UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

BRIAN RICHARDSON and SUSAN RICHARDSON, husband and wife,

Plaintiffs,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC., CONCEPTUS, INC., ESSURE, ESSURE PROMISE, and JOHN DOE CORPORATIONS I-X,

Defendants.

Case No. 4:15-cv-00443-BLW

MEMORANDUM DECISION AND ORDER

INTRODUCTION

The Court has before it Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Essure Inc.'s (collectively, "Bayer") Motion for Judgment on the Pleadings (Dkt. 13), and Plaintiffs Brian and Susan Richardson's Motion to Amend/Correct Amended Complaint (Dkt. 14). Bayer asserts that Plaintiffs' state law claims are expressly and impliedly preempted by federal law.

From a procedural standpoint, this case is a bit convoluted. Bayer provided substantial briefing in support of their original Motion for Judgment on the Pleadings. Plaintiffs' only substantive "response" was their motion to amend the amended complaint, which includes a copy of their Proposed Second Amended Complaint. *See*

Motion to Amend, Dkt. 14; *Supplement to Motion to Amend*, Dkt. 16. Plaintiffs' Proposed Second Amended Complaint is extensive, detailed, and almost brief-like, including at least one case citation. *Id.* at ¶ 12. Plaintiffs' actual "response" to the motion was a simple one-page "brief" that cited their Proposed Second Amended Complaint.

Bayer then responded to Plaintiffs' motion to amend with more substantial briefing, essentially making the same arguments as to the Proposed Second Amended Complaint that they made against the Amended Complaint. Plaintiffs failed entirely to respond to Bayer's opposition brief, which was filed on March 4, 2016. Plaintiffs' failure to respond to Defendants' arguments has placed this Court in a somewhat difficult position, particularly given the complexity of the legal arguments involved.

Rule 15 of the Federal Rules of Civil Procedure provides that leave to amend "shall be freely given when justice so requires." Fed.R.Civ.P. 15(a). In the interest of efficiency and thoroughness, the Court will grant Plaintiffs' Motion to Amend (Dkt. 14), and will address Bayer's arguments as they apply to the Second Amended Complaint. Thus, the Court essentially has before it a second motion for judgment on the pleadings or motion to dismiss the Second Amended Complaint. And the Court will note that Plaintiffs have been given an opportunity to respond to Bayer's arguments as they apply to both complaints. Accordingly, to the degree the Court grants dismissal, the Court will not give Plaintiffs yet another chance to amend – that right has already been granted by allowing the Second Amended Complaint, which Plaintiffs filed after having the opportunity to review Defendants' briefs.

BACKGROUND

The Richardsons' claims arose after Susan Richardson had the birth control device, Essure, implanted in her fallopian tubes on or around December 27, 2011 to prevent future pregnancies. *Proposed Am. Complaint*, at ¶ 4, Dkt. 16-1. About a year later, Plaintiffs discovered that Susan was pregnant despite the procedure. *Id.* at ¶ 6. An ultrasound later revealed that she was pregnant with twins. *Id.* Plaintiffs' Second Amended Complaint alleges ten state common-law causes of action asserting liability for the negligent and defective manner in which Essure was "manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold." *Id.* at ¶ 75. Bayer is responsible for the manufacturing and distribution of the Essure birth control device. *Id*. at ¶ 3.

Plaintiffs' claims arise in the context of an extensive federal regulatory scheme. Medical devices are regulated by the FDA pursuant to the Food, Drug, and Cosmetics Act ("FDCA") and the Medical Device Amendments of 1976 ("MDA"). 21 U.S.C. § 360c *et seq*. Pursuant to the MDA, Essure is conditionally 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 ("PMA"). *See Second Am. Compl.* at ¶ 33, Dkt. 16; *see also* 21 U.S.C. § 360e. Essure's "conditional" status is conditioned on further trial testing, but the device is still regulated under the MDA statutory scheme until such status is otherwise revoked. *See Am. Compl.* at ¶ 42. A device is classified under Class III (and therefore subject to PMA) 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 PMA status and be marketed if the FDA finds, based on 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.*, 552 U.S. 312, 317–18 (2008) (describing PMA 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. In addition to regulating the device's actual design and application, the FDA must approve its labeling, including whether it is false or misleading under § 360e(d)(1)(A), and requires post-approval clinical investigations, scientific studies, and periodical reports to the FDA. *See* 21 C.F.R. § 814.84(b)(2).

Because Essure is a Class III device subject to the FDA's PMA process, all relevant regulations under the FDCA and MDA are applicable. Bayer's motion is based on the assertion that Plaintiffs' state law claims are both expressly and impliedly preempted by the federal statutory scheme encompassed in the FDCA and the MDA.

LEGAL STANDARD

FRCP 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief," to "give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While a complaint attacked by an FRCP 12(b)(6) motion to dismiss "does not need detailed factual allegations," it must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555. To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim for relief that is plausible on its face." *Id.* at 570. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* at 556. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Id.* Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* at 557.

Rule 15 of the Federal Rules of Civil Procedure provides that leave to amend "shall be freely given when justice so requires." Fed.R.Civ.P. 15(a). Indeed, while the decision to grant leave to amend is within the Court's discretion, the Court "must be guided by the underlying purpose of Rule 15 to facilitate decision on the merits rather than on the pleadings or technicalities." *U.S. v. Webb*, 655 F.2d 977, 979 (9th Cir.1981).

This "policy of favoring amendments to pleadings should be applied with extreme liberality." *Id.* (internal quotation marks omitted).

To determine "whether justice requires granting leave to amend," courts consider "the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party and futility of the proposed amendment." *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 538 (9th Cir.1989) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). "Generally, this determination should be performed with all inferences in favor of granting the motion." *Griggs v. Pace Am. Group, Inc.*, 170 F.3d 877, 880 (9th Cir.1999) (citing *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir.1987)). Nevertheless, the "general rule that parties are allowed to amend their pleadings. . .does not extend to cases in which any amendment would be an exercise in futility or where the amended complaint would also be subject to dismissal." *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1298 (9th Cir.1998) (citations omitted). Futility alone can justify a court's refusal to grant leave to amend. *See Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir.1995).

ANALYSIS

1. Express and implied preemption under the MDA and FDCA

Under the MDA, many state law claims asserting liability for allegedly faulty medical devices are expressly preempted by federal law. *See* 21 U.S.C. § 360k(a); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Additionally, even claims not expressly preempted by the MDA may be impliedly preempted under the FDCA's greater

enforcement scheme. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

A. *Express preemption under the MDA*

Unless a state seeks a specific exemption available under the statute, the MDA provides that no state may establish or enforce any requirement that is inconsistent with those required federally:

> (a) General rule
>
> > 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.

21 U.S.C § 360k. In *Riegel*, the United States Supreme Court reaffirmed the determination reached in *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) that the MDA's preemption provision is "substantially informed by the FDA regulation set forth at 21 C.F.R. § 808.1(d)." *Riegel*, 552 U.S. at 322 (citing *Lohr*, 518 U.S. at 495). Section 808.1(d) states that State laws are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to *a particular device*." *Id.* (emphasis added). In addressing the *Riegel* dissent's concerns that the preemption provision will "remove all means of judicial recourse for consumers injured by FDA-approved devices," the majority

responded summarily that "this is exactly what a pre-emption clause for medical devices does by its terms." *Riegel*, 552 U.S. at 326 (citing dissent of Ginsburg, J. *Id.* at 337).

While the MDA's preemption provision is broad, the *Riegel* court still recognized that § 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." *Id.* at 330. Thus, claims that are analogous to a violation of the MDA regulations may not be expressly preempted so long as they also violate a parallel state duty. *See De La Paz v. Bayer Healthcare LLC*, 2016 WL 392972 at *4 (N.D. Cal. Feb. 2, 2016). However, any claims which are asserted that may be viewed as "in addition" to the FDA regulations will be preempted. *Riegel*, 552 U.S. at 330.

B. Implied preemption under the FDCA

Even those "parallel claims" not expressly preempted directly under the MDA may be impliedly preempted by the federal statutory enforcement scheme under the FDCA, which provides that the exclusive mechanisms of enforcement must be brought by the United States government, or alternatively on behalf of the States. *See Buckman*, 531 U.S. at 348; *see also Perez v. Nidek Co., Ltd.*, 711 F. 3d 1109, 1119–20 (9th Cir. 2013). The FDA is solely responsible for investigating potential violations of the FDCA (which the MDA is a subsection thereof). *See* 21 U.S.C §§ 332–34, 372. The Act provides the FDA "with a range of enforcement mechanisms, such as injunction proceedings, civil and criminal penalties, and seizure." *Perez*, 711 F. 3d at 1119.

However, the FDCA precludes private enforcement of all relevant provisions, as "all such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Whereas citizens may "petition the FDA to take administrative action, 21 C.F.R. §§ 10.25(a) and 10.30, private enforcement of the statute is barred." *Perez*, 711 F. 3d at 1119.

In *Buckman*, plaintiffs brought state tort claims against a medical device manufacturer for fraudulent misrepresentations the company had allegedly made while obtaining approval from the FDA for the use of orthopedic "bone screws" – a Class III device. *Buckman*, 531 U.S. at 343. Because the claims were based on alleged violations of the MDA, rather than "additional state requirements," the claims *were not* necessarily preempted by the MDA's express preemption provision. *Id.* at 348. Instead, the Court found that the alleged fraud claims "exist solely by virtue of the FDCA disclosure requirements" and as such, the plaintiff's private cause of action was impliedly preempted by the government enforcement requirement under 21 U.S.C. § 337(a). *Id.* at 353.

The Ninth Circuit applied *Buckman* to a claim against a generic medical device manufacturer on a "fraud by omission" claim that the company improperly concealed the fact that the FDA had not approved the device for a specific eye surgery procedure. *Perez*, 711 F. 3d at 1112. After holding that the plaintiff's claims were improper under two different California state laws, the Ninth Circuit ultimately held that because "the existence of these [FDCA regulations] is a critical element in [the plaintiff's] case," the

claims were preempted under the *Buckman* rationale. *Id.* at 1119. Thus, even those claims that aren't preempted under *Riegel* still must fall outside the *Buckman* preemption in order to state a private cause of action.

C. Most of the Richardsons' claims are either expressly or impliedly preempted

The Ninth Circuit has expressly recognized that between the respective preemptions under the *Riegel* and *Buckman* line of cases, there is only a "narrow gap through which a state-law claim must fit to escape preemption by the FDCA." *Perez*, 711 F. 3d. at 1120 (internal quotations omitted). Essentially, "the plaintiff must be suing for conduct that *violates* the FDCA . . . but the plaintiff must not be suing *because* the conduct violates the FDCA." *Id.* Absent a stand-alone state law that precisely mirrors the MDA, a plaintiff's claim against a Class III medical device manufacturer for violations of the MDA will likely be preempted.

The claims asserted in the Richardsons' Second Amended Complaint fall into three separate categories: 1) claims asserting that Essure's design is defective or unreasonably dangerous; 2) claims asserting defects in Essure's manufacturing process; and 3) claims asserting that Bayer misrepresented Essure's safety and effectiveness or failed adequately to warn of its risks. *See Second Am. Compl.* at ¶¶ 67–140, Dkt. 16; *see also Defs' Opposition to Motion to Amend*, at 9, Dkt. 22. All ten claims are for state common-law torts based on the alleged "adulteration" of the Essure product per FDA protocol, expressly citing the conditional PMA requirements. *Second Am. Compl.* at ¶ 50. The majority of these claims are exclusively governed by FDCA regulations which are

therefore required to be challenged ". . . by and in the name of the United States." 21 U.S.C. § 337(a).

The Richardsons' claims are almost exactly the same as those brought by the plaintiff against Bayer in *De La Paz v. Bayer Healthcare LLC*, 2016 WL 392972 (N.D. Cal. Feb. 2, 2016), who had to have one of her fallopian tubes removed after complications arose from the Essure device. *Id.* at *2. In *De La Paz*, the plaintiff also brought suit against Bayer based on the "adulteration" of the Essure product under FDA regulations. *Id.* at *3 (The plaintiff's ten claims were for (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). *Id.* In each instance, the *De La Cruz* court held that the claims, as pleaded, were insufficient and had to be dismissed. *Id.* at *7–11. In several instances, however, the *De La Paz* court also found that the facts alleged *could* possibly afford relief, and the court dismissed some claims without prejudice so to allow the plaintiff the opportunity to amend her complaint. *Id.*

Overwhelmingly, this Court agrees with the decision and analysis underlying the *De La Paz* court's decision to dismiss the plaintiff's claims. However, some factors that led the *De La Paz* court to allow the plaintiff leave to amend are inapplicable in this case, and the Court must consider the facts of this case independently based on the evidence and applicable law before it. The Court will therefore address each set of claims

individually. And as noted above, the procedural posture of this case also affects the Court's decision not to allow yet another amendment.

(1) Plaintiffs' First, Second, and Fifth Causes of Action are preempted by the FDCA as they relate to alleged manufacturing and design defects

Plaintiffs' first cause of action for "manufacturing defect," second cause of action for "design defect," and fifth cause of action for strict liability (so far as it relates to the alleged design and manufacturing defects) are entirely preempted, either expressly or impliedly, by federal law under the FDCA. As a conditionally approved Class III medical device, the manufacturing and design of Essure is solely under the authority of the FDA. *See Riegel*, 552 U.S. at 330; *see also Buckman*, 531 U.S. at 353. Plaintiffs' have not asserted an independent state statutory scheme by which relief may be granted, but rather rely on common-law tort claims. Therefore, insofar as Plaintiffs could seek liability for conduct not encompassed in the FDCA, such claims for the manufacturing and design of the Essure device is expressly preempted under 21 U.S.C § 360k(a). Alternatively, insofar as the Richardsons seek liability for noncompliance with the FDCA requirements regarding the manufacture and design of the product, such claims are impliedly preempted under 21 U.S.C. § 337(a). *Buckman*, 531 U.S. at 348 (claims must be brought "by and in the name of the United States"). Plaintiffs' first, second, and fifth claims will therefore be dismissed.

(2) Plaintiffs' Third Cause of Action is partially preempted by the FDCA, and alternatively, has not been adequately pleaded to allege a proper claim for Bayer's alleged "failure to train"

Plaintiffs' third cause of action is for negligence, suggesting Bayer "failed to use reasonable care in designing Essure." *Second Am. Compl.* at ¶ 83, Dkt. 16. Plaintiffs specifically state six ways in which Bayer "failed to use reasonable care,"

a. Failed to properly and thoroughly **test** Essure before releasing the system to market;

b. Failed to properly and thoroughly **analyze the data** resulting from the premarketing tests of Essure;

c. Failed to **conduct sufficient post-market testing** and surveillance of Essure;

d. **Designed, manufactured, marketed, advertised, distributed, and sold** Essure to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Essure and without proper instructions to avoid the harm which could foreseeably occur as a result of using the system;

e. Failed to exercise due care when **advertising and promoting** Essure; and

f. Negligently continued to **manufacture, market, advertise, and distribute** Essure after Defendants knew or should have known of its adverse effects.

Second Am. Compl. at ¶ 83, Dkt. 16 (emphasis added).

The Richardsons' negligence claims, as pleaded, are preempted for precisely the same reasons as the first and second causes of action are preempted. All of the manufacturing, marketing, advertising, warnings, and distribution of the Essure product are approved per the conditional PMA process. *See Riegel*, 552 U.S. 312, 317–18. All

alleged negligence stems solely from a failure to adhere to FDA protocol, rather than an independent state duty. As noted above, a claim that Defendant failed to comply with the FDCA requirements must be brought under 21 U.S.C. § 337(a).

However, ¶ 10 of the Second Amended Complaint discusses alternative assertions for negligence that fail for different reasons:

> Plaintiff's first cause of action is based on Defendants' negligence in 1) failing to adequately train Plaintiff's implanting physician ('the implanting physician"); and 2) entrusting the implanting physician with specialized hysteroscopic equipment she was not qualified to use. . . .

Second Am. Compl., at ¶ 10, Dkt. 16. In *De La Paz*, the court gave the plaintiff leave to amend her complaint for the "failure to train" claim, because under California law, "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." *De La Paz*, 2016 WL 392972 at *8 (N.D. Cal. Feb. 2, 2016) (citing *Scott v. C.R. Bard, Inc.*, 231 Cal.App. 4th 763, 774, 180 Cal.Reptr.3d 479 (2014)). But in this case, facts have not been pleaded (nor is this Court aware of relevant law) sufficient to demonstrate that a manufacturer owes a duty under Idaho law to train physicians. Absent an independent state law claim, the Richardsons' claim for failure to train is impliedly preempted. 21 U.S.C. § 337(a).

Similarly, Plaintiffs allege that Bayer "entrusted" physicians with "hysteroscopic equipment" that "is not part of any CPMA." *Second Am. Compl.*, at ¶ 10, Dkt. 16. If the equipment indeed is not regulated under the MDA, liability for such products would not be expressly preempted. *See* 21 U.S.C § 360k. While there is no Idaho case law expressly holding that a "failure to train" is a breach of a duty owed by manufacturers or

distributors under Idaho law, the Court is not prepared to foreclose the possibility of such a claim at this point. However, as currently pled, the Second Amended Complaint does not allege a causal connection between the Richardsons' injuries and any improper use of the equipment by the implanting physician. From this standpoint, the plaintiffs' Second Amended Complaint pleads facts that are "merely consistent with" a defendant's liability, meaning it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Twombly*, 550 U.S. at 557. Particularly given the deficit of argument provided by the plaintiffs regarding this aspect of their Second Amended Complaint, the third cause of action will also be dismissed, but with leave to amend.

(3) Plaintiffs' Fourth Cause of Action – Failure to Warn claim are not preempted

Plaintiffs seek liability for a number of claims generally stemming from allegations that Bayer failed to adequately warn of Essure's risk to consumers. *See Second Am. Compl.*, ¶ 86–98, Dkt. 16. Plaintiffs argue that their claims "based entirely on the express warranties made by Defendants to plaintiff[s]" are not preempted by the MDA under *Stengel v. Medtronic Inc.*, 704 F. 3d 1224, 1334 (9th Cir. 2013). *Second Am. Compl.*, ¶ 12, Dkt. 16.

In *Stengel*, the Ninth Circuit held that a negligent "failure to warn" claim against an MDA product was not preempted under Arizona law. *Id.* There, the *Stengel* plaintiffs' Proposed Amended Complaint alleged that Medtronic was negligent because it "had become well aware of [ ] risks but had failed to inform the FDA, even though the MDA required Medtronic to do so." *Id.* at 1227. The Ninth Circuit specifically construed this

argument as a "failure to warn the FDA claim." *Id.* at 1233. Construing the claim as a "failure to warn the FDA" is important because the MDA requires the company to report to the FDA about complications that arise through the device's use (but not necessarily to the doctors or ultimate users) – otherwise it would be an "additional" requirement that is expressly preempted under §360k(a). *See Riegel*, 552 U.S. at 330; *see also Stengel*, 704 F. 3d at 1234 (Watford, J. concurring) ("claim on an alleged state law duty to warn doctors directly would have been expressly preempted").

To avoid preemption under *Buckman* however, the *Stengel* plaintiffs also needed to show that *Arizona law* required the company to report to the FDA. Notably, Arizona law provides for a duty to warn third parties if "there is reasonable assurance that the information will reach those whose safety depends on their having it." *Id.* (citing *Anguiano v. E.I. DuPont de Nemours & Co.*, 808 F. Supp. 719, 723 (D. Ariz. 1992)). Provided Arizona's broad scope of duty for a failure to warn claim, the court found that the FDA was a "third party," whom if reported to, "there is reasonable assurance that the information will reach those whose safety depends on their having it." *Id.* Thus in that case, there was a "parallel" state claim that could be used to enforce duties that also arose under federal law.

As applied to the Richardsons' "Failure to Warn" claim against Bayer here, the Richardsons' Second Amended Complaint states:

> Defendants were cited by the FDA and the Department of Health for (1) failing to report and actively concealing 8 perforations which occurred as a result of Essure; (2) erroneously using non-conforming material in the manufacturing of Essure; (3) failing to use pre-sterile and post-sterile cages;

> (4) manufacturing Essure at an unlicensed facility and (5) manufacturing Essure for three years without a license to do so.

Second Am. Compl., at ¶ 16, Dkt. 16. Bayer was allegedly required to report at least 1) the occurrence of the eight perforations and (2) the use of non-conforming material to the FDA under 21 C.F.R. § 814.84(b)(2). In Idaho, a manufacturer may be liable under either theory of strict liability or negligence for a failure to warn if "[1] the defendant has reason to anticipate that danger may result from a particular use of his product and [2] fails to give adequate warnings of such danger." *Puckett v. Oakfabco, Inc.*, 979 P.2d 1174, 1181 (Idaho 1998). Such danger must not have been so "open or obvious" that the user would be on notice of the dangers presented. *Id.* Plaintiffs' Second Amended Complaint, at least on its face, has pleaded sufficient factual details that could plausibly support a "failure to warn the FDA" claim. *See id.*

Citing these same FDA violations, the *De La Paz* court applied *Stengel* when it allowed the plaintiff leave to amend her complaint for a "Failure to Report to the FDA" claim. 2016 WL 392972 at *10 (N.D. Cal. Feb. 2, 2016). The *De La Paz* Court allowed leave to amend in order for the plaintiff 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." *Id.* The *De La Paz* court's remand was similar to the *Stengel* concurrence's concern that the party had demonstrated causation, but found that such information was not necessary at the pleading stage. *See Stengel*, 704 F. 3d at 1234–35 (Watford, J. concurring) (Plaintiff would ultimately need to prove causation "that

information [reported to the FDA] would have reached Mr. Stengel's doctors in time to prevent his injuries").

Idaho law contemplates that a "third party intermediary" may play a critical role in adequately warning users of a foreseeably dangerous product. *See Sliman v. Aluminum Co. of America*, 731 P.2d 1267, 1272 (Idaho 1986). As such a claim relates to third parties, such as the FDA, the Idaho Supreme Court has relied on the Restatement (Second) of Torts § 388 & Comment n (1965), as well as the Eighth Circuit decision in *Hopkins v. Chip-in-Saw, Inc.*, 630 F. 2d 616, 619 (8th Cir. 1980):

> When a manufacturer can reasonably foresee that the warnings it gives to a purchaser of its product will not be adequately conveyed to probable users of the product, then its duty to warn *may extend beyond the purchaser* to those persons foreseeably endangered by the product's use. *Warnings given to the purchaser do not necessarily insulate the manufacturer from liability to injured users of the product.*

Sliman, 731 P.2d at 1272 (quoting *Hopkins*, 630 F. 2d at 619) (emphasis added). Therefore, under Idaho law a manufacturer of a product may have a duty to forewarn a user of the product, regardless whether the user is the direct purchaser of the product or not. *Id.* In the context of Class III medical devices, that should be construed to include warnings and reports to the FDA. Just as under *Stengel*, Idaho law provides an independent, but "parallel" remedy for the failure of a manufacturer of a MDA device to properly report known dangers of its product to the FDA.

The Richardsons' failure to warn claims differ from the "fraud-on-the-FDA" claims at issue in *Buckman* because the *Buckman* fraudulent statements were made "solely by virtue of the FDCA disclosure requirements" and thus are impliedly preempted

by the FDCA enforcement scheme. *Buckman*, 531 U.S. at 353. In contrast, the failure to warn requirement merely "parallels" the requirement under 21 C.F.R. § 814.84(b), but is actually derived from the independent duty to actively warn potential third-party users, even through disclosure to regulatory bodies.

It must be noted, however, that the Richardsons have failed to allege facts that tend to show the plaintiffs would have opted to "forego" the Essure procedure had the information been disclosed to the FDA. *See De La Paz*, 2016 WL 392972 at *10 (N.D. Cal. Feb. 2, 2016). But under Idaho law, there is no insinuation that "reliance" is a necessary element required to plead a failure to warn claim. Instead, whether Bayer's disclosure to the FDA would have provided warning to the Richardsons is an element of the warning's "adequacy" under a failure to warn claim, which "is for the jury to determine. *See Sliman*, 731 P.2d at 1272 (manufacturer must give an "adequate" warning). Whereas the plaintiffs will ultimately have the burden of proving the "inadequacy" of the FDA's warnings, they have pleaded sufficient factual information to survive the Defendants' motion.

Just as the Ninth Circuit stated in *Stengel*, "we do not decide whether plaintiffs can prevail on their state-law failure-to-warn claim. That question is not before us." 704 F. 3d at 1233. For these reasons, the Court will not dismiss claims three, four, and five as they relate to Bayer's alleged failure to warn.

(4) Causes of Action six through ten are preempted by federal law

Plaintiffs sixth cause of action for breach of implied warranty, seventh cause of action for breach of express warranty, eighth cause of action for negligent misrepresentation, ninth cause of action for fraudulent misrepresentation, and tenth cause of action for fraudulent concealment are all expressly and impliedly preempted by federal law. All five claims are based upon Bayer's alleged "designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making[,] constructing, assembling, advertising, and distributing of Essure." *Second Am. Compl.*, at ¶ 113, Dkt. 16. These are all affirmative actions taken by Bayer and disclosed to the FDA for their review. As discussed in subsection (1) *supra*, all of the allegedly improper conduct is based implicitly on duties that are imposed under the FDCA, and must therefore be enforced soley by the FDA. *See Riegel*, 552 U.S. at 330; *see also Buckman*, 531 U.S. at 353.

The Court recognizes that it may initially seem counterintuitive that the warranty and fraudulent misrepresentation claims are preempted, whereas the failure to warn claims are not – particularly when the fraud by concealment claim addresses essentially the same conduct as the failure to warn claim. However, the relevant FDCA reporting requirements are instructive. Under 21 C.F.R. § 814.84(b), the FDA requires device manufacturers to produce a "periodic report" relating to known risks, but it is ultimately up to the FDA to require changes in the "packaging, labeling, producing, [*et cetera*]. . ." that is the basis of the Richardsons' warranty and misrepresentation claims. *Second Am.*

Compl., at ¶ 113, Dkt. 16. The FDA's role in receiving reports under the MDA is passive, whereas their role in approving the warranty-related conduct is active. Such is the difference between a "parallel" duty under independent state law, and those duties that exist solely due to the FDCA. This distinction is indicative of the "narrow gap" in the law described by the Ninth Circuit in *Perez*. 711 F. 3d. at 1120.

Idaho law cannot require stronger duties than the FDA actively requires under the MDA, even if the Court could presume some likelihood the FDA would require changes to the warranties made by Bayer had it known of the allegedly non-disclosed risks. For these reasons, causes of action six through ten are either expressly or impliedly preempted by federal law. Bayer's motion will be granted as to those claims.

ORDER

IT IS ORDERED:

1. Plaintiff's Motion to Amend Amended Complaint (Dkt. 14) is **GRANTED**, and the Court has addressed the motion for judgment on the pleadings as it applies to the Second Amended Complaint.
2. Defendant's Motion for Judgment on the Pleadings (Dkt. 13) is **GRANTED IN PART** and **DENIED IN PART**. All claims except those relating to Plaintiffs' failure to warn allegations are dismissed. Plaintiffs are granted leave to amend the claims in the Second Amended Complaint regarding the failure to train the implanting physician in the use of the hysteroscopic

equipment. Any amended complaint must be filed on or before September 13, 2016.

DATED: August 30, 2016

B. Lynn Winmill
Chief Judge
United States District Court