UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

APRIL NORMAN, *Plaintiff*, v. BAYER CORP. et al., *Defendants*.	No. 3:16-cv-00253 (JAM)

RULING GRANTING MOTION TO DISMISS

This is a products liability case about Essure, a permanent contraceptive device that is allegedly manufactured and marketed by defendant Bayer Corp. and related defendants. Plaintiff April Norman alleges that this device caused her injuries after she had it implanted. Essure is a Class III medical device that passed the Food and Drug Administration's stringent premarket approval process before being sold to the general public. Because all of plaintiff's claims are either preempted by the federal law or fail to allege facts that give rise to plausible grounds for relief, I will grant defendants' motion to dismiss.

BACKGROUND

The following facts are described as alleged in the complaint. Essure is a Class III medical device designed to effect permanent female birth control. The device involves insertion of metal coils called "micro-inserts" to block the fallopian tubes and prevent pregnancy. It is manufactured, marketed, and sold by defendants.[1]

The complaint extensively describes the device's features, history, and associated marketing materials. The following allegations are the most significant: The federal Food and

[1] The defendants are Bayer Corp., Bayer Healthcare, LLC, Bayer Essure, Inc. (F/K/A Conceptus, Inc.), Bayer Healthcare Pharmaceuticals, Inc., and Bayer A.G. The distinctions between these defendants are immaterial for purposes of this motion.

Drug Administration (FDA) issued a pre-market approval (PMA) of Essure as a Class III medical device in 2002. Such approvals involve an intensive application process and also impose extensive and ongoing regulatory requirements to ensure the safety and effectiveness of the device. Among other requirements were that defendants had to report certain adverse events involving the device. Defendants' manufacturing plants were also subject to FDA inspection.

According to the complaint, the FDA cited defendants for multiple violations of FDA regulations on various dates from 2003 to 2013, including that defendants were producing devices at an unlicensed facility, that defendants had used "non-conforming material" for the devices at one facility, and that defendants had failed to report to the FDA adverse events including perforations of the fallopian tubes from the device. Plaintiff also alleges that defendants inadequately trained doctors to perform the Essure insertion procedure by, for example, allowing trained company representatives—who were not physicians—to conduct the training.

In plaintiff's 29-page complaint, only four short paragraphs relate to her personal experience with Essure. In March 2013, plaintiff wanted a traditional tubal ligation, but her doctor instead recommended the Essure device, and she underwent the procedure. She later suffered from pelvic pain, weight gain, heavy bleeding, blood clots, painful intercourse, hair loss, and depression, and had a hysterectromy to remove the device. The complaint does not allege any facts to indicate that the device was improperly implanted, that it broke, or that it had any other manufacturing defect. Nor does the complaint allege that plaintiff or her doctor consulted or relied upon any particular information or warnings about the device.

Plaintiff now brings this lawsuit alleging seven counts, titled as follows: Strict Products Liability (Count One); Negligent Failure to Warn (Count Two); Negligence in Training (Count

Three); Negligence in Manufacturing (Count Four); Negligence / Negligence Per Se (Count Five); Negligent Misrepresentation (Count Six); and Breach of Express Warranty (Count Seven). Defendants have moved to dismiss the complaint in its entirety, contending that every count of the complaint is either preempted by the FDA's regulatory scheme, or fails to allege sufficient facts to give rise to plausible grounds for relief. Doc. #31.

DISCUSSION

The principles governing this Court's consideration of a Rule 12(b)(6) motion are well established. First, the Court must accept as true all factual matter alleged in a complaint and draw all reasonable inferences in the plaintiffs' favor. *See Johnson v. Priceline.com, Inc.*, 711 F.3d 271, 275 (2d Cir. 2013). But, "'[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Preemption of State Law Claims Involving Medical Devices

Defendant argues that many, if not all, of plaintiff's claims are preempted by the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. It is well established that "Congress has the power to preempt state law." *Arizona v. United States*, —— U.S. ——, 132 S.Ct. 2492, 2500–01 (2012). But a federal statute will not be found to preempt claims arising under state law unless Congress' intent to do so is "clear and manifest." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Medical devices are governed by the Medical Device Amendments (MDA) to the FDCA, and the MDA includes the following express preemption provision:

> [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). Therefore, for medical devices that have been subject to the FDA's rigorous pre-marketing approval process, any state law that imposes obligations on a medical device producer "different from, or in addition to" the requirements of the MDA is expressly preempted under § 360k(a). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). The Supreme Court has further held that a state law claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

A plaintiff's state-law claim arising from the use of a medical device must therefore fit into a "narrow gap" to avoid express or implied preemption. "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 Products Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). Thus, a plaintiff must plead a state-law claim that parallels federal law requirements but that is not wholly derivative of federal law; "the difficulty of crafting a complaint sufficient to satisfy all these demands [of express and implied preemption] has been compared to the task of navigating between Scylla and Charybdis." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1334, 1340 (10th Cir. 2015).

Strict Liability & Manufacturing Defect (Counts One and Four)

Plaintiff brings claims for strict products liability and for negligent manufacturing. In support of these claims, she principally relies on the Form 483—an FDA violation report—indicating defendants had used "non-conforming material" in production of Essure at at least one plant. Under the Connecticut Products Liability Act, Conn. Gen. Stat. § 52-572n, in order to prove a strict liability claim, plaintiff must prove the device was "in a defective condition unreasonably dangerous to her and that this defect caused the injury for which she seeks damages." Such defective condition may be "due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions."[2] *Simoneau v. Stryker Corp.*, 2014 WL 1289426, at *5 (D. Conn. 2014).

In order to avoid preemption on a manufacturing defect claim, plaintiff must allege that her device was not manufactured in conformance with the specifications approved by the FDA. *See McConologue v. Smith & Nephew, Inc*., 8 F. Supp. 3d 93, 106 (D. Conn. 2014). Plaintiff alleges that there may have been some devices produced with "non-conforming materials," but does not allege any plausible reason to think that *her* device came from the non-conforming batch, or that it suffered from any other manufacturing defect. In any case, she does not allege any facts that would make it plausible that the complications she suffered—which were known potential side effects—were due to any defect in the device. She does not, for example, allege that the device broke off, that it migrated from her fallopian tubes, or that it caused a puncture. *See De La Paz v. Bayer Healthcare LLC*, __ F. Supp. 3d __, 2016 WL 392972, at *7 (N.D. Cal. 2016) (dismissing nearly identical manufacturing defect claims in an Essure case because the

[2] To the extent the strict liability claim is premised on inadequate warnings, those claims are addressed below under the failure-to-warn claim. To the extent the "inadequate instructions" are based on supposedly inadequate training, it is addressed below under the negligent training claim.

plaintiff made no allegation that "the irregularities documented in the Form 483s resulted in a manufacturing defect that caused her injuries"). I will therefore dismiss the claims based on an alleged manufacturing defect.[3]

Failure to Warn the FDA (Count Two)

Plaintiff next argues that defendants may be liable because they were required to report certain adverse events to the FDA and failed to do so. Because I conclude that Connecticut law creates no parallel duty to report such events to the FDA, I will also dismiss this claim.

First, it is clear that plaintiff cannot bring a claim because defendants failed to warn plaintiff personally—at least insofar as plaintiff has not identified any FDA requirement that defendants must provide such a direct consumer warning—because such a claim would be expressly preempted as imposing obligations beyond those of the FDCA. *See McConologue*, 8 F. Supp.3d at 108 (dismissing failure-to-warn claim because the plaintiff "failed to allege the existence of any FDA requirements applicable to consumer warnings such that the Court may determine whether a state failure to warn claim is 'different from, or in addition to' FDA requirements"). Plaintiff instead alleges that defendants failed to adhere to the FDA's reporting requirements, as evidenced by the FDA's violation reports.

A tort for failure to warn a victim exists under Connecticut law. *See* Conn. Gen. Stat. Ann. § 52-572q. But this is a duty to the plaintiff herself, not to some third party, who might then report the danger to the plaintiff. There is no general or background duty under Connecticut law to report risks *to a regulatory body*. To avoid preemption, a claim must be "premised on the type of conduct that would traditionally give rise to liability under state law—

[3] To the extent plaintiff also intended to raise a design defect claim, that will also be dismissed. *See* Doc. #34 at 25. The FDA has approved the design of the Essure. Therefore, any finding that defendants were liable for that design would necessarily impose requirements "in addition to, or different from" those imposed by the FDA. The claim is therefore preempted. *See Riegel*, 552 U.S. at 330.

and that would give rise to liability under state law even if the FDCA had never been enacted." *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013). The failure-to-warn claim arises solely from the MDA's reporting requirements, and therefore is subject to implied preemption. *See Buckman*, 531 U.S. at 353; *McLaughlin v. Bayer Corp.*, 2016 WL 1161578, at *13 (E.D. Pa. 2016).

I recognize that this analysis is in tension with the Ninth Circuit's holding in *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013). In *Stengel*, the plaintiffs alleged that defendant failed in its common law "duty to use reasonable care" when it failed in its reporting requirements under the MDA. The court held that this stated a plausible claim for relief, and that the state law duty paralleled the federal duty. According to the *Stengel* court, the state law duty did not solely arise from the federal duty because "Arizona law contemplates a warning to a third party such as the FDA," since a manufacturer could satisfy its duty to warn by providing the warning to a third party if there was a "reasonable assurance that the information will reach those whose safety depends on their having it." *Stengel*, 704 F.3d at 1233.

Whatever the merits of this analysis under Arizona law, it does not accurately describe Connecticut law. The language quoted in *Stengel* regarding a "reasonable assurance that the information will reach" the plaintiff is from a comment to the Second Restatement of Torts. *See* Restatement (Second) of Torts, § 388, Comment n. The comment addresses situations where a dangerous product is provided to one person (such as a store owner) for the use of another (such as a customer). In context, the quoted language means that the seller cannot escape liability on a failure-to-warn claim merely because he informed the *distributor*—rather than the customer—of the risks, unless he has a very good reason to believe that the distributor will

impart that information to the customer. In this sense, the comment accurately describes Connecticut law. *See* Conn. Gen. Stat. § 52-572q.

But it does not follow from this principle that defendants had a state-law duty to warn the FDA, a third party with no relationship to plaintiff. The analogous party to the shop owner in the above example is plaintiff's doctor—who had a direct relationship with plaintiff and provided the device—not the FDA. Further, because of the FDA's independence and bureaucratic process, defendants hardly would have had any "reasonable assurance" that the reported information would have reached plaintiff. Absent the specific reporting requirements of the FDCA, no Connecticut court would have imposed a duty on defendants to report adverse events *to the FDA*, rather than alter the warning label or communicate with plaintiff and her doctor. The failure-to-warn claim here is wholly derivative of the MDA's requirements and is therefore preempted.

Even if the claim were not preempted, plaintiff fails to plead facts that plausibly connect defendants' alleged reporting violations to her injuries. Plaintiff alleges that, at least in part due to the discovery of more adverse events, the FDA is now planning to require defendants to employ a so-called "black box warning," which doctors and professionals recognize as a more serious warning. Plaintiff's theory of causation seems to be that, had defendants kept up with their reporting requirements, this black box warning would have been issued earlier, and she would not have chosen to get the device implanted. But the FDA was aware of these reporting issues years before plaintiff's device was implanted, and the new *type* of warning did not change any of the warnings' substance—defendants, for example, were already required to advise physicians about the possibility of perforations. *See* Doc. #32 at 22-23. Therefore,

plaintiff "has failed to plausibly show that her injuries would have been prevented if Bayer had properly reported the perforation events." *De La Paz*, 2016 WL 392972, at *10.

Negligent Training (Count Three)

Plaintiff next argues that defendants are liable because they were negligent in training physicians how to implant Essure. The parties dispute whether there is a cause of action under Connecticut law for negligent training. Even assuming for the sake of argument that such a cause of action exists, there is no dispute that it would require plaintiff to show, as for any other tort, a causal connection between the violation of a duty and the harm she suffered. *See De La Paz*, 2016 WL 392972, at *9 ("[T]he [negligent training] claim must also plausibly allege a causal link between an alleged negligence in training and [plaintiff's] injuries."); *McLaughlin*, 2016 WL 1161578 at *7 (same).

Plaintiff fails to allege any facts that could plausibly suggest that her injuries were the result of the alleged negligent training. She does not allege that her device was improperly implanted, that it suffered from any defect from how it was handled by any intermediary, or that her injuries were in any other way the result of a mistake by her doctor. *See De La Paz*, 2016 WL 392972, at *9, *McLaughlin*, 2016 WL 1161578, at *7. Accordingly, this claim will be dismissed.

Negligence* Per Se *(Count Five)

Plaintiff next alleges that defendants were negligent *per se* insofar as defendants violated several FDA statutes and regulations. A defendant may be negligent *per se*—that is, presumed negligent—when she violates certain laws related to the harm the plaintiff suffered. *See Gore v. People's Sav. Bank*, 235 Conn. 360, 376 (1995). The only laws plaintiff identifies here are federal and part of the FDA regulatory scheme. This claim plainly is not parallel to the

federal scheme, but arises directly and wholly derivatively from the violation of federal law. The claim is therefore subject to implied preemption. *See Buckman*, 531 U.S. at 353.

Negligent Misrepresentation/Breach of Express Warranty (Counts Six and Seven)

Plaintiff's final claims are for negligent misrepresentation and breach of express warranty. At this stage, the parties agree that the central question for both claims is whether any of the alleged misrepresentations by defendant were not approved by the FDA during the PMA process. *See, e.g., Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) (finding breach of warranty claims preempted because they were premised on language approved by the FDA); *Pisonneault*, 953 F. Supp. 2d at 1019 ("[T]o the extent that plaintiffs' breach of express warranty claims are based on . . . statements that were . . . approved or mandated by the FDA, such claims are preempted.").

The complaint identifies several statements that plaintiff claims were both misleading and were not approved by the FDA. Defendants' brief compares each of these statements to the labeling approved by the FDA. *See* Doc. #32 at 9-10. For several of these statements—such as the claim that no pregnancies were reported in the clinical effectiveness trials—plaintiff makes no attempt to argue that they differed materially from the FDA-approved labeling, so I will not address them here.

As to those statements that plaintiff does argue were not approved by the FDA, I conclude in each case that the claim is not actionable. For each statement, the claim is either so similar to the approved language as to be substantively the same, or plaintiff has not properly alleged any actual misrepresentation, or that she was actually deceived or that she relied on the alleged "warranty" from defendants.

First, plaintiff argues that it was a misrepresentation for defendants to state that Essure used a "gentle procedure that can be performed in a doctor's office in less than 10 minutes." Doc. #34 at 11. The FDA approved language that the procedure was "simple and does not take a lot of time," "is usually performed in a doctor's office," and "usually takes less than ten minutes." Doc. #32-8 at 5, 7, 10. Plaintiff argues that the word "gentle" was not approved, and alleges that, in fact, "Essure can cause serious, life-altering complications including severe pelvic pain . . . perforation of the fallopian tube . . ., hysterectomy, and other complications." Doc. #34 at 11. First, the claim that the procedure is "gentle" is closely related to FDA-approved claims that the procedure is "simple," "non-surgical," and takes "no downtime to recover." Doc. #32-8 at 6. But even if the "gentle" claim were not preempted, it is clear in context that defendants represented that the procedure itself was "gentle," not that there were no possible complications that could cause pain. Therefore, to the extent this language differed from that approved by the FDA, plaintiff has not alleged it was a misrepresentation or that there was any breach of the alleged "warranty."

Next, plaintiff alleges that defendants warranted that "[s]ince Essure does not contain hormones, it should not cause weight gain." Doc. #34 at 12. The FDA approved language that "Essure inserts do not contain or release hormones." Doc. #32-8 at 6. It did not approve any language specifically about "weight gain." But, even if this were sufficient to escape preemption, plaintiff does not allege that she ever actually read or relied on this statement, and therefore cannot show causation.

Plaintiff also objects to defendant's claim that the "Essure procedure is the most effective form of birth control available." The FDA-approved materials compared Essure to vasectomy, tubal ligation, and other methods of contraception and listed them all at a lower

failure rate than Essure. Doc. #32-8 at 16-20. Defendants' statements are a natural interpretation of the data the FDA approved. At oral argument, plaintiff's counsel noted that these studies were only for fixed periods of time. But that is always true when empirical studies are used, and it does not defeat preemption here. These statements are materially identical, and any claim based on them is preempted.

Plaintiff takes issue with defendants' claim that they would "sign off" on hysteroscopy training for a physician before they would be permitted to implant an Essure device, when in fact non-physicians who were not trained in hysteroscopy were the people "signing off." Similarly, she objects to defendants' alleged representations that the physicians would complete training "with a Conceptus designated preceptor," who turned out to be a company sales representative rather than a medical specialist. But plaintiff does not identify any statement that was outside what was approved by the FDA. The claim based on this statement is therefore preempted.

Defendants also allegedly represent that the Essure's "mechanism of action is the body's natural healing response," and the PET fibers "on the inner core of the micro-insert elicit a benign tissue healing response . . . . The tissue response has been found to be reliable and localized to the micro-insert." Doc. #34 at 13. The FDA-approved material states that "your body will form tissue around the Essure inserts," developing "a natural barrier." Doc. #32-8 at 7. This language is in all material respects identical to claims regarding the "natural healing response" and that the response is "localized to the micro-insert." But even if these differences were sufficient to avoid preemption, plaintiff does not allege that these representations were false or misleading. She alleges that the PET fibers were not the cause of

"inflammatory tissue growth," but the claim regarding the PET fibers *was* in the FDA approved language. *See* Doc. #34 at 13. The claim therefore cannot survive.

Finally, plaintiff objects to defendants' statement that "Essure is contraindicated in patients with a hypersensitivity to nickel" and its accompanying recommendation of "a skin test for a nickel allergy." Doc. #34 at 15. But plaintiff does not allege that this statement was actually a misrepresentation—she only notes that a Bayer representative testified that skin-testing is not a reliable way to tell if someone will have a reaction to a nickel implantable device. Since these facts do not make plausible a claim that the statement was false or misleading, it will be dismissed.

Moreover, even if any of these claims were not preempted by approval from the FDA, plaintiff does not allege that she read or saw any of these statements. She has therefore alleged insufficient facts to support an inference of causation. Accordingly, I will also dismiss the breach of warranty and negligent misrepresentation claims.

Dismissal with Prejudice

In her opposition papers, plaintiff requests leave to amend her complaint for any claims that I dismiss for lack of alleged facts to support a plausible claim for relief. Plaintiff is already on her fourth complaint, *see* Doc. #35, and must be granted leave of the Court before she may file another amended complaint. *See* Fed. R. Civ. P. 15. Generally, a "court should freely give leave [to amend] when justice so requires." *Id.* But "[w]here it appears that granting leave to amend is unlikely to be productive . . . it is not an abuse of discretion to deny leave to amend."*Apotex Inc. v. Acorda Therapeutics, Inc.*, __ F. 3d __, 2016 WL 2848911, at *7 (2d Cir. 2016); *Ruffolo v. Oppenheimer & Co.*, 987 F.2d 129, 131 (2d Cir. 1993). Plaintiff has already amended her complaint three times—once after the motion to dismiss was filed, when

plaintiff was fully aware of the basis for a challenge to the plausibility of her claims. Further, she provides no reason to believe any facts she might include in an amended complaint were not already available to her at the time she filed her previous complaints. *See Apotex*, 2016 WL 2848911, at *7 (upholding denial of leave to amend where the plaintiff already had access to the information it wished to add at the time of filing the original complaint). I conclude that further amendment would be futile, and accordingly will dismiss the complaint with prejudice.

CONCLUSION

The motion to dismiss (Doc. #31) is GRANTED, with prejudice.

The Clerk of Court shall close the case.

Dated at New Haven this 26th day of July 2016.

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge