deception, were implanted with Essure®, and subsequently sustained injuries and damages as described herein. Defendants' deception was a substantial contributing factor in causing Plaintiffs' injuries.

211. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

212. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs seek

punitive damages according to proof.

213. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

214. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

215. The specific express warranties communicated to Plaintiffs and coinciding facts are identified in Plaintiffs' short form complaints.

216. Defendants breached those warranties because the Essure® devices implanted into Plaintiffs and Plaintiffs' experience with Essure® did not conform to the express warranties created by Defendants and instead Plaintiffs suffered severe physical injuries, mental anguish, economic loss, and other injuries.

217. Defendants' express warranties were specifically and expressly communicated to Plaintiffs in such a manner that Plaintiffs understood and accepted them.

218. Defendants' affirmations of fact or promise and descriptions of Essure® created a basis of the bargain for Plaintiffs and/or their physicians.

219. At the time of making of the express warranties, Defendants had knowledge of the purpose for which Essure® was to be used and warranted the device to be in all respects fit, safe, effective, and proper for such purpose. Essure® was unaccompanied by adequate warnings of its dangerous propensities and lack of effectiveness that were either known or knowable to Defendants at the time of distribution and sale.

220. Defendants' breaches of their express warranties under state law parallel their violations of federal law; the Essure® CPMA specifically mandates, and state law, including California law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

221. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract 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."

222. Plaintiffs and/or their healthcare providers reasonably relied upon said express warranties, in choosing to use Essure®.

223. As soon as the true nature of Essure® and the fact that the warranties and representations were false was ascertained, Defendants were on notice of the breach of said warranties.

224. As a proximate result of Defendants' warranties and Plaintiff's and Plaintiff's physician's reliance on same, Plaintiff has suffered and continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

225. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION

MANUFACTURING DEFECT

226. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

227. After Essure® was approved for sale by the FDA in 2002, Defendants had a duty under state law, including California law, to exercise reasonable care in the manufacture of Essure® and to manufacture the Essure® devices consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval.

228. Defendants negligently failed to comply with FDA regulations and specifications for the Essure© device and were cited by the FDA for, *inter alia*:

a. failing to conform to the approved Essure® design specifications;

b. failing to use components that were fully certified;

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

d. manufacturing Essure® at an unlicensed facility;

e. failing to analyze or identify existing potential causes of non-conforming product and other quality problems;

f. failing to track non-conforming product;

g. failing to follow procedures used to control products which did not conform to specifications;

h. failing to have a complete Design Failure Analysis; and

i. failing to document CAPA activities for a supplier correction action.

229. Defendants negligently failed to comply with FDA regulations and its parallel duties under state law, including California law, thereby jeopardizing the health of patients.

230. These violations were not isolated events, but represented ongoing, systematic, and widespread conduct by Defendants that signified problems with the device starting before Plaintiffs received their Essure® implants and continuing through at least August 2015.

231. Conceptus' knowledge that its Essure devices did not comply with regulatory requirements and the PMA specification can be seen throughout its filings with the SEC beginning in 2005 and therein after annually for nearly a decade. Conceptus admits its dependence on, and concerns that, it's third-party sub-contractors may not comply with FDA and other health authority regulations:

a. "We have limited experience manufacturing our product in the volumes that will be necessary to achieve significant commercial sales. To achieve our production volume objectives, we decided to outsource our manufacturing activity to a third party contract manufacturer..."

b. "We transitioned almost all of our internal manufacturing operations to Accellent by the end of 2004 to manufacture the components and assemble our product. Similarly, we have subcontracted with Sterigenics International to handle the sterilization of our products. **We cannot assure you that we, our contract manufacturer, component suppliers or other subcontractors will be able to maintain compliance with all regulatory requirements.**" (Emphasis added).

c. "Furthermore, **we cannot assure you** that if we find it necessary to engage new manufacturers, suppliers or subcontractors to satisfy our business requirements that we will be able to locate **new manufacturers, suppliers or contractors who are in compliance with regulatory requirements**." (Emphasis added).

d. "We depend on our contract manufacturer to supply our commercial product

requirements and we may experience disruption in supply if they are not in compliance with FDA and other health authority regulations ..."

e. "If Accellent does not comply with FDA and other health authority regulations or encounters manufacturing difficulties, this could negatively impact sales of the Essure system."

f. "We may not maintain regulatory approvals for the Essure system, our only product..."

g. "If we or Accellent, our third party manufacturer, do not comply with applicable regulatory requirements, we may be subject to warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of approvals and criminal prosecution, among other penalties."

h. "Our suppliers may encounter problems during manufacturing due to a variety of reasons, including **failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunctions, labor shortages or environmental factors.**" (Emphasis added).

232. The specific facts concerning which Essure® lot Plaintiffs' devices were from, the defects determined to be present in those lots, and the defects present in Plaintiffs' devices are alleged in Plaintiffs' short form complaints.

233. Upon information and belief, the devices implanted into Plaintiffs were negligently manufacturered and contained defects that rendered the device noncompliant with FDA regulations and specifications.

234. The devices are not intended to deform, crack, fracture, or break before, during, or any time after implantation. Defendants received notices of each of these types of failure modes, yet failed to, among other things: (1) promptly investigate the cause of the device failure modes; (2) notify the public that they had occurred; or (3) report the adverse events and the device failure modes to the FDA.

235. As a proximate and legal result of Defendants' failure to manufacture the Essure® devices consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval, Plaintiffs have suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an

amount to be proved at trial.

236. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

EIGHTH CAUSE OF ACTION

LOSS OF CONSORTIUM

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

238. At all relevant times hereto, Spouse Plaintiff was and is the lawful spouse of Plaintiff.

239. As a direct and proximate result of the injuries sustained by Plaintiff and caused by Defendants, Spouse Plaintiff suffered, and will continue to suffer the loss of his wife's consortium, companionship, society, affection, services and support.

240. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

X. REQUEST FOR PUNITIVE DAMAGES

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

242. At all times relevant herein, Defendants:

a. knew or should have known that Essure® was dangerous, defective, and ineffective;

b. concealed the dangers and health risks from Plaintiffs, physicians, other medical providers, the FDA, and the public at large;

c. attempted to misrepresent and did knowingly make misrepresentations to Plaintiffs, their physicians, hospitals, other medical providers, and the public in general, as previously stated herein, as to the safety and efficacy of Essure®; and

d. with full knowledge of the health risks associated with Essure® and without adequate warnings of the same, manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, promoted, marketed, advertised, distributed, and sold Essure® for use.

243. Defendants, by and through its officers, directors, managing agents, authorized sales

representatives, employees, and/or other agents who engaged in malicious, fraudulent, and oppressive conduct towards Plaintiffs and the public, acted with willful, wanton, conscious, and/or reckless disregard for the safety of Plaintiffs and the general public.

244. Defendants' knowingly withheld material information from the medical community and the public, including Plaintiffs, concerning the safety of Essure®. Defendants' conduct was willful, wanton, and undertaken with a disregard for Plaintiffs' rights.

245. Notwithstanding the foregoing, Defendants continued to market Essure® to consumers, including Plaintiff herein, without disclosing the risks.

246. Defendants knew of Essure®'s lack of warnings, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell Essure® without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Essure®.

247. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Essure® against its benefits.

248. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiffs suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiffs have become liable.

249. Defendants are liable jointly and/or severally for all general, special, and compensatory damages to which Plaintiffs are entitled by law. Plaintiffs seek actual and punitive damages from Defendants and allege that the conduct of Defendants was committed with knowing, conscious, careless, reckless, willful, wanton, deliberate, and grossly negligent disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

250. WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorney's fees, and all such other relief as the Court deems appropriate pursuant to common law and statutory law.

XI. AGENCY, ALTER EGO, JOINT VENTURE, AND CONSPIRACY

251. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set

forth herein and further allege as follows:

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

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

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

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

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

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

258. At all times herein mentioned, each of the Defendants was engaged in the business of and/or was a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing,

advertising for sale, and/or selling Essure® device for use by Plaintiffs and their physicians. As such, each of the Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

259. The conduct of Defendants caused Plaintiff harm as described herein. Plaintiffs' harm is not in any way attributable to any fault of Plaintiffs or any third party or instrumentality. Uncertainty may exist regarding which Defendant and/or combination of Defendants caused Plaintiff's harm. Defendants possess superior knowledge and information regarding which Defendant and/or combination of Defendants caused Plaintiffs' injuries. Thus, the burden of proof is upon each Defendant to prove the Defendant did not cause Plaintiff's harm as described herein.

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

261. Due to the above, each cause of action is asserted against each Defendant herein, jointly and severally, even if each and every Defendant is not specifically identified as to each and every count.

XII. EQUITABLE TOLLING/FRAUDULENT CONCEALMENT

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

263. Defendants' failure to report, document, or follow up on the known adverse event complaints, and concealment of adverse events, known defects, serious increased risks, dangers, and complications, constitute fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiff herein.

264. Defendants are 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 defects, suppressed reports and adverse information, failed to satisfy FDA and PMA requirements, failed to satisfy FDA and PMA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and Plaintiffs.

265. Instead, Defendant represented that Essure® was safer, more effective and the best alternative for permanent female sterilization despite their knowledge to the contrary.

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

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

268. Defendants 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 systematic failure to disclose and/or cover up such information from/to Plaintiffs, Plaintiffs' physicians, and the public.

269. Defendants' acts and omissions, before, during, and/or after the act causing Plaintiffs' injury prevented Plaintiffs and/or their physicians from discovering the injury or cause thereof until recently.

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

XIII. RELIEF REQUESTED

WHEREFORE Plaintiffs pray for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1. compensatory damages, including, but not limited to, pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial;
2. economic damages in the form of medical expenses, out of pocket expenses, lost earnings and earning capacity, and other economic damages in an amount to be determine at trial;
3. an award of attorneys' fees and costs;
4. prejudgment interest;
5. post-judgment interest;
6. punitive or exemplary damages according to proof; and
7. for such other and further relief as this Court may deem just and proper.

XIV. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all of her claims.

Date_____

By: _____

EXHIBIT B

_____

_____

_____

_____

_____

[*Counsel for Plaintiffs*]

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF _____ - UNLIMITED JURISDICTION

COORDINATION PROCEEDING SPECIAL TITLE [Rule 1550(b)]	CASE NO. JCCP 4887
	ASSIGNED FOR ALL PURPOSES TO: Judge Winifred Y. Smith Dept. 21
IN RE: ESSURE PRODUCT CASES _____	**SHORT FORM COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**
THIS DOCUMENT RELATES TO:	
_____,	
Plaintiff(s)	
v.	
BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 10, inclusive,	
Defendants	

COMES NOW the Plaintiff(s), _____, and file this Complaint seeking judgment against Defendants BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC.

(F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 10, inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of Plaintiff(s) being implanted with the permanent birth control device Essure®.

Plaintiff(s) incorporate(s) by reference relevant portions of the *Master Long Form Complaint and Demand for Jury Trial* (and any and all amendments thereto approved by this Court) in Judicial Council Coordinated Proceeding No. 4887, *In re Essure Product Cases* ("JCCP 4887"), filed as of _____, under Docket Number _____ in Superior Court of California, County of Alameda, before the Honorable Winifred Y. Smith. Pursuant to Case Management Order No. __, this *Short Form Complaint* is utilized in the above-captioned action. Plaintiff(s) select(s) and indicate(s) by checking off the appropriate spaces, those claims that are specific to his or her case. Where certain claims require additional pleading or case specific facts and individual information, Plaintiff(s) shall add and include them herein.

INDIVIDUAL PLAINTIFF ALLEGATIONS

1. Plaintiff _____ is a citizen and resident of __*[city]*_____, ___*[county]*_____ County, __*[State]*_____.

2. Venue is proper in this county in accordance with §395(a) of the California Code of Civil Procedure because:

_____At all relevant times Plaintiff(s) _____ resided in this county and the injuries alleged herein arose from conduct that occurred in this county.

_____At all relevant times Defendants resided in this county and the injuries alleged herein arose from conduct that occurred in this county.

3. Plaintiff brings this action:

_____ On behalf of herself;

_____ As a representative of _____;

_____ As administrator of the estate of _____ who died on ___*[date]*____

in the state of __*[State]*_____.

4. Plaintiff claims damages as a result of:

_____ injury to herself

_____ injury to the person represented

_____ wrongful death

_____ survivorship action

_____ economic loss

_____ loss of services

5. Plaintiff's action is:

_____ a new case

_____ a case previously filed and ordered coordinated into JCCP No. 4887.

_____ a case previously filed and pending coordination into JCCP No. 4887.

Plaintiff's add-on petition and supporting documents were filed on _____.

6. Plaintiff was implanted with the Essure® permanent birth control device on ___*[date]*__, in the state of __*[state]*_____.

7. At the time of implantation, Plaintiff was a resident of ____*[State]*__.

8. Plaintiff has suffered injuries and complications as a result of implantation of the Essure® permanent birth control device manufactured by Defendants, as described in the forthcoming Plaintiff Fact Sheet.

9. The following claims asserted in the Amended Master Complaint and the allegations with regard thereto in the Amended Master Complaint are herein adopted by reference:

____Count I: Negligence

____Count II: Strict Product Liability

____Count III: Concealment

____Count IV: Intentional Misrepresentation

i. _____

_____

_____

_____

____Count V: Negligent Misrepresentation

i. _____

_____

_____

_____

____Count VI: Breach of Express Warranty

i. _____

_____

_____

_____

____Count VII: Manufacturing Defect

i. _____

_____

_____

_____

____Count VIII: Loss of Consortium

i. Plaintiff _____ (hereinafter "Spouse Plaintiff") was married to Injured from _____to _____, and is a citizen and resident of __*[city]*_____, ___*[county]*_____ County, __*[State]*_____.

ii. As a direct and proximate result of the injuries sustained by Injured and caused by Defendants, Spouse Plaintiff suffered, and will continue to suffer the loss of his/her spouses' consortium, companionship, society, affection, services and support.

10. Plaintiff asserts the following additional facts or theory of recovery against Defendants:

_____

_____

_____

11. The Defendants by their actions or inactions, proximately caused Plaintiff(s)' injuries.

12. As a result of the injuries Plaintiff(s) sustained, he/she/they is/are entitled to recover compensatory damages for past, present and future: pain and suffering, emotional distress, economic loss, as well as punitive damages and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff(s),_____, pray(s) for relief and judgment against Defendants as set forth in the *Master Long Form Complaint and Demand for Jury Trial* as appropriate.

JURY DEMAND

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

Date: _____

Respectfully submitted,

Counsel for Plaintiff(s)

_____

_____

_____

_____

_____

PROOF OF SERVICE

STATE OF DELAWARE)
) SS
COUNTY OF NEW CASTLE)

I am employed in the County of New Castle, State of Delaware. I am over the age of 18 years and not a party to the within action. My business address is 123 Justison Street, Wilmington, Delaware, 19801.

On September 12, 2018, I served the foregoing document(s) described as:

- ✓ **NOTICE OF ENTRY OF CASE MANAGEMENT ORDER NO. 10: MASTER AND SHORT FORM COMPLAINT**
- ✓ **PROOF OF SERVICE**

on all interested parties in this action as follows:

- ✓ (VIA CASE ANYWHERE) I served the above-listed documents electronically to Case Anywhere pursuant to Case Management Order No. 2, [The document will be deemed served on the date that it was uploaded to the website as indicated by the Case Anywhere system].

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 12, 2018 at Wilmington, Delaware

/s/ *Jacquelyn Aguirre*
JAQUELYN AGUIRRE

EXHIBIT 126

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

COORDINATED PROCEEDING SPECIAL TITLE [RULE 1550(b)] ESSURE PRODUCT CASES	No. JCCP 4887 ORDER (1) OVERRULING DEMURRER TO AFFIRMATIVE DEFENSES IN ANSWER, (2) GRANTING IN PART MOTION ON CHOICE OF LAW, AND (3) ADDRESSING CASE MANAGEMENT. DATE 5/16/19 TIME 9:00 AM DEPT 21

The demurrer of plaintiffs to the affirmative defenses of Bayer was set for hearing on 5/16/19 in Department 21, the Honorable Winifred Y. Smith presiding. Plaintiffs and Defendants appeared at the hearing through counsel of record. The Court, after full consideration of all papers submitted in support and opposition to the motion, as well as the oral arguments of counsel, decides as follows: IT IS HEREBY ORDERED: The demurrer of plaintiffs to affirmative defenses 87-480 in Bayer's answer is OVERRULED. The demurrer of plaintiffs is construed as a motion to determine choice of law and is GRANTED IN PART.

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PROCEDURE

The Master Complaint filed 8/28/18 asserts that Bayer is liable to each individual plaintiff because Conceptus and then Bayer developed and marketed Essure without adequately warning consumers about the risks. (CMO 10, Attachment.) The central allegation in the Master Complaint is that from 2002 through 2018 Conceptus and Bayer breached their obligation to update warnings and report adverse events. (Cpt para 53-101).[1] (*Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413, 436 ("*Coleman*").) (Pltf brief filed 5/6/19 at 1:23-2:1. 3:15-19.) The alleged tort potentially spanned 16 years.

Conceptus and Bayer operated out of California for some portion of that time and operated out of New Jersey for some portion of that time. The JCCP includes approximately 27,000 individual plaintiffs who resided in, were prescribed Essure in, had Essure implanted in, and have suffered injury in each of the 50 states. Approximately 10% of the plaintiffs are California residents and 90% are residents of other states. (Status Report filed 4/10/19, page 1.)

On 12/26/18, Bayer filed the Master Answer. The Master Answer was a general denial to counts 1, 2, 3, and 8. The Master Answer has affirmative defenses at paras 88-478 asserting that the claims are precluded or limited by the laws of other states.

On 2/26/19, Plaintiffs filed a demurrer to Bayer's affirmative defenses based on the laws of states other than California. A Plaintiff can file a demurrer to an answer or to affirmative defenses in an answer. (CCP 430.30(b).)

The order of 4/18/19 set out a preliminary proposed tentative decision under which the

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[1] The Master Complaint asserts causes of action for (1) Negligence/failure to warn, (2) Strict Products liability/failure to warn, (3) Concealment of complaints and adverse reactions, (4) negligent misrepresentation/misbranding and misleading marketing, (5) Intentional misrepresentation/misbranding and misleading marketing, (6) breach of express warranty, (7) manufacturing defect/compliance with FDA specifications, and (8) loss of consortium.

court would apply apportionment of liability concepts to choice of law when an alleged wrongful act took place continued over a period of time and in two or more separate states. The supplemental briefing indicates that there is no case law or academic support for that concept.

ORDER ON DEMURRER

The demurrer of plaintiffs to affirmative defenses 87-480 in Bayer's answer is OVERRULED.

The court accepts the factual allegations of the answer as true when hearing a demurrer to affirmative defenses. (*Alameda County Title Ins. Co. v. Panella* (1933) 218 Cal. 510, 512 ["the allegations of the answer, which must be taken as true in passing on the demurrer"].) (See also *Bank of America Nat. Trust & Sav. Ass'n v. Vannini* (1956) 140 Cal.App.2d 120, 126.) The court presumes the allegations of the complaint are not true if they are controverted by the answer. (*MacIsaac v. Pozzo* (1945) 26 Cal.2d 809, 812-813.) (See also *South Shore Land Co. v. Petersen* (1964) 226 Cal.App.2d 725, 733-734.) Bayer's answer was a general denial, so the court presumes that all the allegations in the Master Complaint are not true.

The court denies plaintiffs' request for judicial notice on the demurrer. "The hearing on demurrer may not be turned into a contested evidentiary hearing through the guise of having the court take judicial notice of documents whose truthfulness or proper interpretation are disputable." (*Richtek USA, Inc. v. uPI Semiconductor Corporation* (2015) 242 Cal.App.4th 651, 660) (*Fremont Indem. Co. v. Fremont General Corp.* (2007) 148 Cal.App.4th 97, 114-115.)

The demurrer of plaintiffs to affirmative defenses 87-480 in Bayer's answer is OVERRULED. The court cannot determine on the face of the pleadings that Bayer's affirmative defenses lack merit as to all claims by all plaintiffs in the coordinated proceeding.

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ORDER ON CHOICE OF LAW

The motion of plaintiffs to determine choice of law is GRANTED IN PART.

The substance of the motion is to determine choice of law. A trial court has the authority to construe a motion to reflect what it is rather than the label attached to the motion. (*Austin v. Los Angeles Unified School District* (2016) 244 Cal.App.4th 918, 930.) A motion to determine what law applies is in the nature of a motion in limine. (*Chen v. L.A. Truck Centers, LLC* (2017) 7 Cal.App.5th 757, 768 (review granted); *State Farm Mutual Automobile Ins. Co. v. Superior Court* (2004) 121 Cal.App.4th 490, 502-503.)

Construed as a motion is to determine choice of law, the court considers the allegations in the Master Complaint, grants plaintiffs' request for judicial notice and considers the declarations of Graham and Degen and the exhibits. Both sides use the facts as a framework for discussing the the legal issues and neither side objected to the evidence.

The court will not defer the choice of law question regarding the application of *Coleman*. In coordinated proceedings it is prudent case management to address and decide common issues early. (CCP 404.1; CRC 3.541(b); Std. Jud. Admin 3.10.) The court has the authority as a coordination trial judge managing complex cases to issue an order addressing and resolving a common issue. (*Volkswagen of America, Inc. v. Superior Court* (2001) 94 Cal.App.4th 695, 704-705; *McGhan Medical Corp. v. Superior Court* (1992) 11 Cal.App.4th 804, 805, 812.)

The court cannot alter rules of substantive law to make the JCCP more manageable. "Altering the substantive law to accommodate procedure would be to confuse the means with the ends—to sacrifice the goal for the going." (*City of San Jose v. Superior Court* (1974) 12 Cal.3d 447, 462.) Under California case law, a trial court must adjust case management to accommodate the application of choice of law to the case. In contrast, case law in other states permits the

alteration of choice of law principles to accommodate case management. (*In re Accutane Litigation* (2018) 235 N.J. 229, 258, 194 A.3d 503, 519.)

The court will not make the same error as the trial court in *Clothesrigger, Inc. v. GTE Corp.* (1987) 191 Cal.App.3d 605, and use the choice of law motion as a vehicle to address case management concerns. The court will separate the choice of law question from questions about jurisdiction and case management. (*Bristol-Myers Squibb Co. v. Superior Court* (2016) 1 Cal.5th 783, 813 ["Choice-of-law concerns might very well make a mass tort action unmanageable in certain circumstances, but that issue is not determinative at this stage of the proceedings [concerning jurisdiction]." (Reversed by *Bristol-Myers Squibb Co. v. Superior Court* (2017) 137 S.Ct. 1773.) (See also *Canon U.S.A., Inc. v. Superior Court* (1998) 68 Cal.App.4th 1, 6-8 [case management concerns in nationwide class action]; *Osborne v. Subaru of America, Inc.* (1988) 198 Cal.App.3d 646, 662-663 [same].)

The order sets out the choice of law analysis that the court will apply to the application of *Coleman* in each of the included cases but does not set out the choice of law analysis for the non-*Coleman* issues.[2] California law addresses choice of law questions on an issue by issue basis. (*Chen*, 7 Cal.App.5th at 767 (review granted); *Brown v. Grimes* (2011) 192 Cal.App.4th 265, 275.) A determination that the law of one state applies to the *Coleman* issue does not compel the conclusion that the law of that state applies to other issues.

The order does not reach a decision that the law of California or the law of some other state applies to any specific issue in any specific case. The court will necessarily have to apply the choice of law analysis to each case individually.

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[2] For example, Bayer asserts that there are material choice of law issues regarding whether a state recognizes a strict liability cause of action for medical devices and whether a state has a comparative fault or a contributory negligence system. (Bayer brief filed 5/6/19 at 10-11.)

ESTOPPEL

Plaintiffs argue that Bayer has previously argued that California law applies and is now judicially estopped from arguing that California law does not apply. (Opening at 21-22.) Plaintiffs assert that they drafted the Master Complaint based on the claims available under California law. (Reply at 8-9.)

Bayer is not judicially estopped from arguing that California law does not apply. The Court has not previously addressed the choice of law issue directly. "It is axiomatic that [orders] are not authority for propositions not considered." (*People v. Avila* (2006) 38 Cal.4th 491, 566.)

Furthermore, this is not a regular case. This is a JCCP and the number and nature of the included actions have changed over time. *Ripperger v. Bayer*, RG16-804878, filed on 2/23/16 was one of the original cases included in the JCCP, and it concerned claims by California residents (Cpt para 8) against Bayer regarding an implant in February 2013 when Conceptus was based in California (Cpt para 90). The Status Report filed 4/10/19, page 1, states that the JCCP will have approximately 27,000 individual plaintiffs, of which approximately 90% reside in and were injured outside California. The court's previous orders concerned the status of the JCCP at the time of those orders.

BACKGROUND FACTS

The order makes no factual findings. The following allegations and judicially noticeable information are the factual background for the choice of law analysis:

From approximately 2002 through 6/5/13, Conceptus had its principal place of business in California. (Graham Dec., Exh F at 1-2.)

On 6/5/13, Conceptus became a wholly owned subsidiary of Bayer and was renamed Bayer-Essure. (Graham Dec., Exh F at 3.)

After 6/5/13, when Bayer acquired Conceptus, the Bayer persons or department responsible for regulatory affairs for Essure were in New Jersey. (Graham Dec., Exh F at 4, 14-15.) (See also Exh F at 24, 27, 28, 29, 30, 31)

After 6/5/13, when Bayer acquired Conceptus, the Bayer persons or department responsible for transmitting PMA supplements to the FDA were in New Jersey. (Graham Dec., Exh F at 18-20)

After 10/1/13, the Bayer persons or department responsible for receipt, investigation, processing, and reporting technical and medical complaints were in Brazil and were supervised by persons in New Jersey. (Graham Dec., Exh F at 21.)

In 2014, the Bayer persons or department responsible for investigating technical complaints were in Costa Rica. (Graham Dec., Exh F at 22.)

In 2014, the Bayer Quality Assurance department was transferred to New Jersey. (Graham Dec., Exh F at 23.)

After on 12/31/15, no director who director controlled Bayer Essure resided in California. (Graham Dec., Exh F at 4)

On 4/21/16, Bayer Essure, Inc. moved its principal place of business from California to New Jersey. (Graham Dec., Exh F at 4.)

On 12/31/18, Bayer ceased selling Essure. (Cpt, para 98.)

For purposes of setting out its analysis in this order, the court will use "2013" as the date when responsibility for consumer warnings and related regulatory compliance relocated from California to New Jersey. This is not a finding of fact.

LEGAL ANALYSIS - INTRODUCTION

"[G]enerally speaking the forum will apply its own rule of decision unless a party litigant

timely invokes the law of a foreign state. In such event [that party] must demonstrate that the latter rule of decision will further the interest of the foreign state and therefore that it is an appropriate one for the forum to apply to the case before it." (*Washington Mutual Bank, FA v. Superior Court* (2001) 24 Cal.4th 906, 919.) (See also *Hernandez v. Burger* (1980) 102 Cal.App.3d 795, 798). Bayer has invoked the law of other states in its affirmative defenses. Bayer has the burden of demonstrating that the laws of other states apply.

After the issue is presented, California law on choice of law uses the governmental interest approach. "In brief outline, the governmental interest approach generally involves three steps. First, the court determines whether the relevant law of each of the potentially affected jurisdictions with regard to the particular issue in question is the same or different. Second, if there is a difference, the court examines each jurisdiction's interest in the application of its own law under the circumstances of the particular case to determine whether a true conflict exists. Third, if the court finds that there is a true conflict, it carefully evaluates and compares the nature and strength of the interest of each jurisdiction in the application of its own law 'to determine which state's interest would be more impaired if its policy were subordinated to the policy of the other state' [citation] and then ultimately applies 'the law of the state whose interest would be more impaired if its law were not applied.' " (*McCann v. Foster Wheeler LLC* (2010) 48 Cal.4th 68, 87-88, 100-101.)

GOVERNMENTAL INTEREST TEST – STEP ONE

Plaintiffs presume for purposes of this motion that the relevant law of each of the potentially affected jurisdictions with regard to the particular issue in question is different. (Opening at 10:4-6.) The central choice of law issue is whether federal law preempts state claims for failure to inform or warn a federal agency. California law is that federal law does not preempt

the state claims. (*Coleman*, supra.) The law in several other states is that federal law does preempt the state claims. (E.g., *Conklin v. Medtronic, Inc.* (2018) 245 Ariz. 501, 431 P.3d 571; *Norabuena v. Medtronic, Inc.* (2017) 86 N.E.3d 1198, 1206-1207.)

GOVERNMENTAL INTEREST TEST – STEP TWO

Plaintiffs presume that a true conflict exists between the law of California and the law of the other jurisdictions. (Opening at 10:4-6.) There is a true conflict. California law permits state law claims concerning failure to inform or warn a federal agency and the law in several other states is that such claims are preempted.

GOVERNMENTAL INTEREST TEST – STEP THREE

The focus of the motion is on the third step – whether given "the nature and strength of the interest of each jurisdiction in the application of its own law," "which state's interest would be more impaired if its policy were subordinated to the policy of the other state." (McCann, 48 Cal.4th at 87-88.) There are a few preliminary issues.

IDENTIFICATION, PLACE, AND TIME OF THE ALLEGED WRONG

The parties have a significant and foundational disagreement about the identification of the alleged wrong, which in turn affects the identification of the place and time of the alleged wrong.

Plaintiffs focus on alleged failure by employees of Conceptus and Bayer in California to report information to the FDA, which arguably affected FDA oversight, which arguably resulted in inadequate warnings, which mislead the health professionals who prescribed Essure to the plaintiffs. This is consistent with the *Coleman* analysis, which recognized a non-preempted state law claim for failure to warn the FDA in substantial part because warning the FDA "is the sole permissible mechanism for publicizing the additional risks associated with a medical device."

(*Coleman,* 223 Cal.App.4th at, 428-430.) (See also *Persons v. Salomon North America, Inc.* (1990) 217 Cal.App.3d 168 [duty to warn is duty to warn person who can effectively convey information to end user, not duty to convey information to end user].)

Bayer focuses on the alleged injuries, which would be the last events necessary to make Bayer liable. Bayer cites repeatedly to *Mazza v. American Honda Motor Co., Inc.* (9th Cir., 2012) 666 F.3d 581, 593-594, which states: "California considers the "place of the wrong" to be the state where the last event necessary to make the actor liable occurred. … Here, the last events necessary for liability as to the foreign class members—communication of the advertisements to the claimants and their reliance thereon in purchasing vehicles—took place in the various foreign states, not in California."

The court focuses on the claims alleged in the complaint, which are for failure to warn. If an individual was injured then it was because her health care provider was not adequately warned on the date of the prescription or implantation. If Bayer had adequately informed the FDA and the FDA had the opportunity to transmit that information to health care providers the day before the health care provider made an Essure prescription or implantation, then Bayer arguably would have met its duty to warn even if Bayer had not adequately informed the FDA in previous years.

This is consistent with *Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413. *Coleman* did not recognize or create a private right of action to enforce federal requirements that companies comply with FDA regulations on reporting adverse events or otherwise. *Coleman* held that if there was a pre-existing common law duty to warn, then the FDA regulations did not preempt that common law claim for failure to warn. Therefore, although the facts in the JCCP include an alleged failure to report adverse events as required by FDA regulations, the actual claims in the Master Complaint are common law failure to warn claims.

The California Supreme Court has addressed the distinction between a decision to adopt a policy and a claim for injury resulting from that policy. Addressing the extraterritorial application of California law in *Sullivan v. Oracle Corp.* (2011) 51 Cal.4th 1191, 1208, the Court stated, "But for an employer to adopt an erroneous classification policy is not unlawful in the abstract. … What is unlawful, and what creates liability under the FLSA, is the failure to pay overtime when due." Addressing choice of law issues in *McCann*, 48 Cal.4th at 94 fn 12, the Court stated that where a business designed a product in New York and knew or should have know there was a need for a warning in New York, the warning would not have been effective until it was communicated to the plaintiff in the state where the plaintiff was exposed to the hazard. Also addressing choice of law, in *Zinn v. Ex-Cell-O Corp.* (1957) 148 Cal.App.2d 56, 80 fn 6, the court of appeal stated "[T]he wrong was the misrepresentations. These as well as the sale of the stock occurred only in Washington. No matter where the intention to misrepresent was formed, nor the acts which were misrepresented took place, no wrong was committed until the misrepresentations were communicated to plaintiffs and this took place in Washington. … [T]he place of the wrong is in the state where the last event necessary to make an actor liable for an alleged tort takes place." (See also *Hill v. Novartis Pharmaceutical Corp.* (E.D. Cal. 2012) 2012 WL 967577 at *7 [collecting California law].)

The court concludes that the wrong that allegedly caused the injury to any given plaintiff was the lack of accurate information available to the plaintiff and/or her health care provide at the time of the prescription or implantation. Although Bayer's alleged multiyear course of conduct of failing to inform the FDA might have been a violation of its regulatory responsibilities, that alleged ongoing failure was not a failure to warn any individual plaintiff and caused no injury to any individual plaintiff.

The court has considered the hypothetical situation where a restaurant has a changing, but consistently inadequate, warning on a menu item for a period of years. The focus of a failure to warn claim for a single diner would be the warning on the menu on the date when the diner ordered the item that resulted in the injury. The focus would not be on the alleged ongoing multi-year wrong that caused no injury to the plaintiff. If the restaurant changed the warnings on the menu over time, then the focus would be on the information that was on the menu on the date when the diner ordered the item that caused the injury. The same analysis would seem to apply in this case.

The court's hypothetical very consciously concerns a menu and food rather than a warning on a physical product. A restaurant can update dinner items and menus daily and a diner can readily look at a menu each time the diner orders food. This is similar to the situation where a medical device company can update the FDA daily and health care providers can be expected to look at current FDA information each time the health care provider prescribes a device. In contrast, if a manufacturer sells, or a business buys, a vehicle with a painted warning on the interior that it has no seatbelts, then the painted warning in the vehicle might be the only warning the consumer sees before she suffers injury. In the manufacturer hypothetical, an inadequate warning made years ago could be the cause of a recent injury, which might then support using the law of the place of the manufacture, sale, or purchase. (*Chen*, 7 Cal.App.5th 757 (review granted) [California law on products liability applied where vehicle without seat belts was manufactured in Indiana, sold to a California company for use as a tour bus, delivered in Las Vegas, rolled over in Arizona, and injured Chinese nationals].)

THE NATURE OF THE CLAIMS.

The Master Complaint asserts a variety of torts. The alleged torts sound in negligence

with the exception of the cause of action for intentional misrepresentation. The distinction between the law on torts and the law on consumer protection and intentional torts might be significant under California law.

California case law suggests that the purpose of a legal requirement can affect the choice of law analysis. In *Hurtado v. Superior Court* (1974) 11 Cal.3d 574, 583, the court observed that with regard to laws regulating conduct, the state of the place of the place of wrong "is concerned with conduct within her borders and as to such conduct she has the predominant interest of the states involved" but that with regard to law enhancing or limiting damages, the state where the plaintiff resides has the predominant interest. *Hurtado* clarified that there are separate state interests for regulating conduct, providing adequate compensation for injured persons, and protecting defendants from excessive financial burdens. (*Hurtado*, 11 Cal.3d at 582-583.)

Cases involving torts tend to focus on compensation and damages and to hold that the law of the place of the injury applies to the case. *McCann* does not state what claims were alleged, but they appear to be based on negligent exposure to asbestos. In *McCann*, the plaintiff was living in Oklahoma and was exposed to asbestos in Oklahoma when installing a boiler designed by a New York company and the plaintiff later moved to California. The Supreme Court held that Oklahoma law applied. In *Offshore Rental Co. v. Continental Oil Co.* (1978) 22 Cal.3d 157, the plaintiff asserted a claim for negligence. The plaintiff was a California company seeking relief because one of its key employees had been injured in Louisiana as a result of negligence in Louisiana by the employee of a Delaware corporation that was headquartered in New York and did business in Louisiana. The Supreme Court held that Louisiana law applied. In *Hurtado*, the decedent was a Mexican national who was killed by a California resident driving a California registered vehicle in an auto accident in California. The Supreme Court held that California law

applied.

In contrast, cases involving consumer protection tend to focus on regulating conduct and therefore might be more likely to apply the law of the state of the conduct. The court uses the word "might" because this is less than clear. The court's tentative decision before the hearing on 5/16/19 cited to *Diamond Multimedia Sys., Inc. v. Superior Court* (1999) 19 Cal.4th 1036, 1062-1063, for the proposition that consumer protection statutes apply outside California. *Diamond*, however, concerned whether the statute had extraterritorial application and did not address choice of law issues.

The court's tentative decision also cited to *Clothesrigger, Inc. v. GTE Corp.* (1987) 191 Cal.App.3d 605, 614, for the proposition that California's consumer protection statutes apply outside California. *Clothesrigger*, however, concerned the trial court's denial of a motion for leave to amend to allege a nationwide class. *Clothesrigger* held that the trial court failed to examine both (1) whether it would be constitutional for nonresident plaintiffs to apply California's laws outside of California and (2) whether in a choice of law analysis California law should apply to the claims of nonresident plaintiffs. *Clothesrigger* did not decide the choice of law issue. *Clothesrigger* concluded, "Under certain facts California may have an important interest in applying its law to punish and deter the alleged wrongful conduct. (Cite.) Conversely, that interest may be minimal and outweighed by other states' interests. However, in denying Clothesrigger's motion [to amend the complaint], the court did not identify any proper reason California law would not likely apply to nonresident plaintiffs."

Consistent with the distinctions identified in *Hurtado* and the results in *McCann, Offshore*, and *Hurtado*, the purpose of a legal requirement informs the choice of law analysis. Looking to another state, under New Jersey's most-significant-relationship test, "When the tort rule primarily

serves a deterrent purpose, the state where the harmful conduct took place will likely have the dominant interest with respect to that rule" and "When the tort rule is designed primarily to compensate a victim for his or her injuries, the state where the injury occurred, which is often where the plaintiff resides, may have the greater interest in the matter." (*Fu v. Fu* (Sup. Ct. N.J., 1999) 160 N.J. 108, 1234, 733 A.2d 1133, 1141.)

BREAKING UP THE CHOICE OF LAW THIRD STEP INTO FOUR CATEGORIES

This is a coordinated proceeding and not a class action, but the analysis in class actions can be instructive. The court will follow the analysis in *Norwest Mortgage, Inc. v. Superior Court (*1999) 72 Cal.App.4th 214, 222, for the extraterritorial application of California law. In *Norwest*, the court held that legislature intended the UCL to regulate both conduct emanating from California and conduct injuring persons in California. The court held that it would be unconstitutional to apply the UCL to conduct outside of California that injured persons outside of California. (72 Cal.App.4th at 225-227.) To assist its analysis, the *Norwest* court divided the proposed nationwide class into four categories. Put in grid form, the *Norwest* analysis looks like:

	Putative class member is California resident	Putative class member is not California resident
Wrongful conduct is in California	Category IA – California law (UCL) can apply	Category II –California law (UCL) can apply
Wrongful conduct is not in California	Category IB – California law (UCL) can apply	Category III – California law (UCL) cannot apply.

Because *Norwest* decided the case based on the extraterritorial reach of the UCL, the court did not reach the choice of law issue. (72 Cal.App.4th at 228.) *Norwest* concluded: "If on remand plaintiffs seek certification of a class to include Category II members, the court must analyze the choice of law issues anew to determine whether California law or the laws of other states should govern the claims of Category II members. If the court determines the laws of other states will

control some or all of the claims of Category II members, the court must [consider how choice of law issue affect manageability]." *Norwest* left open the possibility that California law might not apply when the court did the choice of law analysis for Category II.

The court applies the *Norwest* grid to the claims in this case. The court reaches a different conclusion because it is answering a different question (choice of law, not extraterritorial application of law), because the *Coleman* issue is one of preemption and not substantive law, because the claims are for negligence and not consumer protection. The grid in this JCCP is:

	Plaintiff in California	Plaintiff not in California
Conceptus/Bayer in California (pre 2013)	Category IA – California law	Category II – The law of the plaintiff's non-California residence
Conceptus/Bayer in New Jersey (post 2013)	Category IB – California law	Category III – Either the law of the plaintiff's non-California residence or the law of Bayer's New Jersey residence

CATEGORY IA – PLAINTIFF IN CALIFORNIA AND CONCEPTUS/BAYER IN CALIFORNIA (PRE-2013)

The court will apply the California case of *Coleman* in cases where both (1) the Plaintiff had the Essure device prescribed and implanted in California and (2) Conceptus/Bayer was located in California when the Essure device was prescribed and implanted.

In this scenario, the prescription, implantation, injury, and the causal action are all in California. *Hurtado v. Superior Court* (1974) 11 Cal.3d 574, 584, states, "California has a decided interest in applying its own law to California defendants who allegedly caused wrongful death within its borders."

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CATEGORY IB – PLAINTIFF IN CALIFORNIA AND CONCEPTUS/BAYER IN NEW JERSEY (POST-2013)

The court will apply the California case of *Coleman* in cases where (1) the Plaintiff had the Essure device prescribed and implanted in California but (2) Conceptus/Bayer were located in New Jersey when the Essure device was prescribed and implanted.

California has a significant interest because the Essure device was prescribed and implanted and caused the injury to the individual plaintiff in California. "[T]he situs of the injury remains a relevant consideration." (*Hernandez v. Burger* (1980) 102 Cal.App.3d 795, 802).

New Jersey has a significant interest after 2013 because after 2013 Conceptus/Bayer was located in New Jersey. New Jersey has an interest in how it balances the interests of consumers and businesses. *McCann*, 48 Cal.4th at 91-92, states, "A state has a legitimate interest in attracting out-of-state companies to do business within the state, both to obtain tax and other revenue that such businesses may generate for the state, and to advance the opportunity of state residents to obtain employment and the products and services offered by out-of-state companies." New Jersey also has a specific interest in the companies that design and manufacture FDA approved products. The New Jersey Products Liability Act "limits the liability of manufacturers of FDA-approved products by reducing the burden placed on them by product liability litigation. The Legislature carefully balanced the need to protect individuals against the need to protect an industry with a significant relationship to our economy and public health." (*Rowe v. Hoffman-La Roche, Inc.* (2007) 189 N.J. 615, 626.)

Comparing the interests of the states, this court finds that California's interest in providing claims and potentially compensation to California residents who have suffered injury outweighs New Jersey's interest in regulating conduct that emanates from New Jersey generally and interest

in regulating that conduct of its medical device industry specifically. The New Jersey Supreme Court has recognized that that the state of the prescription and use of an FDA-approved product in that state outweighs the interests of New Jersey as the state where the product was developed. (*Rowe v. Hoffman-La Roche, Inc.* (2007) 189 N.J. 615, 629 ["To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law and obtain compensation for his injuries in this State's courts completely undercuts Michigan's interests, while overvaluing our true interest in this litigation."].)

Furthermore, if a business based in New Jersey or any other state decides to sell products to consumers in California, then it can reasonably expect that the law of California will apply if it fails to warn consumers of the hazards of those products and they cause injury to California residents. In *Bernhard v. Harrah's Club* (1976) 16 Cal.3d 313, 322-323 (superseded by statute on other grounds) the Supreme Court addressed choice of law in the context of a Nevada drinking and gambling establishment that sold alcohol to a California resident who then returned to California and caused a traffic accident in California. The court applied California law, stating, "California cannot reasonably effectuate its policy if it does not extend its regulation to include out-of-state tavern keepers such as defendant who regularly and purposely sell intoxicating beverages to California residents in places and under conditions in which it is reasonably certain these residents will return to California and act therein while still in an intoxicated state."

CATEGORY II –PLAINTIFF NOT IN CALIFORNIA AND CONCEPTUS/BAYER IN CALIFORNIA (PRE-2013)

The court will *not* apply the California case of *Coleman* in cases where (1) the Plaintiff had the Essure device prescribed and implanted outside California and (2) Conceptus/Bayer were

located in California when the Essure device was prescribed and implanted.

Regarding California's interest in non-California plaintiffs, "California has no interest in compensating injured plaintiffs who are neither injured in California nor California residents." (*Chen*, 7 Cal.App.5th at 771.) That said, other states do not have a significant interest in limiting the ability of their residents rely on California law to recover damages.

Regarding California's interest in regulating the conduct of businesses located in California, *McCann*, 48 Cal.4th at 97-98, states, "California choice-of-law cases … continue to recognize that a jurisdiction ordinarily has "the predominant interest" in regulating conduct that occurs within its borders." Similarly, *Clothesrigger, Inc. v. GTE Corp.* (1987) 191 Cal.App.3d 605, 614, remarked on "California's interest in deterring fraudulent conduct by businesses headquartered within its borders and protecting consumers from fraudulent misrepresentations emanating from California."

Other states, however, also have an interest in ensuring that any limitations on liability that apply in their state apply equally to both businesses based in that state *and businesses that choose to do business in that state*. *McCann*, 48 Cal.4th at 91-92, states:

> When a state adopts a rule of law limiting liability for commercial activity conducted within the state in order to provide what the state perceives is fair treatment to, and an appropriate incentive for, business enterprises, we believe that the state ordinarily has an interest in having that policy of limited liability applied to out-of-state companies that conduct business in the state, as well as to businesses incorporated or headquartered within the state. …
>
> In the absence of any explicit indication that a jurisdiction's "business friendly" statute or rule of law is intended to apply only to businesses incorporated or headquartered in that jurisdiction …, *as a practical and realistic matter the state's interest in having that law applied to the activities of out-of-state companies within*

the jurisdiction is equal to its interest in the application of the law to comparable activities engaged in by local businesses situated within the jurisdiction.
(Emphasis added.)

Contrary to this *McCann* analysis is the more recent analysis in *In re Qualcomm Antitrust Litigation* (N.D. Cal. 2018), 328 F.R.D. 280, 313-314 (appeal filed), which states, "The other states' interest in preventing excessive antitrust recovery for defendants is not implicated in the present case, where the sole defendant is a California resident." *Qualcomm* did not cite to *McCann*.

The court will follow *McCann* and not *Qualcomm*. *McCann* is the California Supreme Court. (*Auto Equity Sales, Inc. v. Superior Court of Santa Clara County* (1962) 57 Cal.2d 450, 455.) *Qualcomm* is not only a trial court opinion but it is a federal court applying California law. (*Haberbush v. Charles & Dorothy Cummins Family Limited Partnership* (2006) 139 Cal.App.4th 1630, 1635 fn 16 ["Decisions of the lower federal courts on federal questions are persuasive but not binding on state courts"].)

Comparing the interests of the states, this court finds that California's interests in providing claims and potentially compensation to non-California residents and in regulating the conduct of business activities emanating from California are outweighed by the interests of other states in determining the regulatory environment for businesses operating in those states and the predictable application of federal preemption to claims for injuries in those states.

Significantly for the purpose of examining California's interest in regulating the conduct of Conceptus/Bayer before 2013, the substantive laws of the other states do not permit California businesses to engage in conduct that California prohibits. Rather, the other states have determined that the duty to submit adverse event reports to the FDA is a federal law requirement and that federal law preempts state claims arising from a failure to report. Bayer is required to comply

with FDA regulations. Bayer must report adverse incidents and provides the FDA with several enforcement mechanisms. (*Conklin v. Medtronic, Inc.* (2018) 245 Ariz. 501, 505, 431 P.3d 571, 575; *Norabuena v. Medtronic, Inc.* (2017) 86 N.E.3d 1198, 1205.) As a matter of substantive law, the FDA, California, and all of the other 49 states share a common standard for the regulation of Bayer's conduct.

California's public interest in regulating Bayer's conduct is therefore in the enforcement of federal FDA requirements through California private party civil litigation rather than in the application of California-specific substantive standards. California has an interest in both the substantive standards in California law and in ensuring that its laws are enforced. To that end, certain California statutes have permitted private parties to bring actions on behalf of the state to regulate conduct in the state. (Labor Code 2699(a) and 2699.3 [PAGA]; Govt Code 12652(c) [False Claims Act]; Health and Safety Code 25249.7(d) [Prop 65].) Other statutes contain provisions for the award of attorneys' fees to encourage the prosecution of private claims that serve a public interest by regulating conduct in the state. (Govt Code 12965(b) [FEHA].) In light of those specific statutes permitting or encouraging private individuals to prosecute claims that serve public purposes by regulating conduct and the absence of statutes suggesting that tort claims for personal injuries serve a public purpose, the court will not find that California has a public interest in the enforcement of California tort law. More specifically, the the court will not find that California has a significant interest in permitting out of state plaintiffs to pursue private civil claims against California businesses as a means of enforcing federal law.

Also related to comparing the interests of the states, the claims in the Master Complaint are torts and generally sound in negligence. Tort law exists to provide compensation for injuries rather than to regulate conduct and tort claims tend to be governed by the law of the state of the