IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

SHERRI FERGUSON,

Plaintiff,

v. No. 2:21-cv-00664-MLG-GBW

BAYER ESSURE, INC. (F/K/A CONCEPTUS, INC.), BAYER U.S. LLC, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and JOHN DOES 1-50,

Defendants.

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS AND DENYING PLAINTIFF'S MOTION TO AMEND

This matter comes before the Court on Defendants Bayer Essure, Inc., Bayer U.S. LLC, Bayer Corporation, Bayer Healthcare LLC, and Bayer Healthcare Pharmaceuticals, Inc.'s Motion to Dismiss ("Motion"). Doc. 4. The Motion seeks dismissal of all claims brought by Plaintiff Sherri Ferguson related to a permanent birth control device that was manufactured by Defendants. Following briefing and a motion hearing on the issues held on May 17, 2023, the Court grants the Motion.

BACKGROUND

I. Statutory and Regulatory Framework

The Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c-360n, to the Federal Food, Drug, and Cosmetic Act ("FDCA") of 1938, 21 U.S.C. § 301 *et seq.*, impose detailed federal oversight on new medical devices intended for human use prior to their introduction to the market. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) ("[The MDA] swept back some state

obligations and imposed a regime of detailed federal oversight."). Each medical device awaiting FDA approval is assigned one of three classifications based on the device's risk level and possibility of injury or illness. 21 U.S.C. § 360c(a)(1); *Riegel*, 552 U.S. at 316. Devices posing heightened risk received heightened FDA scrutiny prior to approval. *Id.* Class I devices are subject to "general controls"—the lowest level of oversight—because they present little to no unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(A); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996). Class II devices—which are potentially more harmful—are subject to "special controls" which include performance standards, post-market surveillance, and patient registries. 21 U.S.C. § 360c(a)(1)(B). Class III devices either "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). These devices are subject to the greatest extent of FDA scrutiny and regulation because insufficient information exists to determine their "safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C)(i); *see* §§ 360c(a)(1)(C)(ii), 360e(c), (d); 21 C.F.R. § 814.20.

Prior to obtaining FDA approval, a Class III device must undergo the "pre-market approval" ("PMA") process. *See* 21 U.S.C. § 360e; *Riegel*, 552 U.S. at 322-23. "Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews." *Lohr*, 518 U.S. at 477; *see* 21 U.S.C. § 360e(d)(2). This data is compiled in a multivolume application that includes:

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(c)(1)) (quotation marks omitted). The FDA must review a device's proposed labeling to ensure it is neither false nor misleading. *See* 21 U.S.C. § 360e(d)(1)(A).

If a device receives PMA, the FDA may condition PMA "on adherence to performance standards, 21 C.F.R. § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, 21 C.F.R. § 814.82." *Riegel*, 552 U.S. at 319. The FDA is "also free to impose device-specific restrictions." *Id.* (citing 21 U.S.C. § 360j(e)(1)). For example, a manufacturer is prohibited from making changes to design specifications, manufacturing processes, labeling, or other qualities that would affect safety or effectiveness without FDA permission or completion of a PMA supplement.[1] 21 U.S.C. § 360e(d)(5)(A)(i); 21 C.F.R. § 814.39(a).

Manufacturers are also subject to post-PMA reporting requirements that include a manufacturer's obligation to inform the FDA of new clinical investigations or scientific studies, 21 C.F.R. § 814.84(b)(2), report incidents in which the device may have caused or contributed to death or serious injury, or report device malfunctions that would likely cause or contribute to death or serious injury. 21 C.F.R. § 803.50(a); *see, e.g.*, Doc. 1-1 ¶¶ 34-37 (describing Essure's Conditional PMA Orders). Based on these reports or other existing information, the FDA must withdraw a device's PMA if it is unsafe or ineffective under the conditions of its approval. 21 U.S.C. §§ 360e(e)(1)(A), 360h(e); *Riegel*, 552 U.S. at 319-20. Once a Class III device is approved via the PMA process, it may then be sold to consumers. *See* 21 U.S.C. § 360l; 21 C.F.R. § 814.82(a); U.S. Food & Drug Admin., *Premarket Approval (PMA)* (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma.

[1] The PMA supplement is "evaluated under largely the same criteria as an initial application." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 CFR § 814.39(c)).

II. Pertinent Factual Background

Essure, a permanent birth control device, was produced and marketed by Defendants from 2002 until 2018. Docs. 1-1 ¶ 31; 4-9 at 2. Essure consists of three components: "(1) two micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer." Doc. 1-1 ¶ 18; *see also* Docs. 4-2 at 2-6; 4-5 at 1; *see generally* Doc. 4-7. The micro-inserts are made of two metal coils which expand and anchor into the fallopian tubes' tissue, causing fibrous tissue growth and, in turn, bilateral occlusion of the fallopian tubes. Docs. 1-1 ¶¶ 18, 22; 4-7 at 2. Essure received PMA as a Class III device in 2002, and the FDA has never withdrawn or suspended its approval prior to the FDA restricting its sale and distribution in 2018. Docs. 4-3 at 2; 4-4 at 2; 4-9 at 3.

Ferguson was implanted with Essure on June 3, 2010.[2] Doc. 1-1 ¶ 131. Ferguson claims her Essure device caused injuries including "pain, bleeding, infection, and the need for additional surgery." *Id.* ¶ 131; *see* Doc. 4-5 at 6-8 (discussing side effects). Because of these issues, she had surgery to remove the device. Doc. 1-1 ¶ 132. Ferguson subsequently filed suit alleging multiple theories of liability, including negligence claims (failure to report, Doc. 1-1 ¶¶ 140-45, 210-12, failure to warn, *id.* ¶ 140-45, 191-97, negligence per se, *id.* ¶¶ 168-71, failure to train implanting physicians, *id.* ¶¶ 182-88), products liability claims (manufacturing defects, *id.* ¶ 167-81, 200-08, 213, strict products liability, *id.* ¶¶ 190-216), breach of express and implied warranty claims, *id.* ¶¶ 217-39, and fraud, *id.* ¶¶ 240-54.[3]

[2] The Complaint is inconsistent as to the dates when Ferguson was implanted with Essure. Elsewhere, Ferguson states implantation occurred either in March 2014 or in 2014 generally. *See* Doc. 1-1 ¶¶ 174, 181.

[3] Ferguson filed her original complaint ("Complaint") in New Mexico state court on February 15, 2021. Doc. 1 ¶ 1. Defendants removed the case to this Court on July 20, 2021. *See generally id.*

III. Defendants' Motion to Dismiss and Ferguson's Response

In lieu of filing an answer, Defendants filed a Motion to Dismiss, asking the Court to dismiss the case with prejudice under Federal Rules of Civil Procedure ("Rules") 8, 9, and 12(b)(6). Doc. 4 at 1. Defendants argue that Ferguson's theories of liability are "expressly preempted by [21 U.S.C.] § 360k(a), impliedly preempted by [21 U.S.C.] § 337(a), or both." Doc. 4 at 7. Additionally, Defendants argue Ferguson's claims are inadequately pled because (1) Ferguson fails to plead facts showing Defendants' actions caused her injuries, and (2) the misrepresentation and fraud claims are not pled with the particularity required by Rule 9(b). Doc. 4 at 19, 21.[4]

Ferguson maintains her claims are not preempted because they are "based on New Mexico common law that [is] 'parallel' to FDA requirements related to medical devices." Doc. 13 at 3. Ferguson argues that she has avoided preemption because she "meticulously enumerated [Defendants'] tortious acts and omissions" and that each of her claims have been adequately pled to show Defendants' conduct proximately caused her injuries. *Id.* at 5, 10-11.

Following a hearing on the motion to dismiss, Doc. 30, Ferguson filed her Opposed Motion for Leave to File First Amended Complaint. Doc. 31. Ferguson now seeks to include a claim for breach of ordinary care under New Mexico law and rename her fraud claim as a violation of the

[4] The Court acknowledges Defendants' arguments that Ferguson abandoned some of her claims. *See* Doc. 14 at 2. A failure to respond to an issue may constitute a waiver and therefore may warrant dismissal. *Rock Roofing, LLC v. Travelers Cas. & Surety Co. of Am.*, 413 F. Supp. 3d 1122, 1128 (D.N.M. 2019). However, "even if a plaintiff does not file a response to a motion to dismiss for failure to state a claim, the district court must still examine the allegations in the plaintiff's complaint and determine whether the plaintiff has stated a claim upon which relief can be granted." *Issa v. Comp USA*, 354 F.3d 1174, 1178 (10th Cir. 2003). Thus, a party's "[f]ailure to respond to an argument is not inherently enough to merit dismissal for failure to state a claim." *Doe v. Farmington Mun. Sch.*, Case No. 1:21-cv-103 SCY/KK, 2022 U.S. Dist. LEXIS 17683, at *11 (D.N.M. Feb. 1, 2022). Following the Court's discussion of MDA federal preemption, *infra* Analysis Section I, the Court need not reach Defendants' abandonment arguments.

Unfair Trade Practices Act of New Mexico, NMSA 1978, § 57-12-1 (2003). *Compare* Doc. 1-1 *with* Doc. 31-1. Defendants oppose allowing Ferguson to amend her complaint. Doc. 32.

LEGAL STANDARD

A complaint must state a claim upon which relief can be granted or else be dismissed under Federal Rule of Civil Procedure 12(b)(6). To survive a Rule 12(b)(6) motion, the complaint must contain factual allegations that "raise a right to relief above the speculative level . . . on the assumption that all of the complaint's allegations are true." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *id.*). "To withstand a motion to dismiss, a complaint must have enough allegations of fact, taken as true, to state a claim to relief that is plausible on its face." *Fisher Sand & Gravel, Co. v. Giron*, 465 F. App'x 774, 778 (10th Cir. 2012) (internal brackets and citations omitted). 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." *Iqbal*, 556 U.S. at 678 (citations omitted).

ANALYSIS

I. Federal preemption under the MDA

The MDA includes two preemption provisions: express and implied. The MDA's express preemption provision provides:

> [N]o 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(a). The United States Supreme Court established a two-part test to evaluate a

claim for express preemption. *Riegel*, 552 U.S. at 321-22. First, a district court must ask whether the FDA has established any requirements applicable to the device at issue. *Id.* at 321. Second, a district court must determine whether the plaintiff's state law claims impose requirements that relate to the safety or effectiveness of the device and whether state law is either different from or adds to the federal requirements under the MDA. *Id.* at 322-23. As long as the duties sought to be imposed "parallel" the duties found in the FDCA, it does not enact new requirements on device manufacturers. *Lohr*, 518 U.S. at 495. A state law is "parallel" to a federal law either when the laws are identical or when the elements of the state law cause of action "make the state requirements narrower, not broader, than the federal requirement." *Id*.

By contrast, implied preemption arises from statutory language providing, "all such proceedings for the enforcement, or to restrain violations, of [Chapter 9 of the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with the medical device provisions."). Thus, a plaintiff may not file a tort claim arising "solely by virtue" of an FDCA violation. *Id.* at 353. Rather, "[a]ny such claim must be *predicated on* conduct that violates the FDCA" but rests on traditional state tort law. *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1279 (10th Cir. 2021), *cert. denied*, 142 S. Ct. 477 (2021). Section 337(a) therefore does not preempt claims that would traditionally give rise to liability under state tort law if the FDCA had never been enacted. *Compare Lohr*, 518 U.S. at 474 (allowing claim for common law negligence against manufacturer for alleged defective pacemaker lead), *with Buckman*, 531 U.S. at 353 (preempting state tort claim for defrauding the FDA during the approval process because the FDCA's existence was "a critical element" of the plaintiff's case).

Taken together, the MDA's express and implied preemptive scope leaves "only a narrow gap within which a plaintiff can plead a tort claim arising from the failure of a medical device." *Brooks*, 985 F.3d at 1276. "The plaintiff must be suing *for* conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (citation omitted and emphasis altered). "And when the pleader misses the gap—that is, when federal law preempts a claim—the court should dismiss that claim." *Brooks*, 985 F.3d at 1279.

II. Preemption as applied to Ferguson's claims

As a threshold matter, Ferguson does not dispute that device-specific FDA regulations and requirements apply to Essure. *See Riegel*, 552 U.S. at 321. Essure endured the PMA process and was subject to PMA and post-PMA reporting requirements. Docs. 1-1 ¶¶ 34-37; 4-3; 4-4; 4-9. Thus, the first prong of the *Riegel* express preemption analysis is met for each claim. Further, Ferguson does not allege that Defendants deviated from Essure's FDA-approved design specifications, labels, or warnings, nor that Defendants failed to adhere to the PMA process. Consequently, the Court's analysis focuses on the second step of the *Riegel* test—whether Ferguson has cited New Mexico law that imposes requirements relating to the safety and effectiveness of Essure, and if that law is "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a)(1).

A. Failure to Warn Claim

Defendants argue Ferguson's failure to warn claims are expressly and impliedly preempted because she does not allege that Essure's labeling deviated from that approved by the FDA. Doc. 4 at 8. Ferguson maintains, "General common law negligence claims imposed by a state regarding

failure to provide adequate warnings on medical device manufacturers have consistently been held not expressly or impliedly preempted by the MDA because they are parallel claims." Doc. 13 at 4.[5]

It is undisputed that the FDA heavily regulates device labeling and a manufacturer's duty to warn. *See* 21 C.F.R. §§ 801.1-.18 (general labeling provisions); 801.109-.128 (exemptions from adequate directions for use). Generally, "once the FDA approves a device's label as part of the premarket approval process (as it has here), the manufacturer usually may not alter the label's warnings without prior agency approval." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015); *see, e.g.*, 21 C.F.R. § 814.39(a)(2) (requiring that during the PMA process manufacturers submit a PMA supplement if labeling changes affect the safety or effectiveness of the device); 21 C.F.R. § 814.39(b) (stating a PMA supplement is not necessary if a labeling change on a device change would not affect its safety or effectiveness). Provided the prescription devices are labeled in a manner approved by the FDA, manufacturers are generally absolved of liability pertaining to a device that must be provided "under the supervision of a practitioner licensed by law to direct [its] use" because "'adequate directions for use' cannot be prepared" and due to the device's potential for harm, method of use, or general lack of safety. 21 C.F.R. § 801.109.

So, the Court looks to the second *Riegel* step and whether any New Mexico law, including general common law negligence, imposes requirements relating to the safety and effectiveness of Essure that are "different from, or in addition to" the federal requirements. 21 U.S.C. § 360k(a)(1).

[5] This contention was rejected in *Garcia v. Bayer Essure, Inc., et al.* (*Garcia I*), 631 F. Supp. 3d 1026, 1036-39 (D.N.M. 2022); the court ultimately concluded the plaintiff's claims were preempted. *See id.* After the district court allowed the plaintiff to amend her complaint, *id.* at 1040, the court dismissed the case without prejudice because the plaintiff's claims were still either preempted or inadequately pled. *Garcia v. Bayer Essure, Inc., et al.* (*Garcia II*), No. 1:21-CV-0066-MIS-JFR, 2023 U.S. Dist. LEXIS 112416, at *21-22 (N.M.D. June 28, 2023). Many of those claims were nearly identical to the claims Ferguson brings here.

Ferguson alleges Defendants breached their duty, imposed by state law, to warn the FDA, patients, and physicians of the alleged health risks posted by Essure. Doc. 1-1 ¶¶ 143-45. Ferguson also claims Defendants "persistently and knowingly withheld adverse event information from the FDA to enable a thorough review of warnings." Doc. 13 at 6. She references 21 C.F.R. §§ 803, 814, and 820 as parallel federal regulations and cites Uniform Jury Instruction ("UJI") 13-1402 (2021) to argue that "[m]anufacturers and suppliers of a product in New Mexico have a 'duty to use ordinary care to avoid a foreseeable risk of injury caused by a condition of the product or manner in which it is used.'" Doc. 13 at 4-5. If a manufacturer later learns of a condition that could cause risk of injury, they "must then use ordinary care to avoid the risk." *Id.* (citing UJI 13-1402, 13-1405 (defining ordinary care)).

FDA regulations explicitly preempt a state law prohibition that "has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement . . . if the requirement is different from, or in addition to, a Federal requirement established under the [FDCA]." 21 C.F.R. § 808.1(d)(6)(ii); *see Brooks*, 985 F.3d at 1280 ("[A]bsent a federal requirement that they do so, federal law expressly preempts any state-law duty requiring a manufacturer to update its labeling."); *see, e.g.*, *In re Medtronic*, 623 F.3d at 1205 (claims that manufacturer "was required to give additional warnings" beyond approved labeling are preempted). Because the duties proposed under UJI 13-1402 and 13-1405 would be in addition to or different from the duties imposed by federal law, the Court concludes Ferguson's failure to warn claim is expressly preempted.

B. Negligence Per Se Claim

Defendants argue that Ferguson's negligence per se claims are preempted under binding Tenth Circuit precedent because "'liability under negligence per se' based on violations of federal

regulations does not 'exist[] independently under state law.'" Doc. 4 at 14 (quoting *Brooks*, 985 F.3d at 1279). In *Brooks*, the Tenth Circuit held, "Any negligence per se action premised on an MDA violation necessarily seeks to enforce the MDA rather than a parallel state-law duty. And only the United States may enforce the MDA." 985 F.3d at 1280. "When we ask whether liability under negligence per se exists independently under state law, regardless of the FDCA or MDA, we must answer 'no.'" *Id.* (referencing *Buckman*, 531 U.S. at 349 n.4).

Ferguson alleges that Defendants violated multiple federal regulations which she argues also constitute violations of parallel state duties. Doc. 1-1 ¶ 168. She cites to the "New Mexico Food, Drug and Cosmetic Act," which the Court assumes is referring to the New Mexico Drug, Device and Cosmetic Act ("DDCA"), NMSA 1978, § 26-1-1 through -26 (1987). Doc. 1-1 ¶ 169. The DDCA does outline prohibited acts pertaining to devices in New Mexico under Section 26-1-3 (1987), but Ferguson does not specifically cite these provisions, nor does she explain how they evade preemption. Following established Tenth Circuit precedent, the Court holds that her negligence per se claim is impliedly preempted.

C. Negligent Training Claim

Defendants argue Ferguson's negligent training claim is expressly and impliedly preempted because she fails to allege how the departure from the training guidelines caused her injuries. Doc. 4 at 17. Defendants also argue that the complaint fails to allege causation as to this departure and her injuries. *Id.* at 18. Ferguson responds that this claim is not preempted because she has shown "Defendants deviated from the approved training by using sales representatives to train physicians" and it was "materially different than the training approved by the FDA." Doc. 13 at 8 (citing Doc. 1-1 ¶¶ 110, 174h, 188).

Any training requirement must appear in a device's approved labeling if the device is

restricted in sale, distribution, or use by the Secretary of Health because a licensed practitioner must authorize its administration or use. 21 U.S.C. § 360j(e). Essure's instructions for use (i.e., its labeling) provides:

> Federal law restricts this device to sale by or on the order of a physician. This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the Essure training program. Completion of the Essure training program includes preceptoring in Essure placement until competency is established, which is typically expected to be achieved in 5 cases.

Doc. 4-5 at 2 (2002 instructions for use); Doc. 4-7 at 1 (2008 instructions for use). According to the instructions for use, the physician training manual contains detailed information about the device and insertion procedure. Docs. 4-5 at 20; 4-7 at 5.

In the Complaint, Ferguson alleges Defendants "undertook a duty of training physicians, including the implanting physician, on how to properly use (1) its own mechanism of delivery and (2) the specialized hysteroscopic equipment manufactured by a third party." Doc. 1-1 ¶ 182. She claims Defendants were "negligent in not safely and properly training [Ferguson's] implanting physician on how to safely and properly perform the Essure[] procedure." *Id.* ¶ 185. The parties have not provided a copy of the physician training manual, nor has Ferguson detailed what constitutes Essure's training program. Further, the Court cannot discern whether training by individuals other than the sales representatives is a training requirement in the FDA's mandated labeling for Essure. The instructions for use simply caution that Essure is only to be used by knowledgeable hysterocopists who have completed the training program. Additionally, Ferguson does not allege how her implanting physician performed the procedure incorrectly or how her physician's subpar training led to her particular injuries. Nor has Ferguson cited parallel New Mexico law as required to evade express preemption.

Given these omissions, the Court concludes Ferguson has not "identified any legally viable federal requirement that might parallel and thus permit her claims." *Caplinger*, 784 F.3d at 1342. The complaint must show "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. Accordingly, Ferguson's claims relating to negligent training fail to state a claim upon which relief can be granted and will be dismissed.

D. Failure to Report Claim

Defendants argue Ferguson's failure to report claim is both expressly and impliedly preempted. Doc. 4 at 9. Ferguson argues she enumerated parallel federal and state regulations and statutes concerning medical device reporting, post market PMA supplements, and updated risk assessments. Doc. 13 at 5-6. In her complaint, Ferguson alleges "Defendants failed to timely, completely, or accurately report their knowledge of risks and complications associated with" Essure. Doc. 1-1 ¶ 60.

The FDA has promulgated multiple regulations concerning manufacturers' reporting about their medical devices. *See* 21 C.F.R. §§ 803.1-.19 (general provisions); §§ 803.50-.58 (manufacturer reporting requirements). For example, 21 C.F.R. § 803.1(a) requires device manufacturers to report deaths and serious injuries or certain device malfunctions their device has or may have caused or contributed to. *See* 21 C.F.R. § 803.10 (outlining timing of report submissions).

Though Ferguson argues Defendants violated parallel New Mexico law, she does not cite traditional state tort causes of action that might withstand preemption. Doc. 13 at 6. Law concerning implied preemption generally labels failure to report claims as "fraud-on-the-FDA." The United States Supreme Court barred claims for such fraud under implied preemption; the Supreme Court reasoned, "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's

responsibility to police fraud consistently with the [FDA's] judgment and objectives." *Buckman,* 531 U.S. at 350. Following *Buckman*, the Tenth Circuit held, "only the federal government may enforce reporting requirements and investigate and respond to suspected fraud." *Brooks*, 985 F.3d at 1281. In other words, "[c]laims based on alleged failures to properly conduct post-PMA reporting are therefore impliedly preempted as improper private 'attempts to enforce the MDA.'" *Garcia I*, 631 F.Supp. 3d at 1036 (quoting *Brooks*, 985 F.3d at 1281). Thus, Ferguson's failure to report claim is impliedly preempted and will be dismissed.

E. Manufacturing Defect Claim

Defendants argue Ferguson's manufacturing defect claim is expressly and impliedly preempted. Doc. 4 at 14. Defendants also contend she "fails to identify violations of federal requirements that produced actual defects in *her* specific device and caused her injuries." *Id.* Ferguson does not specifically address Defendants' arguments in her response brief.

The FDA prohibits the manufacture of a device that was not made in a manner consistent with its PMA approval order. 21 C.F.R. § 814.80; *see* 21 C.F.R. § 820.5 (requiring each manufacturer establish and maintain a "quality system" that is tailored to the specific device manufactured). If a device is not manufactured in accordance with federal requirements, it may be deemed "adulterated" because "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation" were not followed. 21 U.S.C. § 351(h).

Ferguson alleges her Essure device was manufactured in a facility that violated FDA requirements and good manufacturing practices, Doc. 1-1 ¶¶ 89-97; was "defective and unreasonably dangerous," *id.* ¶ 174; was incorporated with components that could not "stand up to normal usage," *id.* ¶ 174e; was manufactured with "non-conforming material," *id.* ¶ 82; and was an "adulterated" device. *Id.* ¶ 75.

Ferguson cannot state a viable legal claim based on Defendants' alleged adulteration of certain devices in violation of only the FDCA—that claim exists solely by virtue of the statute and is impliedly preempted. *See Buckman*, 531 U.S. at 353. However, had Ferguson stated a state law claim based on the New Mexico Drug, Device and Cosmetic Act, which prohibits the adulteration or misbranding of any device, and the sale of such a device, that claim might have survived express preemption. *See* NMSA 1978, § 26-1-3(A), (B) (1987). But Ferguson fails to allege the nature of the manufacturing defect as to her device, what might have caused the defect, which components could not stand up to its use, or what constituted the "non-conforming material." Her complaint also fails to allege how Essure's manufacturing defect caused her injuries. Accordingly, her manufacturing defect claim shall be dismissed.

F. Products Liability and Design Defect Claims

Defendants argue Ferguson's product liability claims are expressly preempted. Doc. 4 at 7. Ferguson maintains that her strict product liability claim—which presumably includes her design defect claim—is not preempted because Defendants violated New Mexico strict products liability law. Doc. 13 at 8. She argues Defendants are liable because they failed to warn of a "non-obvious risk" and she has proved causation. *Id.* at 9.

The parties do not dispute that the FDA approved the Essure device, and Ferguson does not allege that Defendants deviated from the design approved by the FDA. Instead, she claims her Essure device was "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" harm. Doc. 1-1 ¶ 196. Additionally, the coils on her particular Essure device "became unpassivated, making it vulnerable to degradation, deterioration, leaching, breakage, and fragmentation." *Id.* ¶ 213.

Design defect claims rarely survive preemption because such a claim would challenge the FDA-approved design. *See De La Paz v. Bayer HealthCare Ltd. Liab. Co.*, 159 F. Supp. 3d 1085, 1094-95 (N.D. Cal. 2016) (dismissing claim that Essure device had fundamental design defects). Under federal law, after a device receives premarket approval, the MDA forbids the manufacturer from making changes in design specifications that would affect the device's safety or effectiveness without FDA permission. 21 U.S.C. 360e(d)(5)(A)(i); *Riegel*, 552 U.S. at 319.

Ferguson argues that under New Mexico law, "a supplier in the business of putting a product on the market is liable for harm caused by an unreasonable risk of injury resulting from a condition of the product or from a manner of its use." UJI 13-1406 (2021) NMRA; *see* Doc. 13 at 8. Ferguson also cites *Parker v. E.I. DuPont de Nemours & Co.*, 1995-NMCA-086, ¶ 11, 121 N.M. 120, 909 P.2d 1, and *Stang v. Hertz Corp.*, 1972-NMSC-031, ¶ 22, 83 N.M. 730, 497 P.2d 732, for the principles of strict liability in the state. Doc. 13 at 8-9. New Mexico "applies the rule of strict liability upon a manufacturer . . . of unreasonably dangerous products where the dangerous condition of the product is shown to exist when it left the manufacturer's . . . control." *Parker*, 1995-NMCA-086, ¶ 11.

Thus, in order for her to avoid preemption, Ferguson would need to show that the irregularities documented during the Essure production process caused her injuries when the device left the manufacturing facility. However, Plaintiff does not draw these connections between the facts and the alleged harm. Consequently, the Court concludes Ferguson's strict products liability and design defect claims do not provide sufficient factual allegations to state a plausible claim for relief that survives dismissal.

III. Ferguson's fraud claim is not pled with the particularity required by Rule 9(b).

Defendants contend Ferguson's fraud claim should be dismissed because she has failed to

plead it with the particularity demanded by Rule 9(b). Docs. 4 at 21; 14 at 7-8. A plaintiff alleging fraud or misrepresentation must "must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "More specifically, [the Tenth Circuit] requires a complaint alleging fraud to 'set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof.'" *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1236 (10th Cir. 2000) (quoting *Lawrence Nat'l Bank v. Edmonds (In re Edmonds)*, 924 F.2d 176, 180 (10th Cir. 1991)).

Ferguson argues Defendants violated the New Mexico Unfair Trade Practices Act, NMSA 1978, § 57-12-1 *et seq.* (2003), because "Defendants made knowingly false statements of material fact" and "made affirmative representations to [her] and/or her physicians" about Essure's safety and efficacy that she and/or her physician relied upon. Doc. 1-1 ¶¶ 241, 244. Yet, Ferguson does not detail the false statements or representations nor how she or her physician encountered them. Ferguson's fraud claim is not pled with the particularity required by Rule 9(b). This claim will be dismissed.

IV. Claims for breach of express and implied warranties are barred by the statute of limitations under the New Mexico Uniform Commercial Code.

Defendants argue that Ferguson's breach of warranty claims are "are facially barred by the statute of limitations" of the New Mexico Uniform Commercial Code ("UCC") - Sales, NMSA 1978, § 55-2-101 *et seq.* (2005). Doc. 4 at 19; *see id.* at 22. Specifically, Defendants argue New Mexico law bars any of Ferguson's warranty claims because she "acquired" the Essure device more than four years before the complaint was filed. *Id.* at 22; Doc. 14 at 8. Ferguson does not address the possible statute of limitations barring her claims.[6]

[6] Again, the Court will address the merits of Ferguson's claims before deciding whether they have

The UCC provides the requisite statute of limitations in contracts for sale: "[a]n action for breach of any contract for sale must be commenced within four years after the cause of action has accrued." NMSA 1978, § 55-2-725(1). Further,

> [a] cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance, the cause of action accrues when the breach is or should have been discovered.

Section 55-2-725(2).[7]

Ferguson alleges she discovered the medical issues caused by her Essure device on or about June 13, 2019. Doc. 1-1 ¶ 133. The date of "delivery" of her Essure device was June 3, 2010.[8] *Id.* ¶ 131; *see Nowell v. Medtronic, Inc.*, 372 F. Supp. 3d 1166, 1241-42 (D.N.M. 2019) (concluding "delivery" occurred when medical device was implanted and dismissing warranty claims on timeliness grounds). Her complaint containing the warranty claims was filed in state court on February 15, 2021. Doc. 1. This falls outside of the four-year statute of limitations of Section 55-2-275(1). *See Garcia I*, 631 F. Supp. 3d at 1039 (dismissing the plaintiff's claims for breach of warranty as untimely due to the statute of limitations under Section 55-2-275(1)). Thus, Ferguson's breach of warranty claims are untimely and shall be dismissed.

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been abandoned and are subject to dismissal. *See Issa*, 354 F.3d at 1178; *Doe*, 2022 U.S. Dist. LEXIS 17683, at *11. Additionally, neither Ferguson nor Defendants address Count VI or VII in her complaint. As a result, the Court deems these claims abandoned.

[7] NMSA 1978, Sections 55-2-313 (1961) and 55-2-315 (1961), define the requirements for express and implied warranties.

[8] Again, the Court notes that the Complaint is inconsistent as to the dates when Ferguson was implanted with Essure. *See* Doc. 1-1 ¶¶ 174, 181 (referencing March 2014 or just "2014"). Even if March 2014 is the date of implantation, the filing of her case in state court still falls outside the four-year statute of limitations.

V. The Motion to Amend

Ferguson asks this Court for leave to amend her pleadings under Federal Rule of Civil Procedure 15(a)(2).[9] Doc. 31. In reply, Defendants argue her motion to amend should be denied because the amendment is futile and unduly delayed. Doc. 32 at 1. To support this argument, Defendants specifically argue that Ferguson's proposed arguments regarding "common law principles of ordinary care," Doc. 31-1 ¶ 1, cannot survive preemption and amending her complaint is futile. Doc. 32 at 1. Also, Defendants emphasize that Ferguson has not explained the two-year delay in seeking to amend her complaint. *Id.*

Federal Rule of Civil Procedure 15(a) provides that leave to amend shall be given freely. *See Bradley v. Val-Mejias*, 379 F.3d 892, 900 (10th Cir. 2004) ("The grant or denial of an opportunity to amend is within the discretion of the District Court."). A "district court should refuse leave to amend 'only [upon] showing of undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment." *Wilkerson v. Shinseki*, 606 F.3d 1256, 1267 (10th Cir. 2010) (alteration in original) (citation omitted). "A proposed amendment is futile if the complaint, as amended, would be subject to dismissal." *Jefferson County Sch. Dist. No. R-1 v. Moody's Investor's Services, Inc.*, 175 F.3d 848, 859 (10th Cir. 1999).

Ferguson seeks to amend her complaint to include a claim for breach of ordinary care under New Mexico law and rename her fraud claim as a violation of the Unfair Trade Practices Act of

[9] Ferguson previously asked this Court for leave to amend her pleadings in a one-sentence request in her response to Defendants' motion to dismiss. Doc. 13 at 11. Ferguson did not attach a proposed amended complaint alongside this request, which did not comply with D.N.M. LR-Civ. 15.1 ("A proposed amendment to a pleading must accompany the motion to amend."). *See Brooks*, 985 F.3d at 1283 ("[B]are requests for leave to amend do not rise to the status of a motion and do not put the issue before the district court."). At the hearing on Defendants' motion to dismiss, the Court instructed Ferguson that she should file a motion seeking leave to amend instead of the single sentence in the response and an oral request at the hearing. *See* Doc. 30.

New Mexico, NMSA 1978, § 57-12-1 *et seq.* (2003). Doc. 31-1. Instead of citing specific provisions of New Mexico law, Ferguson turns to principles of ordinary care. *See, e.g.*, Doc. 31-1 ¶ 125. Ferguson still does not cite New Mexico state law for her negligence or products liability claims.

This Court and other district courts have rejected similar arguments to those proposed in her Amended Complaint as insufficient to surmount MDA preemption. *See, e.g.*, *Garcia I*, 631 F. Supp. 3d at 1035 (dismissing, on preemption grounds, complaint alleging Bayer failed to exercise "ordinary care"); *Garcia II*, 2023 U.S. Dist. LEXIS 112416, at *11 (dismissing plaintiff's negligence claims for failure to allege parallel requirements); *Noel v. Bayer Corp.*, 481 F. Supp. 3d 1111, 1127 (D. Mont. 2020) (dismissing, on preemption grounds, the complaint alleging Bayer failed to exercise "reasonable care"); *De La Paz*, 159 F. Supp. 3d at 1100 (same); *Hawkins v. Bayer Corp.*, No. 1:21-CV-646-RP, 2022 U.S. Dist. LEXIS 126306, at *1-3 (W.D. Tex. Feb. 23, 2022) (same); *Olmstead v. Bayer Corp.*, No. 3:17-CV-387, 2017 U.S. Dist. LEXIS 129222, at *9 (N.D.N.Y. Aug. 15, 2017) (same); *Norman v. Bayer Corp.*, No. 3:16-cv-00253, 2016 U.S. LEXIS 96993, at *21 (D. Conn. July 26, 2016) (same).

Moreover, "untimeliness alone is a sufficient reason to deny leave to amend, especially when the party filing the motion has no adequate explanation for the delay." *Frank v. U.S. West, Inc.*, 3 F.3d 1357, 1365-66 (10th Cir. 1993) (citations omitted); *see also Pallottino v. City of Rio Rancho*, 31 F.3d 1023, 1027 (10th Cir. 1994). Ferguson has not offered an explanation as to her delay to seek amending her complaint until after the May 17, 2023, motion hearing.

The Court concludes Ferguson's proposed amended complaint is still not sufficient despite its amendments—the amended complaint lacks the required factual and legal specificity to avoid preemption. Ferguson does not explain why her request to amend the complaint waited until

Defendants' motion to dismiss and when the Court prompted her to amend. Ultimately, the Court concludes Ferguson's request to amend her complaint is both futile and untimely.

CONCLUSION

The Court concludes the MDA expressly preempts Ferguson's failure to warn claim under the *Riegel* test and binding Tenth Circuit precedent. Where Ferguson did not cite parallel New Mexico law, the Court did not endeavor to make Ferguson's argument for her—the Court is not "under an obligation to perform that work for her, searching out theories and authorities she has not presented for herself." *Caplinger*, 784 F.3d at 1342; *see, e.g.*, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-03 (11th Cir. 2011) (affirming the dismissal of a complaint where plaintiff failed to identify a parallel federal duty); *In re Medtronic*, 623 F.3d at 1205-07 (same). The Court also concludes 21 U.S.C. § 337(a) impliedly preempts both her negligence per se claim, because it cannot exist independently under state law, and her failure to warn/fraud-on-the-FDA claim because it is the quintessential claim the Supreme Court rejected in *Buckman*, 531 U.S. at 352.

Further, when taking all the facts in the complaint as true, Ferguson has not stated her negligent training, manufacturing defect, strict products liability, or design defect claims with sufficient facial plausibility to survive dismissal. Ferguson's fraud and misrepresentation claims are not pled with the particularly required by Rule 9(b). Also, Ferguson's claims for breach of express and implied warranties are timed barred by the New Mexico UCC, § 55-2-725(1).

Lastly, the Court concludes that Ferguson's motion to amend her complaint is both futile and untimely.

For the foregoing reasons, it is hereby ordered that Defendants' Motion to Dismiss, Doc. 4, is granted, and Ferguson's claims are dismissed with prejudice.

It is further ordered that Ferguson's Motion to Amend, Doc. 31, is denied.

UNITED STATES DISTRICT JUDGE
MATTHEW L. GARCIA