IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TANYA DE LA PAZ, an individual,

Plaintiff,

v.

BAYER HEALTHCARE LLC, a Delaware limited liability company, BAYER ESSURE INC., a Delaware corporation, BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware Corporation, and DOES 1–10, inclusive,

Defendants.
_____/

No. C 15-03995 WHA

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

In this personal-injury action involving a permanent female contraceptive device, defendants have moved to dismiss plaintiff's amended complaint. For the reasons stated below, defendants' motion is **GRANTED**.

STATEMENT

Plaintiff Tanya De La Paz is an individual who resides in South Carolina who sought to have Essure, a permanent female contraceptive device, implanted in her fallopian tubes in July 2012. This action arises from several complications that De La Paz suffered as a result of alleged defects with the Essure device.

Defendants Bayer HealthCare LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals, Inc., (collectively "Bayer"), manufactured, sold, distributed, and marketed Essure. Essure was first designed and manufactured by Conceptus, Inc., which merged with

Bayer in 2013 (for the purpose of this order, references to "Bayer" include Conceptus). Bayer also trained physicians how to use Essure and equipment related to implanting the device.

1. THE ESSURE DEVICE.

Bayer designed the Essure device to insert a metal coil known as a "micro-insert" into each of a patient's fallopian tubes. Once released, the micro-inserts expanded and anchored themselves into the fallopian tubes, and fibers in the micro-inserts elicited tissue growth, ultimately blocking the fallopian tubes and preventing pregnancy. Patients' physicians implanted the micro-inserts with a "disposable delivery system" that included a handle for the physician to control the delivery and release of the micro-inserts, which were attached to the handle with a wire (Amd. Compl. ¶¶ 19–21, 24–26).

Physicians used hysteroscopic cameras in order to visualize the implanting procedure. Bayer did not manufacture hysteroscopic equipment; however, it provided equipment manufactured by a third party to physicians as part of its efforts to market Essure in exchange for physicians' commitments to purchase two Essure kits per month and trained them in the use of that equipment (*id.* ¶¶ 22–23, 50–64).

Three months following any implanting procedure, patients were scheduled for hysterosalpingogram tests, which confirmed whether the micro-inserts anchored in the correct location and that tissue had grown to completely block the fallopian tubes as intended.

2. PREMARKET APPROVAL.

Medical devices are regulated by the Food and Drug Administration pursuant to the Food, Drug, and Cosmetics Act and the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. 360c *et seq.* Pursuant to the MDA, Essure was (and remains) designated as a Class III medical device, which means its design, manufacturing process, and labeling underwent the rigorous scrutiny of the FDA's premarket approval process. *See* 21 U.S.C. 360e. A device is classified under Class III (and therefore subject to premarket approval) when the less stringent classifications cannot provide reasonable assurance of its safety and effectiveness, and the device is used either "in supporting or sustaining human life or for a use which is of substantial

importance in preventing impairment of human health" or it "presents a potential or unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C).

A Class III device may only win approval to be marketed if the FDA finds, based on a multi-volume application including detailed investigations into the safety and effectiveness of the device and its labeling, that there is a "reasonable assurance of safety and effectiveness of [that] device . . . ." 21 U.S.C. 360e(d); *see also Riegel v. Medtronic, Inc.*, 522 U.S. 312, 317–18 (2008) (describing premarket approval in detail). The determination of the safety and effectiveness of a device is made in part by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C.A. 360c.

The FDA approved Essure through the premarket approval process in 2002 subject to certain conditions, such as regular reporting on efficacy, reporting of all adverse events, and seeking approval for any change to the device (Defs.' Request for Judicial Notice, Exh. B).

Bayer received several Form 483s, which are reports written by FDA investigators revealing potential violations discovered during an inspection of a manufacturing facility. Specifically, in June 2008, Bayer received a Form 483 that indicated that since 2005, it had been "manufacturing medical devices . . . at an unlicensed facility," that it had "failed to maintain procedures to control documents" relating to the maintenance of pre-sterile and post-sterile quarantine cages, and that its facility "no longer use[d] pre-sterile and post-sterile cages" (Amd. Compl. ¶¶ 105(d)–(e); Defs.' Supp. Request for Judicial Notice, Exh. D at 1).[1]

In January 2011, Bayer received another Form 483 that indicated its contract manufacturer had "erroneously used non-conforming material in a validation protocol without adequately documenting the disposition of the material," although "the FDA inspection did not note any deficiencies with regard [to] the firm's handling of non-conforming material" and that

[1] A "court may consider a writing referenced in a complaint but not explicitly incorporated therein if the complaint relies on the document and its authenticity is unquestioned." *Swartz v. KPMG LLP*, 476 F.3d 756, 763 (9th Cir. 2007). De La Paz refers to these Form 483s as the factual bases for her claims that Bayer used non-conforming material in the design and manufacture of Essure, and she does not contest the authenticity of the Form 483s submitted by Bayer. Accordingly, this order considers those documents as if incorporated into the complaint in full. The Form 483s in question are Exhibits C and D to Bayer's Supplemental Request for Judicial Notice.

"the firm corrected this discrepancy prior to the close of the inspection." Finally, that Form 483 noted that Bayer "had not properly evaluated eight complaints of peritoneal perforation for reporting to the FDA as an adverse event" (Amd. Compl. ¶¶ 105(b)–(c); Defs.' Supp. Request for Judicial Notice, Exh. C at 1).

3. DE LA PAZ'S EXPERIENCE WITH ESSURE.

De La Paz underwent a procedure to have Essure implanted in July 2012; however, the implanting physician abandoned the procedure after the device perforated one of De La Paz's fallopian tubes, which caused bleeding. De La Paz returned to her physician in September 2012 for a second attempt, which the physician completed. After the second procedure, De La Paz began to experience severe bleeding and constant pain (Amd. Compl. ¶¶ 71–72).

In December 2012, De La Paz returned to her physician for the standard hysterosalpingogram test to confirm that the device had anchored in the proper location and elicited tissue growth. The test revealed that the left micro-insert was properly implanted, but the right micro-insert appeared stretched or broken. Upon discovering this irregularity, De La Paz's physician contacted Bayer, which stated that the right micro-insert needed to be removed. In February 2013, De La Paz underwent surgery to have her right fallopian tube removed along with the broken micro-insert that had anchored there, which she had been informed would relieve her symptoms (Amd. Compl. ¶¶ 73–76).

De La Paz continued to experience daily pain and heavy bleeding, as well as weight gain, stomach issues, pelvic pain, and mental and emotional anguish. She discovered, through Internet research, that other women had similar ongoing symptoms due to the Essure device. In September 2015, De La Paz underwent surgery to have the micro-insert in her left fallopian tube removed (Amd. Compl. ¶¶ 77–79).

* * *

De La Paz commenced this action in federal court here in San Francisco in September 2015 on the basis of diversity jurisdiction. Bayer moved to dismiss the complaint in October 2015. In lieu of a response to Bayer's motion, De La Paz filed an amended complaint, asserting ten claims against Bayer based on the injuries she allegedly suffered as a result of having the

Essure device implanted. Specifically, De La Paz's claims are as follows: (1) manufacturing defect, (2) design defect, (3) negligence, (4) failure to warn, (5) strict liability, (6) breach of implied warranty, (7) breach of express warranty, (8) negligent misrepresentation, (9) fraudulent misrepresentation, (10) fraudulent concealment.[2]

Bayer filed the instant renewed motion to dismiss the amended complaint in November 2015. This order follows full briefing, including supplemental briefs regarding preemption, and oral argument.[3]

ANALYSIS

Bayer contends that each of De La Paz's claims is expressly preempted by the MDA's requirements for premarket approval of Class III medical devices, and that any claims that survive express preemption are impliedly preempted because the FDA has exclusive authority to enforce the MDA. De La Paz responds that her claims overcome the hurdles of both express and implied preemption. To that extent, Bayer further contends that De La Paz has failed to plead a causal link between the conduct alleged and her injuries and that she has failed to plead her fraud claims with the particularity required by Rule 9(b). Finally, Bayer argues that De La Paz's claims are barred by California's two-year statute of limitations on personal-injury claims.

This order begins by detailing the scope of express and implied preemption as they apply to Class III medical devices. It then addresses the substance of each of De La Paz's

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[2] The parties agree that California law, not South Carolina law, applies. The only relevant conflict identified between the laws of either state is that South Carolina's statute of limitations for personal injury claims is three years, while California's is two years. *Compare* S.C. Code § 15-3-530 *with* Cal. Civ. Proc. § 335.1. California's approach to choice of law with regard to a statute of limitations "generally leads California courts to apply California law, and especially so where California's statute would bar a claim." *Deutsch v. Turner Corp.*, 324 F.3d 692, 716 (9th Cir 2003). This order applies California law to the state law issues herein.

[3] The undersigned related three other cases asserting the same claims against these defendants based on alleged defects relating to Essure. *Salaiz v. Bayer HealthCare LLC, et al.*, No. 15-4952 (N.D. Cal.); *Ruiz v. Bayer HealthCare LLC, et al.*, No. 15-4953 (N.D. Cal.); *Patterson v. Bayer HealthCare LLC, et al.*, No. 15-5088 (N.D. Cal.). A consolidated case with five plaintiffs is also pending in the Eastern District of Pennsylvania. *MacLaughlin v. Bayer, Corp., et al.*, No. 14-7315 (Judge John R. Padova). Judge Padova held oral argument on defendants' motion for judgment on the pleadings in that action on January 11, 2016. That motion remains pending.

theories of liability, which she contends overcome the limitations of express and implied preemption. Finally, this order addresses Bayer's statute-of-limitations argument.

1. PREEMPTION.

Section 360k(a) of Title 21 of the United States Code includes an express preemption provision for requirements of the MDA:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) allows the FDA to exempt specific state or local laws from the preemptive sweep of Section 360k(a); however, that exemption is not applicable here because the FDA has not exempted the state laws that make up De La Paz's claims from preemption.

De La Paz brings this action against Bayer because she contends that the Essure device she had implanted in 2012 was unsafe and caused bleeding, pain, and other injuries including the removal of the micro-insert in her left fallopian tube. She also contends that Bayer misrepresented the safety and effectiveness of the device.

The parties agree that as a Class III device that won conditional premarket approval, Essure is subject to "requirements" under the MDA. Bayer contends that De La Paz's claims are based on state laws that impose requirements that are "different from, or in addition to" the federal requirements applicable to Essure and that relate to its "safety and effectiveness of the device or to any other matter included in" an applicable requirement, triggering express preemption under Section 360k(a).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008), the Supreme Court considered whether a plaintiff could bring state law tort claims against a device manufacturer "notwithstanding compliance with the relevant federal requirements . . . ." *Riegel* held such

claims preempted, but left open the possibility that a plaintiff could bring state law claims premised on conduct that violated federal law:

> State requirements are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. Thus, [Section 360k(a)] does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Ibid. In other words, to the extent Bayer has complied with the MDA, any state law claims based on the safety and effectiveness of Essure would be "different from or in addition to" the requirements of the MDA and therefore expressly preempted. On the other hand, De La Paz's claims may escape express preemption if she can allege that Bayer has violated both a federal duty under the MDA as well as a parallel state duty.

To the extent De La Paz can overcome express preemption, she faces a second challenge — implied preemption. The FDCA provides that enforcement of its requirements (including the MDA) "shall be by and in the name of the United States." 21 U.S.C. 337(a). That is, "the Federal Government rather than private litigants . . . [is] authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001). Thus, a claim that "exist[s] solely by virtue" of federal requirements (such as a claim for fraud in submissions to the FDA during the premarket approval process) is impliedly preempted by the MDA, while claims that rely on "traditional state tort law" may proceed (to the extent they can overcome express preemption). *Ibid.*

Thus, our court of appeals has recognized that there is a "'narrow gap through which a state-law claim must fit to escape preemption by the [MDA]." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013). The decision in *Perez* stated:

> The plaintiff must be suing for conduct that violates the [MDA] (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the [MDA] (such a claim would be impliedly preempted under *Buckman*).

Ibid. (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). De La Paz contends that each of her claims falls within this narrow gap either by alleging violations of parallel duties under state and federal law or by alleging

violations of state law outside the scope of the MDA. Bayer responds that to the extent De La Paz alleges it violated both the MDA and specific state law tort duties, her claims are inadequately pled.

Our court of appeals and district courts in our circuit have examined the preemptive effect of the MDA regarding state law tort claims against medical device manufacturers in more than sixty decisions since *Riegel*. Before addressing De La Paz's specific claims, this order pauses to review that extensive body of decisional law.

The overwhelming majority of state law tort claims, including claims based on negligence, design defect, manufacturing defect, failure to warn, fraud, negligent misrepresentation, breach of implied and express warranties, unfair competition, and false advertising, have been held preempted. *See, e.g., Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1117–20 (9th Cir. 2013); *Malonzo v. Mentor Worldwide, LLC*, No. 14-01144, 2014 WL 2212235, at *3 (N.D. Cal. May 28, 2014) (Judge Jeffrey S. White); *Knoppel v. St. Jude Med. Inc.*, No. 13-383, 2013 WL 3803612, at *4 (C.D. Cal. May 7, 2013) (Judge James V. Selna); *Lowe v. Medtronic, Inc.*, No. 11-9551, 2012 WL 3656468, at *1 (C.D. Cal. May 9, 2012) (Judge Manuel L. Real); *Rhynes v. Stryker Corp.*, No. 10-5619, 2011 WL 5117168, at *5 (N.D. Cal. Oct. 27, 2011) (Judge Samuel Conti); *Williams v. Allergan USA, Inc.*, No. 09-1160, 2009 WL 3294873, at *4 (D. Ariz. Oct. 14, 2009) (Judge G. Murray Snow). *Every* design-defect claim considered within our circuit has been held preempted (such a claim would require allegations of deviations from the FDA-approved design). *See Funke v. Sorin Group USA, Inc.*, No. 15-01182, 2015 WL 7747011, at *6 (C.D. Cal. Nov. 24, 2015) (Judge Cormac J. Carney). Nevertheless, certain claims have survived preemption, as now discussed.

Four decisions have allowed manufacturing-defect claims to survive preemption, and each required specific allegations "that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and — based on the same deficiency — was defectively manufactured under California law." *Id.* at *6 (holding manufacturing defect inadequately pled, but giving leave to amend); *see also Seedman v. Cochlear Americas*, No. 15-00366, 2015 WL 4768239, at *8 (C.D. Cal. Aug. 10, 2015) (Judge James V. Selna); *O'Neil v. St. Jude Med., Inc.*,

No. 13-0661, 2013 WL 6173803, at *2 (W.D. Wash. Nov. 22, 2013) (Judge Robert S. Lasnik); *Prudhel v. Endologix, Inc.*, No. 09-0661, 2009 WL 2045559, at *8 (E.D. Cal. July 9, 2009) (Judge Lawrence K. Karlton).

In *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc), our court of appeals considered a claim under Arizona law that imposed a duty to warn of the dangers of a product on manufacturers. *Stengel* held that the MDA did not preempt the state law claim inasmuch as it imposed a duty to warn third parties (such as the FDA), if such a warning offered "reasonable assurance that the information [would] reach those whose safety depend[ed] on their having it." *Ibid.* (quoting *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992) (Judge Richard Bilby), *aff'd* 44 F.3d 806 (9th Cir. 1995)). Numerous decisions have allowed failure-to-warn-the-FDA claims in light of *Stengel*. *See, e.g., Funke v. Sorin Group USA, Inc.*, No. 15-01182, 2015 WL 7747011, at *4 (C.D. Cal. Nov. 24, 2015) (Judge Cormac J. Carney); *Thibodeau v. Cochlear Ltd.*, No. 13-02184, 2014 WL 3700868, at *4 (D. Ariz. July 25, 2014) (Judge David G. Campbell).

In *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 428–29 (2014), as modified (Feb. 3, 2014) (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1002 (1991)), the California Court of Appeal specifically acknowledged that California's duty to warn of product defects extended to warning the FDA "if that is the sole permissible mechanism for publicizing the additional risks associated with a medical device." The California Court of Appeal noted that to prevail on a failure-to-warn-the-FDA claim, the plaintiff "will ultimately have to prove that if [the defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent" the alleged injuries. *Id*. at 430 (quoting *Stengel*, 704 F.3d at 1234 (Judge Paul J. Watford, concurring)).

Indeed, numerous district court decisions have also recognized that a causal link between a manufacturer's failure to warn the FDA and a plaintiff's injury is a necessary element of such a claim. *Michajlun v. Bausch & Lomb, Inc.*, No. 14-1365, 2015 WL 1119733, at *8 (S.D. Cal. Mar. 11, 2015) (Judge Jeffrey T. Miller); *Eidson v. Medtronic, Inc.*, 981

F. Supp. 2d 868, 889 (N.D. Cal. 2013) (Judge Lucy H. Koh); *Simmons v. Boston Scientific Corp.*, No. 12-7962, 2013 WL 1207421, at *5 (C.D. Cal. Mar. 25, 2013) (Judge Percy Anderson); *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (Judge Andrew J. Guilford).

In *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1041 (9th Cir. 2015), our court of appeals recognized that a plaintiff could bring a negligence *per se* claim premised on a manufacturer's failure to comply with the FDA's labeling requirement without running afoul of MDA preemption. That decision distinguished the fraud-on-the-FDA claim that *Buckman* held impliedly preempted from the negligence *per se* claim because the former relied on a duty that existed *solely* due to the premarket approval process (and thereby fell within the FDA's exclusive jurisdiction), while the latter relied on an independent state law duty (albeit one that incorporated the standard of care from federal law). That is, absent the premarket approval process, manufacturers would still be required to comply with the state law standard of care with regard to warnings.

Several decisions have allowed warranty, fraud, and misrepresentation claims arising out of marketing and promotion of off-label uses for devices (uses that have not been approved by the FDA) to escape preemption. "The FDA forbids [off-label promotion] because the FDA's review of a device's safety and effectiveness was not universal; it focused only on the intended use specified by a manufacturer." *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 990 (D. Ariz. 2013) (Judge G. Murray Snow); *see also Anderson v. Medtronic, Inc.*, No. 14-00615, 2015 WL 2115342, at *7 (S.D. Cal. May 6, 2015) (Judge Cynthia Bashant); *Poll v. Stryker Sustainability Solutions, Inc.*, No. 13-440, 2014 WL 199150, at *6 (D. Ariz. Jan. 17, 2014) (Judge Cindy K. Jorgenson); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868 (N.D. Cal. 2013) (Judge Lucy H. Koh); *Kashani-Matts v. Medtronic, Inc.*, No. 13-01161, 2013 WL 6147032, at *5 (C.D. Cal. Nov. 22, 2013) (Judge Cormac J. Carney); *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1104 (D. Or. 2013) (Judge Paul Papak).

Suckow v. Medtronic, Inc., 971 F. Supp. 2d 1042, 1049 (D. Nev. 2013) (Judge Gloria M. Navarro), recognized that a claim for breach of express warranty based on statements that went

"beyond the FDA approved statements," even with regard to approved uses, could survive preemption, to the extent it did not rely on a contradiction of the FDA's conclusions in the premarket approval process. *Suckow* ultimately dismissed those claims as inadequately pled. *Ibid.* Thus, although there remains the possibility that warranty or fraud claims based on statements relating to an FDA-approved use might survive preemption, no such claim has been pled.

* * *

This order now addresses each of De La Paz's claims grouped into the following categories — manufacturing defect, design defect, failure to warn, negligent training, breach of warranty, and misrepresentation/fraud.

2. MANUFACTURING-DEFECT CLAIMS.

De La Paz's first claim alleges that the Essure device she had implanted in 2012 suffered from manufacturing defects that rendered the product "unreasonably dangerous" and caused her to undergo the surgical removal of the micro-insert in her left fallopian tube, among other injuries. Her fifth claim alleges that as the manufacturer and supplier of Essure, Bayer is strictly liable for any injuries caused by manufacturing defects in the product (among other bases for strict liability discussed below) (Amd. Compl. ¶¶ 107–12, 146–48, 152).

De La Paz contends that her manufacturing-defect claims escape express preemption because she has plausibly alleged that Bayer allowed its Essure devices to become "adulterated" as defined by the MDA. She further contends that the claims escape implied preemption because under California law, Bayer is strictly liable for any injuries resulting from manufacturing defects in Essure devices.

The MDA provides that a device is deemed "adulterated" if "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements" in the FDA's requirements for that device. 21 U.S.C. 351(h). De La Paz alleges that Bayer allowed its Essure devices to become adulterated, based on the observations of FDA investigators during inspections of Bayer's facilities as documented in certain Form 483s issued in 2008 and 2011. Specifically, she alleges that the investigators

indicated that Bayer "erroneously used non-conforming material," "no longer use[d] pre-sterile and post-sterile cages," and "failed to obtain a valid license . . . prior to manufacturing medical devices" (Amd. Compl. ¶¶ 105(c)–(e)). The Form 483s offer plausible support for the inference that Bayer produced some adulterated devices, even if not conclusive.

Nevertheless, to escape implied preemption De La Paz must allege that the irregularities documented in the Form 483s resulted in a manufacturing defect that caused her injuries. In other words, she cannot state a claim based solely on Bayer's adulteration of certain Essure devices, since any such claim would "exist solely by virtue of the [MDA] . . . requirements." *Buckman*, 531 U.S. at 353. De La Paz has failed to allege such a manufacturing defect.

The complaint offers no description of the "non-conforming material" used in manufacturing the device, or how the use of that material caused a defect in the product itself. In fact, the Form 483 indicated that Bayer's contract manufacturer used the "non-conforming material" in a validation protocol, not in the actual manufacture of the product. Moreover, the report indicated that the manufacturer had erred by failing to adequately *document* the disposition of that material, not by using the material itself (Defs.' Request for Judicial Notice, Exh. C). De La Paz has provided no basis for concluding that the failure to document the disposition of non-conforming material in a validation protocol caused a manufacturing defect in any Essure device.

Similarly, neither the complaint nor the Form 483s referenced offer any explanation of the function of "pre-sterile and post-sterile cages" in the manufacturing process, nor do they offer any explanation for how Bayer's alleged operation without a license led to any manufacturing defect. Thus, De La Paz has failed to allege that the irregularities identified in the Form 483s led to a breach of any parallel state law duties that could escape implied preemption. *Buckman*, 531 U.S. 341, 349 n.4; *see also Cornwell v. Stryker Corp.*, 10-00066, 2010 WL 4641112, at *4 (D. Idaho Nov. 1, 2010) (Judge Edward J. Lodge) (dismissing claim based solely on allegation that device was "adulterated" as impliedly preempted).

De La Paz's claims also fail because she offers only conclusory allegations that the alleged irregularities caused her injuries. Specifically, she alleges, "[a]s a direct and proximate

result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses" (Amd. Compl. ¶¶ 117, 152). That conclusory allegation is not entitled to the presumption of truth on a motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009). De La Paz's failure to allege a causal link between any adulteration of Bayer's Essure device and her injuries is fatal to her manufacturing-defect claims. *Soule v. Gen. Motors Corp.*, 8 Cal. 4th 548, 573 (1994). Thus, her first and fifth claims (to the extent the latter relates to manufacturing defects) are hereby **DISMISSED**.

In her opposition to Bayer's motion to dismiss, De La Paz states that she is prepared to amend her complaint to add "allegations regarding specific regulations related to manufacturing that [Bayer] violated" as well as allegations that Bayer's "deviation from the FDA-approved plan and specifications was the cause of [her] injur[ies]" (Pl.'s Opp. at 10–11). De La Paz may seek leave to amend her manufacturing-defect claims for those purposes.

3. DESIGN-DEFECT CLAIMS.

De La Paz concedes that her design-defect claims cannot survive preemption, inasmuch as she cannot allege that Bayer departed from the design for Essure approved by the FDA (Pl.'s Supp. Brief at 5). Indeed, her design-defect claims suffer from the same preemption and causation issues as her manufacturing-defect claims. Accordingly, her second and fifth claims (to the extent the latter relates to design defects) are **DISMISSED**. De La Paz may not seek leave to amend as to those claims.

4. NEGLIGENT-TRAINING CLAIM.

California law recognizes that "if a manufacturer undertakes to train physicians and fails to exercise reasonable care in that undertaking, it may be held liable for harm caused to" the patient. *Scott v. C.R. Bard, Inc.*, 231 Cal. App. 4th 763, 774 (2014). De La Paz concedes that her claim for negligence in training physicians "could have been better developed" (Pl.'s Opp. at 12). In fact, although the complaint briefly refers to Bayer's training procedure, De La Paz's negligence claim (claim three) does not mention training — this proposed claim appears only in her brief (Amd. Compl. ¶¶ 128–131). De La Paz seeks leave to specifically allege that Bayer

negligently trained her physician in the use of hysteroscopic equipment during the implanting procedure. Bayer argues that such an amendment would be futile, inasmuch as it would be expressly preempted. This order addresses Bayer's argument to the extent possible on these pleadings.[4]

Bayer specifically argues that the FDA reviewed and approved its training manual for the procedure to implant Essure, so De La Paz cannot state a claim for negligent training unless she alleges Bayer deviated from those materials (which she has not) (Defs.' Request for Judicial Notice, Exh. D; Defs.' Supp. Request for Judicial Notice, Exh. E). The only decision that has considered a failure-to-train claim in this context held that claim survived preemption only to the extent the manufacturer failed to provide the training required by the premarket approval process. *Chao v. Smith & Nephew, Inc.*, No. 13-0114, 2013 WL 6157587, at *4 (S.D. Cal. Oct. 22, 2013) (Judge Marilyn L. Huff).

Here, De La Paz has not alleged that Bayer ever deviated from the approved training as to Essure; however, she alleges that Bayer also trained physicians in the use of hysteroscopic equipment, which equipment was never part of the premarket approval procedure for Essure. Indeed, she alleges that Bayer's website warned physicians, "[i]n order to be trained in Essure you must be a skilled operative hysteroscopist" (Amd. Compl. ¶¶ 50–70, 84–86, 91(j)). Bayer's training materials did *not* include a training manual for hysteroscopic equipment, the materials approved by the FDA only mentioned hysteroscopes in passing as equipment necessary for the Essure implant procedure.[5]

De La Paz may seek leave to amend her complaint to include a claim for negligent training to the extent the claim relates to training physicians to use hysteroscopic equipment or to the extent it alleges that Bayer deviated from the training materials for Essure approved by

[4] As pled, claim three alleges that Bayer acted negligently by failing to adequately test and analyze data relating to Essure, which requirements are part of the premarket approval procedure. De La Paz has made no attempt to rescue that aspect of claim three from preemption. Nor could she, inasmuch as the FDA approved Essure notwithstanding the alleged negligence.

[5] Judicial notice of the training materials approved by the FDA is appropriate inasmuch as they are matters of public record and appear on the FDA's website.

the FDA. The proposed claim must also plausibly allege a causal link between any alleged negligence in training and De La Paz's injuries.

5. FAILURE-TO-WARN-THE-FDA CLAIM.

De La Paz's fourth claim is for failure to warn the FDA of adverse events, and her fifth claim is for strict liability for, *inter alia*, failure to warn. The FDA requires device manufacturers to report any time its device "may have caused or contributed to a death or serious injury . . . ." 21 C.F.R. 803.50(a). As stated, our court of appeals has recognized that a claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty (although a claim based on a failure to warn physicians or patients of adverse events would be preempted). *Stengel*, 704 F.3d at 1234. California law recognizes such a duty. *Coleman*, 223 Cal. App. 4th at 429. To state a failure-to-warn claim under California law, De La Paz "will ultimately have to prove that if [Bayer] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [her] doctors in time to prevent [her] injuries." *Id.* at 429–30 (quoting *Stengel*, 704 F.3d at 1234).

Here, De La Paz alleges that Bayer failed to report eight incidents of perforations of patients' fallopian tubes caused by Essure to the FDA, thereby breaching the state law duty to warn the FDA (Amd. Compl. ¶ 44(c)). De La Paz alleges that if she had known of these adverse events, "she never would have had Essure implanted" (Amd. Compl. ¶ 18). Nevertheless, she has pled no facts that plausibly indicate that she or her physician would have become aware of these adverse events if Bayer had timely reported them to the FDA.

In fact, the FDA already required Bayer to warn physicians and patients about the possibility of perforations. Moreover, although the Form 483 did not indicate when the unreported perforations occurred, it did establish that the FDA became aware of these adverse events more than a year before De La Paz underwent the procedure and informed Bayer of its failure to properly report those events (Defs.' Supp. Request for Judicial Notice, Exh. C at 1; Amd. Compl. ¶ 44(c)). The FDA did not require Bayer to take any action to further warn physicians or patients of the possibility of perforations, beyond the warnings already in place.

Thus, De La Paz has failed to plausibly show that her injuries would have been prevented if Bayer had properly reported the perforation events — a necessary element of her failure-to-warn-the-FDA claim. *Coleman*, 223 Cal. App. 4th at 429–30. Accordingly, claims four and five must be **DISMISSED**. De La Paz may seek leave to amend to allege facts plausibly showing that if Bayer had timely reported the perforations, the FDA would have required some enhancement to the perforations warning already in place, which would have caused De La Paz to forego the Essure procedure.

6. WARRANTY CLAIMS.

De La Paz's sixth claim is for breach of the implied warranty of merchantability, and her seventh claim is for breach of several express warranties.

A breach of the implied warranty of merchantability occurs if the product lacks "even the most basic degree of fitness for ordinary use." *Mocek v. Alfa Leisure, Inc.*, 114 Cal. App. 4th 402, 406 (2003) (citing Cal. Comm. Code § 2314(2)). De La Paz's claim for breach of the implied warranty of merchantability is preempted. A determination of whether the Essure device is fit for ordinary use bears directly on its safety and effectiveness. De La Paz's failure to plead parallel federal and state law violations with regard to manufacturing defects is similarly fatal to her implied warranty claim. Thus, her sixth claim fails and is hereby **DISMISSED**.

To state a claim for breach of an express warranty, De La Paz must allege: (1) Bayer made an "affirmation of fact or promise" or a "description" of Essure, (2) the statement was "part of the basis of the bargain," and (3) that warranty was breached. *Weinstat v. Dentsply International, Inc.*, 180 Cal. App. 4th 1213, 1227 (2010) (citing Cal. Comm. Code § 2313(1)(a)). As stated, the only claims for breach of the express warranty that have survived preemption are those that went "beyond" statements approved by the FDA. *Suckow*, 971 F. Supp. 2d at 1049. The only such claims that have been adequately pled are those based on the promotion of off-label uses of a device, which uses have not been approved by the FDA. *E.g.*, *Ramirez*, 961 F. Supp. 2d at 990.

Here, De La Paz identifies a laundry list of "warranties" that Bayer made on its website, in advertisements, on fact sheets, on statements by agents, in brochures, in their SEC filings, and in various statements to the FDA (Amd. Compl. ¶¶ 91–105). These statements averred that Essure had "zero pregnancies" in clinical trials, that Essure was "worry free," "surgery free," and "anesthesia free," and that "correct placement . . . is easily performed," among other similar claims. With one exception, each of De La Paz's examples is a statement that has been approved, or even required, by the FDA as a descriptor for Essure (Defs.' Request for Judicial Notice, Exh. G; Defs.' Supp. Request for Judicial Notice, Exh. E). Any claim for breach of express warranty based on those statements would require a determination that Essure did not conform to the descriptions approved by the FDA. Such claims are preempted.

The sole exception is that De La Paz alleges she read a blog published by Bayer and purportedly written by a user of Essure named "Judy." The blog was in fact written by a woman named Debbie Donovan, who had never used the device. De La Paz submitted questions to "Judy" about the Essure device, which Judy answered in her blog posts (Amd. Compl. ¶ 97).

There is no indication that the FDA approved the "Judy" blog, so a claim based on that blog could plausibly survive preemption. Nevertheless, De La Paz has failed to include any allegations of the contents of the blog. The only "fact" about the blog she has alleged is that it was ghost-written, which is not a "promise" or a "description" of the Essure product, so failure to conform with some warranty that "Judy" was real cannot give rise to a claim with regard to Essure. There is also no indication that the Essure device failed to conform to the statements made by "Judy," such that the blog's contents could form the basis of a claim for breach of express warranty.

De La Paz has failed to plead facts that plausibly indicate that Bayer breached a warranty made *beyond* statements approved by the FDA. Accordingly, her seventh claim is hereby **DISMISSED**. De La Paz may seek leave to amend her sixth and seventh claims to allege breaches of warranties made beyond the scope of the FDA's premarket approval and to allege

the specific contents of the "Judy" blog, which may have set forth express warranties about the Essure product.

7. MISREPRESENTATION AND FRAUD CLAIMS.

De La Paz's eighth claim is for negligent misrepresentation, her ninth claim is for fraudulent misrepresentation, and her tenth claim is for fraud by concealment. The misrepresentation claims are based on the same statements that form the basis of De La Paz's claim for breach of express warranties, and they are preempted for the same reasons as that claim (namely, the statements conformed to statements approved by the FDA), with the exception of the "Judy" blog (which, as discussed below, is inadequately pled under Rule 9(b)).

De La Paz's tenth claim, for fraud by concealment, is based on the same allegations as her failure-to-warn-the-FDA claim and is preempted for the same reason — there is no causal link between Bayer's alleged concealment of facts from the FDA and De La Paz's injury.

Moreover, each of De La Paz's eighth through tenth claims include reliance as an element. *Lazar v. Superior Court*, 12 Cal. 4th 631, 638 (1996). De La Paz has failed to allege that she ever encountered, much less relied on, any statements or omissions made by Bayer in electing to undergo the Essure procedure, with the exception of the "Judy" blog. As to the "Judy" blog (as well as the other allegedly fraudulent statements identified in the complaint), De La Paz's fraud and negligent misrepresentation claims based thereon fail to meet the heightened pleading standard for Rule 9(b).[6]

Pursuant to Rule 9(b), a plaintiff's allegations for any claims sounding in fraud require a particularized statement of "the who, what, when, where, and how of the misconduct charged." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009). Here, De La Paz has offered only bare descriptions of Bayer's statements. She has failed to offer particularized details, such as when (if ever) she encountered the alleged misrepresentations and how she came to rely on them. She has failed to allege how she came under the impression that "Judy" was a real patient, rather than ghost-written. De La Paz's bare descriptions of statements made by Bayer,

[6] The undersigned has previously held, in accord with the prevailing trend among district courts in this circuit, that Rule 9(b) applies to negligent misrepresentation. *Nasseri v. Wells Fargo Bank, N.A.*, No. 15-04001, 2015 WL 7429447, at *6 (N.D. Cal. Nov. 23, 2015).

without any further details of how she encountered them or relied on them, fall far short of the particularity required by Rule 9(b).

Accordingly, De La Paz's eighth through tenth claims are hereby **DISMISSED**. De La Paz may seek leave to amend her claims to allege a basis for reliance on Bayer's statements, as well as the more particularized facts required by Rule 9(b).

8. STATUTE OF LIMITATIONS.

As stated, each of De La Paz's claims is dismissed, although she may seek leave to amend. Bayer contends that even if De La Paz can overcome the defects addressed above, her claims would remain precluded by California's two-year statute of limitations on personal-injury actions, inasmuch as De La Paz knew about the link between her symptoms and the Essure device since 2012 when the broken coil in her right fallopian tube required a follow-up surgery, three years before she commenced the action. De La Paz responds that her claim did not accrue until 2014, because she had no reason to know of the link between the alleged defects in the Essure device in her left fallopian tube and her symptoms after her surgery to remove her right fallopian tube. Alternatively, De La Paz contends she is entitled to tolling on the basis of fraudulent concealment. This order addresses these arguments to the extent possible with these defective pleadings.

Under the delayed-discovery rule, California law postpones the accrual of a claim "until the plaintiff discovers, or has reason to discover" the essential elements of that claim. *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 807 (2005). The question of when accrual occurred under the delayed-discovery rule is generally "a question of fact unless the evidence can support only one reasonable conclusion." *Ovando v. County of Los Angeles*, 159 Cal. App. 4th 42, 61 (2008) (citations omitted).

Here, De La Paz alleges she became aware of the injuries that give rise to these claims (*i.e.*, those in her left fallopian tube) in 2014 when she read about other women who had Essure implanted experiencing similar symptoms. Bayer responds that De La Paz should have become aware of her injuries when she discovered that her symptoms had not subsided after the removal of her right fallopian tube in 2012.

It is possible that De La Paz could have intuited, when she continued to have some of the same symptoms, that the cause of those symptoms was the remaining coil, however, that is not the only reasonable conclusion. *Ibid.* Rather, on these pleadings it is also reasonable to conclude that De La Paz would attribute her symptoms to some other cause, given that the coil in her left fallopian tube remained intact, and she had been assured her symptoms would subside following removal.

Bayer's citation to *Pooshs v. Philip Morris USA, Inc.*, 51 Cal. 4th 788, 797 (2011), is inapposite. That decision held that "where a plaintiff is aware of both an injury and its wrongful cause but is uncertain as to how serious the resulting damages will be or whether additional injuries will later become manifest[,] . . . the infliction of appreciable and actual harm, however uncertain in amount, will commence the statutory period." Here, the issue is not that De La Paz waited to see whether additional injuries would manifest from the cause of which she was already aware. She alleges that her new injuries resulted from a *separate cause*, namely alleged defects relating to the device that remained implanted in the left fallopian tube, rather than the broken coil in the right fallopian tube.

De La Paz has adequately alleged that her claims, such as they are, accrued within the limitations period pursuant to the delayed-discovery rule. Accordingly, Bayer's statute-of-limitations argument does not foreclose the possibility that De La Paz may amend her complaint to allege a viable claim. This is without prejudice to a renewed argument in response to any motion for leave to amend.[7]

CONCLUSION

For the reasons stated above, Bayer's motion to dismiss is **GRANTED**. To the extent stated above, plaintiff may seek leave to amend her complaint and shall have **FOURTEEN CALENDAR DAYS** from the date of this order to file a motion, noticed on the normal 35-day track, for leave to file an amended complaint. A proposed amended complaint must be appended to the motion, and plaintiff must plead her best case. The motion should clearly

[7] De La Paz's argument that she is entitled to tolling based on fraudulent concealment of the alleged defects cannot be meaningfully addressed on these pleadings, inasmuch as she has neither alleged a cause of her injuries nor reliance on any fraudulent statement.

explain how the amendments to the complaint cure the deficiencies identified herein, as well as any others raised in defendants' briefs. If such a motion is not filed by the deadline, the case will be closed.

Bayer has requested judicial notice of various documents submitted during the FDA premarket approval process and public statements regarding Essure. With the exception of the documents cited above, those documents were not necessary to this order, and Bayer's request is therefore **DENIED AS MOOT**.

IT IS SO ORDERED.

Dated: February 2, 2016.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE