**UNITED STATES DISTRICT COURT**
**DISTRICT OF CONNECTICUT**

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| JENNIFER PRATT,<br>*Plaintiff*,<br><br>v.<br><br>BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, and BAYER HEALTHCARE, LLC,<br>*Defendants*. | No. 3:19cv1310 (MPS) |

**RULING ON MOTION TO DISMISS**

Jennifer Pratt brings this negligence action against Bayer Corporation, Bayer Healthcare Pharmaceuticals, and Bayer Healthcare, LLC (collectively "Bayer"), alleging injuries sustained from Essure, a birth control device that Bayer manufactured and sold. ECF No. 25, First Am. Compl. Bayer moves to dismiss under Fed. R. Civ. P. 12(b)(6) on the grounds that Pratt's complaint is preempted under federal law and otherwise fails to state plausible claims. ECF No. 28. For the reasons that follow, I GRANT Bayer's motion to dismiss with prejudice in part and without prejudice in part, and afford Pratt leave to amend her complaint as to the negligent training claims.

## I. FACTUAL ALLEGATIONS

The following facts are drawn from Pratt's first amended complaint and are accepted as true for the purpose of this motion.

Essure is a Class III medical device approved by the Food and Drug Administration

("FDA").[1] (Am. Compl. ¶¶ 8, 23.) It is a permanent form of birth control for women that is intended to cause bilateral blockage of the fallopian tubes by the insertion of micro-inserts – two metal coils - into a patient's fallopian tubes. (Am. Compl. ¶¶ 3, 17, 19.) The metal coils are comprised of nickel, steel, nitinol, and polyethylene terephthalate (PET) fibers. (Am. Compl. ¶ 15.) The coils are implanted using hysteroscopic equipment in an outpatient, nonsurgical procedure. (Am. Compl. ¶¶ 13, 16, 21.) After the coils are placed in the fallopian tubes, the micro-inserts expand and are intended to anchor into the fallopian tubes. (Am. Compl. ¶ 17.) The PET fibers elicit tissue growth, which blocks the fallopian tubes. (Am. Compl. ¶ 17.) The coils are supposed to remain in place and not migrate, break, or corrode. (Am. Compl. ¶ 18.) After the device is implanted, patients undergo a test to determine that the micro-inserts are in the correct location and that the tissue has created a complete occlusion. (Am. Compl. ¶ 19.)

On September 10, 2013, Pratt had the Essure device implanted. (Am. Compl. ¶ 35.) The Essure device migrated from her fallopian tube and caused an allergic reaction due to the nickel in the device, resulting in a persistent rash over her body. (Am. Compl. ¶¶ 36, 43.) On March 13, 2018, Pratt underwent a hysteroscopy,[2] bilateral salpingectomy (removal of the fallopian tubes), and removal of the device. (*Id*.)

The hysteroscopic equipment needed to place Essure was manufactured by a third party and is not part of Essure. (Am. Compl. ¶ 14.) Bayer provided physicians, including Pratt's

[1] Class III devices include devices that are implanted, such as replacement heart valves, implantable pacemakers, and breast implants. https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.

[2] A procedure that allows a physician to examine the cervix and inside of the uterus. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/hysteroscopy

physician,[3] with the equipment. (Am. Compl. ¶¶ 14, 34(l)). Bayer's distribution plan included requiring physicians to purchase two Essure "kits" per month. (Am. Compl. ¶ 34(s).) Bayer trained physicians, including Pratt's physician, on how to use Essure and the hysteroscopic equipment. (Am. Compl. ¶ 22.). Bayer created an Essure Training Program and a simulator called EssureSim and organized training classes, created checklists, and represented to Pratt that "Physicians must be signed-off to perform Essure procedures." (Am. Compl. ¶¶ 34(i), 38.) Bayer had a duty to comply with federal requirements of the U.S. Food and Drug Administration ("FDA") as to training. (Am. Compl. ¶ 40.) Bayer breached this duty and inadequately trained Pratt's physician in a number of ways, including by not ensuring that he read and understood the Physician Training Manual and successfully completed the required training in Essure placement. (Am. Compl. ¶¶ 34(w), 42(a), (b).)

After the FDA approved Essure in 2002, Bayer became aware of "potential quality and failure modes associated with Essure" but failed to warn Pratt or her physician. (Am. Compl. ¶ 32.) In 2016, the FDA issued new warning labeling and a patient decision checklist to "provide important information about the risks of using Essure and to help women and their doctors be better informed of the potential complications associated with the device." (Am. Compl. ¶34(b), (d).)

Bayer failed to comply "with [its] federal regulatory duties and [its] duties under state law by [failing to] report the known risks and complications in a timely fashion." (Am. Compl. ¶ 34(d)). Had Bayer done so, Pratt and her physician would have had the information before the procedure. *(Id.)*

[3] The complaint does not identify Pratt's physician by name.

Bayer had a duty "under both state and federal law" to have in place a reasonable risk management procedure to ensure that, *inter alia*, (1) adverse reports were reported to the FDA, (2) adverse reports were considered in its risk analysis and that the risk analysis was updated to reflect the same so it could be relayed to Pratt's physician and/or Pratt; and (3) Essure was monitored after pre-market approval and any adverse health consequences reported. (Count 4, ¶ 37.) Bayer's duties to have such plans are embodied in the Code of Federal Regulations. (Count 4, ¶ 38(a)-(s).) Bayer's negligent risk management resulted in its failure to report "thousands of adverse events and complaints" to the FDA, which, in turn, meant that Pratt and her physician were "preclude[ed] . . . from knowing" these adverse events and complaints. (Count 4, ¶ 41.) "[B]ut for [Bayer's] failure to comply" with its federal disclosure obligations, Pratt would not have had Essure implanted. (*Id.*) Further, according to Pratt, Bayer "should have withdrawn the product from the market prior to [Pratt's] implantation" had it properly identified and investigated all of the relevant adverse events and complaints. (*Id.*)

Pratt's complaint against Bayer alleges (1) negligent training (counts 1 - 3) and negligent risk management (counts 4 - 6).[4]

## II. PROCEDURAL HISTORY

Pratt initiated this action in Connecticut state court in August 2019. ECF No. 1-1. Bayer removed on the grounds of diversity. Bayer moved to dismiss the complaint on August 30, 2019. (ECF No. 16.) I ordered Pratt either to file a response to the motion or to "file an amended complaint in which she pleads as many facts as possible, consistent with Rule 11, to address the alleged defects discussed in the defendant's . . . memorandum of law," and stated that "[t]he Court will not allow further amendments after September 20, 2019." (ECF No. 19.) Pratt requested, and

[4] The complaint alleges two counts but alleges each count separately against the three defendants.

I granted, two extensions of time until November 19, 2019, in which to file a response to the motion to dismiss or file an amended complaint. (ECF Nos. 22, 24.) On November 19, 2019, Pratt filed a first amended complaint (ECF No. 25) and Bayer filed a motion to dismiss on December 10, 2019. (ECF No. 28.) Pratt filed an opposition brief on January 14, 2020 (ECF Nos. 31-32) and Bayer filed a reply brief on January 28, 2020. (ECF No. 33.)

## III. LEGAL STANDARD

In deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must determine whether the plaintiff has alleged "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "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." *Ray v. Watnick*, 688 Fed. Appx. 41 (2d Cir. 2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citations and internal quotation marks omitted)). The Court accepts as true all factual allegations in the complaint and "draw[s] all reasonable inferences in favor of the non-moving party." *Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 115 (2d Cir. 2008). "However, the tenet that a court must accept a complaint's allegations as true is inapplicable to '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.'" *Gonzales v. Eagle Leasing Co.*, No. 3:13CV1565(JCH), 2014 WL 4794536, at *2 (D. Conn. Sept. 25, 2014) (quoting *Ashcroft*, 556 U.S. at 678)).

## IV. DISCUSSION

Bayer moves to dismiss the complaint on the grounds that it is preempted by the FDA's regulatory scheme and that it fails to plausibly allege causation. Bayer also contends that Pratt's

common law negligence claims are foreclosed by the Connecticut Product Liability Act, Conn Gen. Stat. §§ 52-572m *et seq*. ("CPLA"). I address these arguments in turn below.

**A. Preemption**

In 1976, Congress enacted the Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq*., to the Food, Drug, and Cosmetic Act ("FDCA"). The MDA "imposed a regime of detailed federal oversight" for medical devices. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 316 (2008). The regulatory scheme established three categories of medical devices, identified as Class I, II, or III, "depending on the risks they present." *Id*. Essure is a Class III device, which is one that "is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). These devices receive the most extensive federal oversight. *Riegel*, 552 U.S. at 317. Before marketing a Class III medical device, the manufacturer must submit a premarket application to the FDA that includes clinical data supporting safety and effectiveness. "Premarket approval is a rigorous process." *Id*. (internal quotation marks omitted). "The FDA spends an average of 1,200 hours reviewing each application . . . and grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id*. at 318 (quoting 21 U.S.C. § 360e(d).) "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id*. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer wishing to make such a change must apply for supplemental premarket approval, which the FDA evaluates under largely the same criteria as the initial application. *Id*. (citing § 360e(d)(6); 21 CFR § 814.39(c)). "After premarket approval, the devices are subject to reporting

requirements." *Id*. (citing § 360i.) "These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, § 803.50(a)." *Id*. "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. § 360e(e)(1); see also § 360h(e) (recall authority)." *Id*. at 319-20. The FDA may also restrict the use of the device to persons with specific training or experience, 21 U.S.C. § 360j(e), and these restrictions must appear in FDA-approved labeling.

The MDA includes the following express pre-emption provision:

> 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.

§ 360k(a). Section 360k(a)(1) expressly pre-empts state requirements to the extent that they are "different from, or in addition to" the requirements imposed by federal law. *Riegel*, 552 U.S. at 330.

Only the federal government may enforce the requirements of the MDA. *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 349 & n. 4 (2001) ("The [Food, Drug, and Cosmetic Act] leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United

States.' 21 U.S.C. § 337(a)."). This has led courts to treat state law claims based solely on a violation of the MDA as impliedly preempted. *Id*. (state law claim alleging fraud-on-the-FDA was preempted because it was entirely dependent on federal law obligations of disclosure to the FDA).

The combined effect of the express preemption provision of the MDA and the implied preemption of state law claims premised solely on violations of the MDA is to make suing for injuries from medical devices a tricky endeavor. Specifically, "[a] plaintiff's state-law claim arising from the use of a medical device must … fit into a 'narrow gap' to avoid express or implied preemption." *Norman v. Bayer Corp*., No. 3:16CV253(JAM), 2016 WL 4007547, at *2 (D. Conn. July 26, 2016) (citing to *Buckman Co*., 531 U.S. at 353). "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) (internal quotation marks omitted). "In other words, the plaintiff's state-law claim must 'parallel[ ] a federal-law duty under the MDA' but also exist 'independent[ly]' of the MDA." *A.F. by & Through Fogel v. Sorin Grp. USA, Inc*., 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (*quoting Stengel v. Medtronic Inc*., 704 F.3d 1224, 1233 (9th Cir. 2013)).

*1. Failure to Train*

Pratt alleges that Bayer negligently trained her physician. (Counts 1 - 3.) Specifically, she maintains that Bayer undertook an "independent duty" to train physicians, including her physician, on how to properly use Essure and place the micro-inserts but that the training it provided "failed to abide by FDA training guidelines." (Count 1 at ¶ 37.) Pratt alleges that Bayer failed to comply with federal training requirements in several respects, including "[n]ot ensuring that the Implanting

Physician completed the required preceptoring in Essure placement until competency" and failing to ensure the physician "read and understood the Physician Training Manual." (Count 1, ¶ 42(a), (b).) According to Pratt, as a result of Bayer's "departure from the training guidelines," the Essure coils migrated from her fallopian tube causing her injuries. (Count 1, ¶ 43.)

Bayer contends that the negligent training claims are impliedly preempted because Connecticut law provides no parallel requirement to train, and alternatively, Pratt has not sufficiently alleged that the allegedly negligent training caused her injuries. (ECF No. 28-1 at 15.) Bayer also argues that these claims are expressly preempted "because the training Plaintiff claims Bayer should have provided does not match FDA's training requirements." (*Id.*)

"Under federal law, when FDA specifies training requirements for Class III medical devices, those requirements must appear in the device's approved labeling." *Hill v. Bayer Corp.*, No. 19-CV-12198, 2020 WL 5367334, at *3 (E.D. Mich. Sept. 8, 2020).

Essure's labeling provides:

> Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competence is established, typically 5 cases.[5]

Pratt alleges that Bayer violated these requirements. Specifically, the Amended Complaint alleges that Bayer breached FDA approved guidelines by not ensuring that her physician (1) read and understood the Physician Training Manual, (2) completed the required preceptoring in Essure placement until competency, and (3) successfully completed "Essure Simulator Training." (Count

[5] I take judicial notice of Essure's label. http://labeling.bayerhealthcare.com. I also note that the parties in this case appear to assume that the language of the label imposes obligations on Bayer. Indeed, Bayer itself notes that "the FDA training requirements are those set forth in Essure's labeling" (ECF No. 33 at 7). Further, as discussed below, several courts have concluded that the language in the label imposes obligations on Bayer. Accordingly, I assume that it does.

1, ¶¶ 42(a), (b), and (e).) Because Pratt's negligent training claim is based on an alleged breach of FDA training requirements, her claim as to these requirements is not expressly preempted by federal law. *See Hill*, 2020 WL 5367334, at *3 (plaintiff's claim that Bayer breached FDA approved guidelines by (1) not ensuring that the implanting physicians completed the requirement of preceptoring in Essure placement until competency, (2) not ensuring that the implanting physicians had read and understood the Physician Training Manual, and (3) not ensuring that the implanting physicians had "successful completion of Essure Simulator Training" was not expressly preempted; but dismissing claim for failure to adequately plead causation); *English v. Bayer Corp*, ___F. Supp.3d.___, 2020 WL 3454877, *3 (W.D.N.Y. June 25, 2020)("To the extent that plaintiffs claim that defendants did deviate from FDA-approved training requirements by failing to ensure that implanting physicians completed preceptoring requirements, read and understood the Physician Training Manual, and successfully completed simulator training, such claims do not seek to impose obligations beyond those mandated by the FDA, and thus are arguably not expressly preempted"; but dismissing negligent training claims on the ground that they were not cognizable under New York law): *McLaughlin v. Bayer Corp*., No. CV 14-7315, 2017 WL 697047, at *3, *5 (E.D. Pa. Feb. 21, 2017)(Plaintiffs' negligent training claims based on a purported failure to ensure that doctors (1) successfully completed five preceptorings during training, (2) read and understood the training manual, and (3) successfully completed Essure simulator training not expressly preempted).

Bayer asserts that the claims fail nonetheless because they are impliedly preempted in that there is no "parallel" state law requirement. (ECF No. 28-1 at 15.) Bayer argues that because the alleged duty to train arises solely from the MDA's requirements, not Connecticut law, it is subject to implied preemption. (ECF No. 28-1 at 15.) Citing *Seguro v. Cummiskey*, 82 Conn. App. 186

(2004) and *Roberts v. Circuit-Wise, Inc.*, 142 F. Supp. 2d 211 (D. Conn. 2001), Bayer contends that Connecticut recognizes failure-to-train claims only in the context of a "direct employer-employee relationship." (ECF No. 28-1 at 15.) However, neither case stands for that proposition.

In *Seguro v. Cummiskey*, the plaintiff alleged that the defendant employer failed to properly supervise its employee, a bartender, and failed to prevent the employee from drinking alcohol and becoming intoxicated on the night of the accident. The appellate court recognized "[u]nder Connecticut law, an employer may be held liable for the negligent supervision of employees," 82 Conn. App. at 191. Because the issue was not before it, the court (unsurprisingly) did not address whether a failure to train claim might be plausible outside the employment context.

Similarly, in *Roberts v. Circuit-Wise, Inc*., a sexual harassment case, the district court stated merely that "[u]nder Connecticut law, a plaintiff may sue an employer for negligent supervision of its employees," again without a discussion of whether a failure to train claim might lie outside an employment relationship. 142 F. Supp. 2d at 214.

Although there does not appear to be Connecticut appellate authority addressing the specific factual context presented here – that is, whether a manufacturer may be liable for the failure to exercise reasonable care in the training it undertook to provide to physicians – I predict that the Connecticut Supreme Court, if faced with such facts, would recognize such a duty. *Travelers Ins. Co. v. 633 Third Assocs*., 14 F.3d 114, 118 (2d Cir. 1994) ("Federal courts sitting in diversity cases will, of course, apply the substantive law of the forum State on outcome determinative issues . . . . Where the substantive law of the forum state is uncertain or ambiguous, the job of the federal courts is carefully to predict how the highest court of the forum state would resolve the uncertainty or ambiguity.") (internal citations omitted). Taking the facts in the complaint as true, Bayer undertook a duty to render services (Essure training) to another (Pratt's

physician) and did so negligently. Connecticut courts have recognized liability to third persons for negligent performance of an undertaking in certain contexts, adopting the following language from § 324A(b) of the Restatement (Second) of Torts: "[o]ne who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if . . . (b) he has undertaken to perform a duty owed by the other to the third person." *Gazo v. City of Stamford*, 255 Conn. 245, 252–53 (2001).[6] *See also Demond v. Project Serv., LLC*, 331 Conn. 816 (2019) (relying on § 324A of the Restatement (Second) of Torts but concluding that plaintiffs had not established that the defendants increased the risk of harm to them within the meaning of § 324A(a) or that the plaintiffs relied on the undertaking for the purposes of § 324A(c)).)[7]

In light of these Connecticut cases recognizing the authority of Section 324A of the Restatement, I find that the Connecticut Supreme Court would impose a duty on Bayer to ensure

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[6] In *Gazo*, the Connecticut Supreme Court held that the defendant, an independent contractor who had entered into a contract with a possessor of property to clear an abutting sidewalk, owed a duty to the plaintiff pedestrian who slipped on an accumulation of ice and snow on the sidewalk. The Court stated it "adopt[ed] § 324A(b), at least in the circumstances of the present case, in which it is clear that the service was performed for consideration and in a commercial context." 255 Conn. at 253. The Court noted that there were "valid public policy reasons for holding [the independent contractor] responsible for his conduct. [The independent contractor's] liability to the plaintiff fits comfortably within the general rule that every person has a duty to use reasonable care not to cause injury to those whom he reasonably could foresee to be injured by his negligent conduct, whether that conduct consists of acts of commission or omission." *Id.* at 251.

[7] Subsections (a) and (c) of Section 324(A) provide in pertinent part:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
> (a) his failure to exercise reasonable care increases the risk of such harm, or . . .
> (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

the adequacy of the physician education program it undertook to provide. The allegations in the complaint plausibly fit with both subsection (a) and subsection (b) of § 324A(a). Consistent with subsection (a), Pratt's allegations suggest that Bayer's failure to ensure proper physician training increased the risk of harm to her. And consistent with subsection (b), Pratt alleges that Bayer undertook to educate her physician about Essure, a device the physician was going to use to treat her – thereby implicating Bayer in the performance of the physician's duty to Pratt. Other courts applying the laws of other states in similar litigation against Bayer have likewise found Section 324A of the Restatement to support negligent training claims. *See Noel v. Bayer Corp.*, No. CV20-27, 2020 WL 5038782, at *7 (D. Mont. Aug. 26, 2020) ("With the Montana Supreme Court's adoption of [Restatement (Second) of Torts] § 324A, this Court concludes Montana law provides a parallel claim for the negligent training Noel alleges."); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 610 (Mo. Ct. App. 2017)(claim that Bayer failed to train physician was not "impliedly preempted as Missouri law recognizes that, in certain situations, a party who undertakes to perform services, such as Bayer undertaking to train Williams's physicians, may be subject to liability to a third party for failing to exercise due care in rendering those services."); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 816 (E.D. Pa. 2016) (plaintiff's negligent training claim was not impliedly preempted because Pennsylvania courts adopted Restatement (Second) of Torts § 324A).

a. Causation

Bayer next argues that Pratt's allegations of causation are conclusory and do not plausibly link the alleged training failure to her injuries, pointing to *Norman*, 2016 WL 4007547, at *5 in which another judge of this court found causation allegations inadequate in a similar case against Bayer.

I conclude, however, that in this case Pratt has alleged sufficient facts concerning causation to satisfy the plausibility standard. Pratt alleges that federal training requirements were intended to ensure that her physician was qualified and competent to perform the Essure procedure and properly to place the device to preclude migration, but that Bayer failed to properly train her physician. (Am. Compl. ¶¶ 40, 43.) Specifically, the complaint alleges that Bayer failed to ensure that her physician read and understood the Physician Training Manual, completed the required preceptoring in Essure placement until competency, and successfully completed "Essure Simulator Training," and that these failures resulted in the improper implantation of the device, causing it to become unanchored and migrate. (Am. Compl. ¶ 43.) Drawing all inferences in favor of Pratt, I find that these allegations are enough plausibly to allege that Bayer's failure to train Pratt's physician in compliance with these FDA-approved training guidelines caused her injuries. *See McLaughlin v. Bayer Corp*., No. CV 14-7315, 2017 WL 697047, at *6 (E.D. Pa. Feb. 21, 2017) (complaint plausibly alleged causation where it "essentially alleges that, because Bayer departed from the required training by failing to ensure that physicians had successfully completed the required training, the physicians did not properly place the Essure device in Plaintiffs, and the device migrated from the fallopian tubes.")

b. Other Training Claims

Pratt alleges other training-related failures, however, that fall outside the FDA's requirements. See Am. Compl. ¶ 40(c) (alleged failure to monitor plaintiff through recovery), (d) (failure to ensure prior to training that physician was knowledge hysteroscopist), and (f) (failure ensure that the physician was certified). These claims are expressly preempted, because they would impose requirements in addition to those imposed by federal law. *See Hill*, 2020 WL 5367334, at *3 (claims based on training requirements beyond those required by the

FDA "such as the alleged failure to train physicians on how to use 'specialized hysteroscopic equipment manufactured by a third party,'. . . or the alleged failure to train physicians on 'how to remove Essure should it fail,' . . . are preempted."); *McLaughlin*, 2017 WL 697047, at *6 ("negligent training claim is expressly preempted insofar as it is grounded on Bayer's alleged failure to (1) confirm that doctors are knowledgeable hysteroscopists prior to training, (2) monitor doctors following their completion of training, or (3) ensure that doctors are 'certified'" because these are not federal requirements); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 610 (Mo. Ct. App. 2017)(Plaintiff's claims that Bayer failed to provide training beyond that set forth in the Essure labeling are expressly preempted because "[s]uch claims would be establishing requirements that were "different from, or in addition to," those set by the Essure PMA, and would thus be expressly preempted.)

*2. Negligent Risk Management*

Pratt also alleges "negligent risk management," which appears to encompass claims that Bayer failed to properly report adverse reports to the FDA, failed to warn, and created an unreasonably dangerous distribution plan. (Counts 4 - 6.)

a. Failure to Report

Pratt alleges that Bayer failed to report adverse events and complaints to the FDA. (See, e.g., Am. Comp. ¶¶ 34(d), 37.) Bayer argues that this claim is impliedly preempted because a parallel claim under Connecticut state law does not exist. (ECF No. 28-1 at 10.) I agree.

While the FDA requires that all manufacturers or importers of medical devices report "whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices . . . may have caused or contributed to a death or serious injury," 21 U.S.C. § 360i(a)(1), "there is no general or background duty under

Connecticut law to report risks to a regulatory body." *Norman*, 2016 WL 4007547, at *4 (concluding that a claim alleging failure to report adverse events to the FDA was impliedly preempted). *See also English v. Bayer Corp.*, ___F. Supp.3d. ___, 2020 WL 3454877, at *3 (W.D.N.Y. June 25, 2020) (because "failure to report adverse events to the FDA" is not a cognizable cause of action under New York law, claim was preempted); *Hill*, 2020 WL 5367334, at *7 (Plaintiff's claim alleging Bayer failed to disclose adverse events to the FDA was impliedly preempted because there was no parallel state law requirement that a manufacturer report adverse events to the FDA.); *Doe v. Bausch & Lomb*, 443 F. Supp. 3d 259, 273 (D. Conn. 2020)(claim that "Defendants failed to abide by their FDA reporting obligations" was "impliedly preempted because it is wholly derivative of the FDCA. Plaintiffs have not identified any duty under Connecticut law that required the Defendants to warn or communicate adverse events to the FDA so as to give rise to a parallel claim under Connecticut law.")

b. Failure to Warn

Pratt alleges that Bayer failed to warn her and/or her physician of various risks associated with Essure. (See Am. Compl. ¶ 32 alleging Bayer failed to warn her and/or her physician about quality issues and failures.) Such claims are expressly preempted because there is no "FDA requirement for Bayer to report consumer complaints directly to healthcare providers and consumers or to update its warnings and labeling as Bayer learns of issues with the device." *Noel*, 2020 WL 5038782, at *4. *See Hill*, 2020 WL 5367334, at *4 (there is no "federal requirement that Bayer had a duty to warn the general public or the medical community, and thus, those claims are expressly preempted because they are 'different from, or in addition to,' the Medical Device Amendments ('MDA') requirements"); *Norman*, 2016 WL 4007547, at *3 (claim that defendants failed to warn her personally was expressly preempted because plaintiff did not identify any FDA

requirement that defendants must provide such a direct consumer warning).

c. Unreasonably Dangerous Distribution plan

Pratt appears to allege that Bayer had an "unreasonably dangerous distribution scheme." This plan included compelling physicians to sell 2 devices per month, failing to report adverse events, using non-conforming material and failing to keep track of the same in the manufacturing of Essure, failing to use pre-sterile and post-sterile cages, manufacturing Essure at an unlicensed facility, and manufacturing Essure for three years without a license to do. (Am. Compl. ¶¶ 34(r), (v), 40 alleging Bayer had "an unreasonably dangerous and negligent risk analysis plan . . . due to the Defendants' failure to report adverse reports to the FDA, to track non-conforming product, update its labeling of Essure, and to consider adverse reports in its risk analysis.")

To the extent that the claim is premised on a failure to warn or failure to report theory, those have already been addressed. As to the allegations regarding negligent manufacturing, Pratt does not allege that her device was not manufactured in conformance with the specifications approved by the FDA. *See Norman*, 2016 WL 4007547, at *3 (dismissing plaintiff's claim where plaintiff alleged that there may have been some devices produced with "non-conforming materials," but did 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."). Further, she fails to allege that any manufacturing defects caused her injuries.

**B. Connecticut Product Liability Act**

As a final matter, Bayer argues that the complaint should be dismissed because Pratt's complaint must be brought under the CPLA, which is not invoked in her complaint.

"The CPLA is the 'exclusive remedy' for products liability claims under Connecticut law." *Philadelphia Indem. Ins. Co. v. Lennox Indus., Inc.*, No. 3:18CV217(CSH), 2020 WL 705263, at

*3 (D. Conn. Feb. 12, 2020). It thus "bars separate common law causes of action in product liability cases," *Densberger v. United Techs. Corp.*, 297 F.3d 66, 70 (2d Cir. 2002), *i.e.*, in "all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product." Conn. Gen. Stat. § 52-572m(b). The CPLA "merges the various theories of liability - including strict liability, negligence, and breach of express or implied warranty - into one cause of action." *Philadelphia Indem. Ins. Co.*, 2020 WL 705263, at *3. "Consequently, any sub-claim brought under the CPLA, such as negligence, strict liability, or breach of warranty, must sufficiently allege all elements that would be required at common law." *Philadelphia Indem. Ins. Co., 2020 WL 705263, at *3. See LaMontagne v. E.I. Du Pont De Nemours & Co., Inc.*, 41 F.3d 846, 855–56 (2d Cir. 1994) (noting that the CPLA does not "alter the substance of a plaintiff's rights or the facts that a plaintiff must prove in order to prevail.").

Here, Bayer concedes that Pratt's claim alleging that Bayer failed to properly instruct her physician about how to use Essure falls within the scope of the CPLA. (ECF No. 28-1 at 20.) *See* Conn. Gen. Stat. § 52–572q(a)) (A product may also be defective "in that adequate warnings or instructions were not provided.") Thus, although it is true that this claim must be asserted under the CPLA, rather than under the common law, the facts alleged in the complaint are sufficient to plead a claim under the CPLA. I therefore grant Pratt leave to amend her complaint to plead the claim under the CPLA.

## V. CONCLUSION

For these reasons, Bayer's motion to dismiss (ECF No. 28) is GRANTED with prejudice as to the negligent risk management claims in Counts 4 – 6 and without prejudice as to the negligent training claims in Counts 1 - 3. I grant Pratt leave to amend to replead the negligent training claims under the CPLA.

IT IS SO ORDERED.

_____/s/_____
Michael P. Shea, U.S.D.J.

Dated: Hartford, Connecticut
September 25, 2020