IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HELEN McLAUGHLIN	:	CIVIL ACTION
v.	:	
BAYER CORPORATION, et al.	:	NO. 14-7315
RUTH RUBLE	:	CIVIL ACTION
v.	:	
BAYER CORPORATION, et al.	:	NO. 14-7316
MELDA STRIMEL	:	CIVIL ACTION
v.	:	
BAYER CORPORATION, et al.	:	NO. 14-7317
SUSAN STELZER	:	CIVIL ACTION
v.	:	
BAYER CORPORATION, et al.	:	NO. 14-7318
HEATHER WALSH	:	CIVIL ACTION
v.	:	
BAYER CORPORATION, et al.	:	NO. 15-384

MEMORANDUM

Padova, J. **March 22, 2016**

Five individual Plaintiffs have initiated separate actions against Bayer Corp., Bayer Healthcare LLC, Bayer Essure, Inc., Bayer Healthcare Pharmaceuticals and Bayer A.G. (collectively, "Bayer"). Each action asserts twelve claims for relief, seeking compensation for injuries that the Plaintiff suffered in connection with her use of Bayer's female birth control device known as "Essure." The five cases were consolidated for resolution of pre-trial motions. In each

of the five cases, Bayer has filed the same Motion for Judgment on the Pleadings Under Federal Rule of Civil Procedure 12(c), asking that we dismiss all of Plaintiffs' claims either as expressly preempted, as impliedly preempted, because they fail to state a plausible or cognizable claim under Federal Rule of Civil Procedure 12(b)(6), or because they fail to plead fraud with particularity as required by Federal Rule of Civil Procedure 9(b). We held oral argument on January 11, 2016. For the following reasons, we now grant the Motion in part and deny it in part, and also grant Plaintiffs the opportunity to file amended complaints.

I. BACKGROUND

The First Amended Complaint in the McLaughlin case ("Compl.") describes Essure as a female birth control device that "is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage."[1] (Compl. ¶ 13.) "The micro-inserts are comprised of two metal coils which are placed in a woman's fallopian tubes via Defendants' disposable delivery system and under hysteroscopic guidance (camera)." (Id. ¶ 34.) The Complaint alleges that, instead of working as intended, "the device migrates from the tubes, perforates organs, breaks into pieces, and/or corrodes." (Id. ¶ 13.)

Each Complaint details specific injuries that the Plaintiff suffered after she had Essure implanted. In all five cases, the Essure device migrated from the Plaintiff's fallopian tubes to the Plaintiff's uterus, rectum or colon. In four of the five cases, the Plaintiff had to have a hysterectomy and, in the fifth case, the Plaintiff not only had her fallopian tubes removed, but also delivered a baby with birth defects. All five Plaintiffs also experienced various additional symptoms, including severe pelvic or abdominal pain, bleeding, rashes, hair loss, insomnia, night

[1] Because all of the Complaints in the five cases are essentially the same, we will cite exclusively to the McLaughlin Complaint for ease of reference.

sweats, fever, limb numbness, weight gain, vision problems, and/or fainting spells.

Essure is a Class III medical device that required premarket approval by the Food and Drug Administration (the "FDA"). (Id. ¶¶ 46, 49.) The FDA separates medical devices into three categories, depending on their level of risk, and Class III devices receive the most federal oversight. Riegel v. Medtronic, Inc., 552 U.S. 312, 316-17 (2008). The Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* (the "MDA"), which amended the Food, Drug and Cosmetic Act ("FDCA"), require new Class III devices to undergo a rigorous premarket approval process, which includes review of all known studies and investigations of the device's safety and effectiveness. Riegel, 552 U.S. at 316–18. The FDA "grants premarket approval only if it finds that there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" Id. at 318 (quoting 21 U.S.C. § 360e(d)). Because the FDA weighs "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use,'" it "may . . . approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." Id. (quoting 21 U.S.C. § 360c(a)(2)(C)).

Following its review, the FDA may either grant approval, deny approval, or "condition approval on adherence to performance standards, restrictions upon sale or distribution, or compliance with other requirements." Id. at 319 (citing 21 U.S.C. § 360e(d), and 21 C.F.R. §§ 814.82, 861.1(b)(3)). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specification, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Indeed, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that that approved form provides a reasonable

assurance of safety and effectiveness." Id. at 323.

The Complaint alleges that the Essure device was first designed and manufactured by Conceptus, Inc. (Compl. ¶ 43.) Because it is a Class III medical device, Essure underwent the above-described scientific and regulatory review by the FDA to evaluate its safety and effectiveness. (Id. ¶ 49.) On November 4, 2002, Essure received conditional premarket approval ("PMA") from the FDA. (Id. ¶ 15; 11/4/02 PMA letter ("PMA Ltr.").[2]) The PMA authorized Conceptus to begin commercial distribution of Essure in accordance with certain specified conditions, including that (1) the device be restricted to prescription use, (2) the labeling specify the requirements that apply to the training of practitioners that use the device, and (3) the sale, distribution and use not violate 21 U.S.C. § 352(q) and (r), which, inter alia, prohibit the use of false or misleading advertising and require all advertising or other descriptive matter to include certain information, such as all relevant warnings, precautions, and side effects. (PMA Ltr. at 1.) The PMA also required Conceptus to conduct studies and collect data regarding pregnancies and outcomes, as well as adverse events, and to report its findings to the FDA annually. (Id. at 1-2.) In addition, it required Conceptus to conduct a study to document the bilateral placement rates for newly trained physicians, to permit an evaluation of training procedures and to update product labeling. (Id. at 2.)

On April 28, 2013, Conceptus merged with Bayer, and Bayer now manufactures, sells, distributes, markets and promotes Essure. (Id. ¶¶ 44, 46.) Bayer also trains physicians on how to use the device and how to implant the device using hysteroscopic equipment. (Id. ¶¶ 47, 67.) Bayer's training program included creation of a physician training manual; creation of a simulator

[2] The November 4, 2002 PMA Letter is referenced in the Complaint and is a matter of public record and, thus, we can consider it on a Motion for Judgment on the Pleadings. See Mayer v. Belichick, 605 F.3d 223, 230 (3d Cir. 2010) (citation omitted).

called EssureSim; the organization of training courses, during which Bayer observed physicians until it believed they were competent; and creation of a Procedures Equipment Supplies checklist. (Id. ¶ 70.) Bayer also represented to Plaintiffs that "[p]hysicians must be signed-off to perform Essure procedures" and that Bayer kept training records of physicians who had been "signed-off" to perform the procedure. (Id. ¶¶ 70, 72.)

The Complaint further alleges, among other things, that Bayer's training of physicians was inadequate and that Bayer provided the hysteroscopic equipment to implanting physicians who were not qualified or competent to use the equipment. (Id. ¶ 66.) The Complaint further alleges that Bayer engaged in an unreasonably dangerous distribution plan aimed solely at capturing market share, insofar as it, inter alia, provided unqualified physicians with specialized hysteroscopic equipment and required implanting physicians to purchase two Essure kits a month, whether or not they used the kits. (Id. ¶¶ 77-80.)

According to the Complaint, Bayer made several statements about Essure, in several different contexts, that were false and/or misleading and which constituted warranties. For example, on its website, Bayer falsely stated that Essure is "Worry free: once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy," and that only skilled operative hysteroscopists would be trained to implant Essure. (Id. ¶ 103(e), (j).) Likewise, in its advertisements, Bayer falsely stated, among other things, that, "[i]n order to be identified as a qualified Essure physician," a physician must perform "a minimum of one Essure procedure . . . every 6-8 weeks." (Id. ¶ 104(b).) Bayer also prepared a brochure for Essure that included false statements, including that Essure is "Worry free," stays secure, and is made from "the same trusted, silicone free material used in hearts stents." (Id. ¶ 111(a)-(c).).

The Complaint also alleges that Bayer failed to report all adverse events to the FDA, as the

PMA required. Among other things, the Complaint alleges that Bayer failed to report eight perforations that occurred, instances of migration, and 16,047 unspecified complaints about the device. (See, e.g., id. ¶¶ 58(c)-(d), (g), 59(e), 111(a)(vi), (b)(ii).) It also alleges that Bayer had notice of 168 perforations but only disclosed 22 to the FDA. (Id. ¶ 60(b).) The Complaint further alleges (and purports to document with an exhibit) that, on multiple occasions in 2010, Bayer failed to timely report to the FDA incidents involving perforation, the Essure coil breaking into pieces, and Essure migration. (Id. ¶¶ 60(a), 111(a)(viii), and Ex. F).)

Each of the five Complaints asserts twelve causes of action.[3] Count I of each Complaint alleges that Bayer negligently trained Plaintiffs' implanting physicians. (Id. ¶ 125.) Count II alleges that Bayer negligently entrusted the hysteroscopic equipment to Plaintiffs' implanting physicians. (Id. ¶ 141.) Count III alleges a claim for "Pharmacovigilance-Negligent Distribution/Advertising/Overpromotion/Reporting" stemming from Bayer's allegedly "unreasonably dangerous distribution, advertising, promotion and reporting plan." (Id. ¶ 151.) Count IV alleges a claim for negligent risk management, asserting that Bayer breached its duty to engage in reasonable risk management, insofar as it failed to notify the FDA of adverse reports, track non-conforming products, and consider adverse reports in its risk analysis. (Id. ¶ 162.) Count V alleges that Bayer breached express warranties. (Id. ¶¶ 179, 184.) Count VI alleges that Bayer violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 Pa. Stat. Ann. § 201-1 *et seq*., by engaging in deceptive conduct. (Id. ¶ 194.) Count VII asserts a claim for fraudulent concealment insofar as Bayer failed to disclose to Plaintiffs and their implanting physicians various complaints about the device and the device's

[3] Initially, the Complaints contained thirteen causes of action, but, at Plaintiff's request, we dismissed Count XIII of each Complaint without prejudice pursuant to Federal Rule of Civil Procedure 41(a)(2) in a January 14, 2016 Order.

non-compliance with FDA standards. (Id. ¶ 205.) Counts VIII and IX allege claims of fraudulent misrepresentation and negligent misrepresentation with respect to Bayer's statements about Essure. (Id. ¶¶ 217, 230.) Count X asserts a strict liability claim, based on an assertion that Essure was unreasonably dangerous insofar as it did not comply with federal law and the PMA, and did not contain adequate warnings and safety devices to prevent harm to consumers. (Id. ¶¶ 242-44.) Count XI alleges that Bayer negligently manufactured Essure by failing to manufacture the device in conformance with FDA specifications, federal regulations, and PMA requirements. (Id. ¶ 268.) Count XII asserts that Bayer negligently failed to warn Plaintiffs and the implanting physicians as required by federal law and the PMA of the risks of the device and manufacturing defects. (Id. ¶ 277.)

II. LEGAL STANDARDS

A. Motions for Judgment on the Pleadings

Under Federal Rule of Civil Procedure 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). Rule 12(c) motions based on the theory that the plaintiff has failed to state a claim are reviewed under the same pleading standards that apply to motions to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Revell v. Port Auth., 598 F.3d 128, 134 (3d Cir. 2010) (citation omitted); Spruill v. Gillis, 372 F.3d 218, 223 n.2 (3d Cir. 2004). When considering a motion to dismiss pursuant to Rule 12(b)(6), we "consider only the complaint, exhibits attached to the complaint, [and] matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." Mayer v. Belichick, 605 F.3d 223, 230 (3d Cir. 2010) (citing Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993)). We take the factual allegations of the complaint as true and

draw all reasonable inferences in favor of the plaintiff. DelRio-Mocci v. Connolly Props., Inc., 672 F.3d 241, 245 (3d Cir. 2012) (citing Warren Gen. Hosp. v. Amgen, Inc., 643 F.3d 77, 84 (3d Cir. 2011)). Legal conclusions, however, receive no deference, as the court is "'not bound to accept as true a legal conclusion couched as a factual allegation.'" Wood v. Moss, 134 S. Ct. 2056, 2065 n.5 (2014) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

A plaintiff's pleading obligation is to set forth "a short and plain statement of the claim," Fed. R. Civ. P. 8(a)(2), which gives the defendant "'fair notice of what the . . . claim is and the grounds upon which it rests.'" Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (alteration in original) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). The complaint must contain "'sufficient factual matter to show that the claim is facially plausible,' thus enabling 'the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged.'" Warren Gen. Hosp., 643 F.3d at 84 (quoting Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009)). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556). "A complaint that pleads facts 'merely consistent with a defendant's liability . . . stops short of the line between possibility and plausibility of entitlement to relief.'" Connelly v. Lane Constr. Corp., 809 F.3d 780, 786 (3d Cir. 2016) (quoting Iqbal, 556 U.S. at 678). "'The plausibility determination is a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" Id. 786-87 (quoting Iqbal, 556 U.S. at 679). In the end, we will grant a motion to dismiss brought pursuant to Rule 12(b)(6) if the factual allegations in the complaint are not sufficient "'to raise a right to relief above the speculative level.'" W. Run Student Hous. Assocs., LLC v. Huntington Nat'l Bank, 712 F.3d 165, 169 (3d Cir. 2013) (quoting Twombly, 550 U.S. at 555).

B. Federal Preemption

1. Express Preemption

The MDA expressly preempts certain state law requirements, stating that:

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

21 U.S.C. § 360k(a).

In the controlling case of Riegel v. Medtronic, Inc, the Supreme Court articulated this provision as setting forth a two-step analysis for determining whether a claim is expressly preempted. 552 U.S. at 321-22. First, the court must ascertain whether the federal government has established requirements applicable to the medical device at issue. Id. Riegel concluded, however, that any Class III device that receives premarket approval, which is specific to individual devices, satisfies this first prong of the § 360k(a) test.[4] Id. at 322 ("Premarket approval . . .

[4] Riegel contrasted its conclusion in this regard with the conclusion of the Court in its prior MDA express preemption case, Medtronic v. Lohr, 518 U.S. 470 (1996). As it explained, Lohr involved a medical device that had undergone "substantial-equivalence" review under § 510(k), which is more limited FDA review reserved for products that are substantially equivalent to devices that were on the market prior to 1976, when the Medical Device Amendments were adopted. Riegel, 552 U.S. at 322 (citing Lohr, 518 U.S at 493-94). Lohr concluded that § 510(k) approval did not impose "device-specific 'requirements'" but, rather, qualified a device for an "exemption [from federal safety review]." Id. (citing Lohr, 518 U.S. at 493-94); see also id. at 323 (stating that "devices that enter the market through § 510(k) have 'never been formally reviewed under the MDA for safety or efficacy'" (quoting Lohr, 518 U.S. at 493)). Lohr therefore held that the only federal "requirements" applicable to the device in that case were general requirements, i.e., "federal manufacturing and labeling requirements applicable across the board to almost all medical devices," which did not preempt the plaintiff's state common law tort claims. Id. at 322. In Riegel, however, the Supreme Court unambiguously stated that premarket approval, which is federal safety review, imposes device-specific "requirements" that satisfy §

imposes 'requirements' under the MDA . . . ."); see also Hughes v. Boston Sci. Corp., 631 F.3d 762, 768 (5th Cir. 2011) ("Riegel established that any Class III device receiving PMA approval from the FDA will satisfy this first prong of the test . . . ." (citing Riegel, 553 U.S. at 322)). Second, the court must determine whether the state common law claims relate to safety and effectiveness and impose requirements that are "different from, or in addition to" those imposed by federal law. Riegel, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)). Where the state requirements do relate to safety and effectiveness and are "different from, or in addition to" the requirements imposed by federal law, any claims for violation of those state requirements are expressly preempted.[5] Id. at 323, 330 (quoting and citing 21 U.S.C. § 360k(a)). The Third Circuit has indicated, albeit in a pre-Riegel opinion, that "a court should carefully examine the

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360k(a)(1). Id. at 322-23.

[5] Plaintiffs repeatedly argue that, if there is no device-specific federal requirement regarding the precise subject matter of Plaintiffs' claim, there is no express preemption of that particular claim, relying largely on (1) Lohr, 518 U.S. 470; (2) a mischaracterization of Riegel; and (3) a brief that the Solicitor General filed in connection with a certiorari petition seeking review of Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013) (en banc), which they attach as Ex. A to their response brief, and which argues that state law claims that implicate no preemptive device-specific federal requirement are not preempted.

However, as explained above, see supra note 4, Lohr concerned a device that was exempted from federal safety review pursuant to § 510(k) and, thus, the FDA approval process had imposed no device-specific requirement regarding any subject matter. Riegel and the cases that have followed it have made clear that once there is any device-specific requirement (as there always is for Class III devices receiving PMA), then all state law claims are preempted if they differ from or add to any federal requirements applicable to the device. See, e.g., Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1340 (10th Cir. 2015) (stating that once a "device [has] endured the premarket approval process, . . . the MDA will preempt all [state law] claims unless federal requirements impose duties that are at least as broad as those [plaintiff] seeks to vindicate though state law.") Moreover, while the Solicitor General has advocated for a different approach (see Ex. A to Pls.' Resp. Br. at 8-13), he also explicitly acknowledges that the courts of appeals, in every case after Riegel that has involved a device subject to premarket approval, have "tacitly dispensed" with the first step of the Section 360k(a) preemption analysis and have concluded that "Section 360k(a) preempts *all* state requirements with respect to the device that are not parallel to some federal requirement." (Id. at 15-16.) We therefore reject Plaintiffs' argument that a state claim can only be preempted if there is a device-specific federal requirement on the precise subject matter of the state law claim.

state common law claim in order to determine whether that claim would *impose* a substantive requirement that conflicts with, or adds a greater burden to, a specific federal requirement." Horn v. Thoratec Corp., 376 F.3d 163, 174 (3d Cir. 2004) (citing Mitchell v. Collagen Corp., 126 F.3d 902, 911-12 (7th Cir. 1997); Kemp v. Medtronic, 231 F.3d 216, 230 (6th Cir. 2000); and Martin v. Medtronic, 254 F.3d 573, 581-83 (5th Cir. 2001)). The express preemption provision "does not[, however,] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330 (quoting Lohr, 518 U.S. at 495, and citing Lohr, 518 U.S. at 513).

2. Implied Preemption

The Supreme Court has held that, in addition to providing for express preemption, the FDCA and MDA impliedly preempt state law claims that amount to "fraud-on-the-FDA claims." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001). In Buckman, the Court noted that § 337(a) of the MDA provides that "'all . . . proceedings for the enforcement, or to restrain violations, of [the MDA] shall be by and in the name of the United States,'" id. at 349 n.4 (quoting 21 U.S.C. § 337(a)), and specifically empowers the FDA to investigate, punish and deter fraud against it. Id. at 349 (citing 21 U.S.C. §§ 332 (providing for injunctive relief), 333(f)(1)(A) (providing for civil penalties), 333(a) (providing for criminal prosecutions), 334(a)(2)(D) (allowing seizure of the device), and 372 (authorizing the FDA to conduct investigations)) (additional citations omitted). The Court essentially reasoned that state law fraud claims that "exist solely by virtue of the FDCA disclosure requirements," id. at 353, necessarily "conflict with the FDA's responsibility to police such violations consistently with the Administration's judgment and objectives." Id. at 350. It therefore concluded that where claims arise "solely from the

violation of FDCA requirements," they are impliedly preempted. Id. at 352-53. At the same time, the Court made clear that a claim that "rel[ies] on traditional state tort law which . . . predated the federal enactments in question[ ]" is not preempted. Id. at 353. The United States Court of Appeals for the Eighth Circuit has observed that, together,

> "Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape 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 Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

III. DISCUSSION

Bayer's Motion for Judgment on the Pleadings asks that we dismiss all twelve Counts of each Complaint pursuant to Rule 12(c), either based on express preemption, implied preemption, failure to state a plausible claim under the Rule 12(b)(6) pleading standards, or failure to plead fraud with particularity as required by Rule 9(b). Plaintiffs contend that none of these arguments support the dismissal of any of their claims.[6] They further request that, if we dismiss any of their

[6] Plaintiffs preliminarily argue that the PMA for Essure, on which Bayer's preemption arguments are dependent, is no longer valid because Bayer failed to comply with certain conditions of that approval. In support of this assertion, they rely on the language in the PMA, which states that "[f]ailure to comply with conditions of approval invalidates this approval order," as well as numerous allegations in the Complaint that Bayer, in fact, failed to comply with various conditions of approval. (Compl. ¶¶ 17-23; PMA Ltr. at 3.) However, at the same time, Plaintiffs specifically concede that the FDA has not recalled Essure's PMA, do not allege that the FDA has declared the PMA invalid, and insist that they are not asking us to invalidate the PMA. (Pls.' Sur-Reply Br. at 3, 5-6.) Thus, their argument rests on a premise that the PMA is self-invalidating. However, we reject this premise. Indeed, Plaintiffs have cited no controlling authority holding that a PMA order automatically invalidates itself when post-approval conditions are not met. Moreover, the Code of Federal Regulations clearly vests authority and discretion in the FDA to withdraw premarket approval from a device if there is a violation of conditions, as the regulations specifically empower the FDA to "issue an order withdrawing approval of a PMA if, from any information available to the agency, FDA determines that . . . (2) Any postapproval

claims, we also grant them leave to amend their Complaints to cure any deficiencies that we have identified. We address each Count of the Complaint in turn, although not entirely in sequential order.[7]

A. Count I – Negligent Training

In Count I, the Complaint alleges that Bayer is liable on a claim for negligent training insofar as it (1) "fail[ed] to abide by the FDA training guidelines with Plaintiff's implanting physician," e.g., providing "training [that was] different from that of the 'Physician Training Manual;'" (2) "fail[ed] to supervise the procedure;" (3) "fail[ed] to train Plaintiff's physician on how to use the hysteroscopic equipment;" and (4) "fail[ed] to advise implanting physicians of the adverse events and non-conforming product." (Compl. ¶ 125.) The Complaint further alleges that "[t]his breach caused Plaintiff's damages" insofar as the Essure device migrated from Plaintiff's fallopian tubes and caused various complications. (Id. ¶ 126.)

Bayer argues that Plaintiffs' negligent training claim should be dismissed as expressly preempted because Plaintiffs seek to impose training requirements different from those in the federal requirements. It further argues that, to the extent that Plaintiffs' claim purports to seek enforcement of federal training requirements, it is impliedly preempted under Buckman because there is no state law duty to engage in the training that Plaintiffs contend should have been done.

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requirement imposed by the PMA approval order . . . has not been met." 21 C.F.R. § 814.46(a). In this case, the Complaint does not allege that the FDA has issued an order withdrawing approval of the Essure PMA or that the FDA has otherwise declared Essure's PMA invalid. Accordingly, we reject Plaintiffs' argument that the PMA is invalid and, thus, cannot provide federal requirements giving rise to preemption.

[7] Specifically, we address Count III, the pharmacovigilance claim, at the conclusion of the Memorandum, because it is a composite of several other claims, and we address Count VI, the UTPCPL claim, immediately following the misrepresentation claims (Counts VIII and IX), because it is a statutory cause of action for the same alleged misrepresentations on which the misrepresentation claims are based.

Finally, it argues that the Count fails to state a plausible claim because, inter alia, it does not include any specific allegation as to how Plaintiffs' damages are tied to the alleged violation of state law.

1. Preemption

Upon consideration of Bayer's preemption arguments, we conclude that, at least to the extent that the claim alleges that Bayer failed to abide by FDA-approved training violations, the negligent training claim does not seek to impose training requirements different from those in the federal requirements and, thus, is not expressly preempted on that basis but, rather, asserts a permissible parallel claim. See Riegel, 552 U.S. at 330 (stating that express preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements" (citation omitted)). Moreover, we reject Bayer's argument that the negligent training claim is impliedly preempted because there is no state law on which to base a negligent training claim. Instead, we conclude that Pennsylvania law recognizes that, in certain contexts, one who undertakes to render services to another may be subject to liability to a third party for failure to exercise due care in rendering those services, when the services were necessary for the protection of that third party. See Seebold v. Prison Health Sys., Inc., 57 A.3d 1232, 1244-45 (Pa. 2012) (citing Restatement (Second) of Torts § 324A (1965));[8] see also Myers v. Garfield & Johnson

[8] The Restatement provides that:

> 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
>
> (b) he has undertaken to perform a duty owed by the other to the third person, or
>
> (c) the harm is suffered because of reliance of the other or the third person

Enters., Inc., 679 F. Supp. 2d 598, 616 (E.D. Pa. 2010) (citations omitted). Accordingly, we deny Bayer's request that we dismiss Plaintiffs' negligent training claims on preemption grounds.

2. Plausibility

Bayer argues in the alternative that we should dismiss the negligent training claim for failure to state a claim upon which relief can be granted. In order to state a negligence claim under Pennsylvania law, a plaintiff must allege (1) a duty owed to the plaintiff by the defendant; (2) a breach of that duty; (3) a causal connection between the breach and the resulting injury; and (4) actual loss or damages. City of Philadelphia v. Beretta U.S.A. Corp., 277 F.3d 415, 422 n.9 (3d Cir. 2002) (citing Martin v. Evans, 711 A.2d 458, 461 (Pa. 1998)); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 439 (E.D. Pa. 2004) (citing Morena v. S. Hills Health Sys., 462 A.2d 680, 684 n.5 (Pa. 1983)).

Reading the Complaint in the light most favorable to Plaintiffs, it alleges that Bayer, by training Plaintiffs' physicians, assumed a duty to do so non-negligently; that Bayer breached that duty by failing to follow the FDA-imposed training guidelines; and that Plaintiffs' injuries, all of which are alleged to have arisen from the migration of the Essure device from Plaintiffs' fallopian tubes, were caused by Bayer's training deficiencies. However, the Complaint does not allege how Bayer's training departed from the FDA-approved guidelines,[9] much less any facts that give

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upon the undertaking.

Restatement (Second) of Torts § 324A (1965).

[9] At oral argument, Plaintiffs pointed to the Complaint's allegations that Bayer failed to disclose adverse events involving Essure to the implanting physicians and failed to train doctors in hysteroscopy after providing the doctors with hysteroscopic equipment, and they suggested that these alleged failures were violations of FDA-required training guidelines. (See N.T. 1/11/16 at 17-18.) However, the Complaint does not allege that either disclosure of adverse events or training in the basics of hysteroscopy are part of the FDA-mandated training. We further note that, to the extent that Plaintiffs argue that Pennsylvania law imposes an independent duty on Bayer to train physicians in hysteroscopy when providing them with hysteroscopic equipment,

rise to a recognizable theory as to how any departure from the training guidelines may have caused each Plaintiff's Essure device to migrate from her fallopian tubes. Plaintiffs asserted at oral argument that they were unable to plead their negligent training claim with greater specificity because they do not know what the federal requirements are with respect to training. (See N.T. 1/11/16 at 21, 33-34, 36.) However, at the same time, the Complaint alleges that the training provided was different from that set forth in the "Physician Training Manual" (Compl. ¶ 125), and Plaintiffs admitted at argument that they had a copy of that manual (N.T. 1/11/16 at 36). Accordingly, Plaintiffs' assertion that they did not have the ability to plead with greater specificity that the training provided to Plaintiffs' doctors departed from the training standards is unfounded. We conclude that the Complaint's bald allegations of both negligence and causation do nothing more than posit a "sheer possibility that [Bayer] has acted unlawfully," without setting forth a plausible claim of negligent training. Iqbal, 556 U.S. at 678; see also Connelly, 809 F.3d at 786. Accordingly, we conclude that Count I fails to state a claim upon which relief can be granted and dismiss Count I on that basis.

B. Count II – Negligent Entrustment

In Count II, the Complaint alleges that Bayer is liable because it negligently entrusted specialized hysteroscopic equipment to physicians who were not qualified or competent to use that equipment. (Compl. ¶¶ 133-34; see also id. ¶¶ 73, 77.) The Complaint alleges that Bayer had a duty not to provide sophisticated equipment to unqualified physicians; that it knew that Plaintiffs' implanting physicians were not qualified to use the hysteroscopic equipment; that it nevertheless

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thereby allowing a state law negligence claim based on the breach of such a duty, we have found no state law that appears to impose such a duty. In addition, unlike Plaintiffs, we cannot discern such a training requirement in the FDA's mandated warning label for Essure, which simply cautions that Essure is only to be used by knowledgeable hysterocopists. See generally infra n.10 and accompanying text.

provided the equipment to the physicians; and that Plaintiffs were injured as a result of the negligent entrustment insofar as the Essure device migrated from Plaintiffs' fallopian tubes. (Id. ¶¶ 140-45.)

Bayer argues, among other things, that this Count should be dismissed because Plaintiffs' negligent entrustment claim is pre-empted under Riegel. Specifically, Bayer argues that, in light of the Essure PMA, Plaintiffs' claim against it for negligent entrustment of hysteroscopes is expressly preempted because Plaintiffs seek to impose requirements that are "different from, or in addition to" federal requirements concerning Essure's safety. In that regard, Bayer notes that the PMA expressly sets forth certain training requirements and protocols for physicians who use Essure and does not require Bayer (or any other hysteroscope provider) to do anything more than what the PMA requires. It argues that the FDA expressly approved Instructions for Use that contained (1) a warning that Essure is to be "used only by physicians who are knowledgeable hysteroscopists, . . . and have successfully completed the Essure training program," as well as (2) instructions regarding the use of a hysteroscope to implant Essure.[10] Bayer therefore contends that Plaintiffs cannot proceed on any negligent entrustment claim that imposes a requirement that Bayer not entrust hysteroscopy equipment to unqualified physicians; it reasons that, pursuant to the PMA process, the FDA has determined that the safeguards that it has put in place for the implantation of Essure are sufficient and, under express preemption principles, the state cannot impose safety requirements that would be "different from, or in addition to" the requirements that the FDA imposed.

[10] Although there are no explicit allegations in the Complaint regarding the Instructions for Use, Plaintiffs concede in their responsive brief that the Instructions for Use were FDA-approved and also concede that the Instructions contain the quoted language. (Pls.' Resp. Br. at 99.) The Instructions for Use are also a matter of public record and available on the FDA website. (See http://www.hcp.essure-us.com/assets/pdf/Link%20Essure%20IFU.pdf (last visited March 9, 2016).)

In response to this argument, Plaintiffs maintain that their claim is outside the scope of any such federal preemption because it concerns the safety of the hysteroscopic equipment, not the safety of Essure, and the PMA concerned only Essure, not hysteroscopes.[11] In this regard, they argue that the alleged entrustment has "absolutely nothing to do with Essure and the product of Essure," emphasizing that that hysteroscopic equipment is "very specialized" and dangerous in its own right, such that "if you use[] it wrong, you can actually kill somebody." (N.T. 1/11/16 at 37.)

However, we cannot reconcile this characterization of the claim with the allegations of the Complaint, because the Complaint plainly alleges that Bayer was negligent in entrusting the hysteroscope to Essure-implanting physicians, that Bayer's motivation was to increase sales of the Essure device, and, most importantly, that the damage that flowed from this alleged negligent entrustment was that Plaintiffs' Essure device migrated following implantation, not that Plaintiffs were injured by the hysteroscope itself. (Compl. ¶¶ 133, 135, 141-42.) As such, we cannot read

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[11] Plaintiffs also argue that their claim for negligent entrustment of the hysteroscope is not expressly preempted under Riegel and § 360k(a), because the claim is based on a general common law duty not to entrust a dangerous instrumentality to someone who is unable to use it safely, and claims based on such laws of general applicability, i.e., laws that are not only applicable to medical devices, are not preempted. They rely on 21 C.F.R. § 808.1(d)(1), which provides that § 360k(a):

> does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such a general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1).

However, Riegel considered the effect of 21 C.F.R. § 808.1(d)(1) and refused to give it the effect that Plaintiffs seek to give it here, observing, inter alia, that "[n]othing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general," and that the regulation "add[ed] nothing to [the preemption] analysis but confusion." 552 U.S. at 328-29 (underlining added). Moreover, Plaintiffs have cited to no authority that has given 21 C.F.R. § 808.1(d)(1) the very broad effect they seek to give it. Accordingly, we reject Plaintiffs' argument that § 808.1(d)(1) dictates that claims based on general state requirements that are not specific to medical devices are not preempted and, more specifically, reject their claim that their negligent entrustment claim is not preempted on this basis.

the Complaint to assert a claim concerning hysteroscopes that is divorced from the safety of Essure. Rather, we can only conclude that the claim, as pled, seeks to impose a state requirement relating to the safety of Essure (i.e., a requirement that suppliers not provide hysteroscopic equipment to Essure-implanting physicians who are not competent hysteroscopists), which is in addition to the FDA's own safety requirements and, therefore, is expressly preempted under Riegel. Moreover, the negligent entrustment claim is not based on state law that imposes duties that "'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330 (allowing that a state law claim premised on duties that parallel rather than add to federal requirements is not expressly preempted (citation omitted)). We thus dismiss Count II for failure to state a claim upon which relief can be granted because it is expressly preempted,[12] and we deny Plaintiffs leave to amend this claim because we conclude that its express preemption renders it futile.[13]

C. Count IV – Negligent Risk Management

Count IV of the Complaint alleges that Bayer is liable for breaching a "duty to have in place a reasonable risk management procedure" that ensured that non-conforming products could be tracked appropriately, and that adverse reports were considered in its risk analysis.[14] (Compl.

[12] Bayer also argues, inter alia, that Count II fails to state a claim upon which relief can be granted because Pennsylvania would not recognize a claim of negligent entrustment under the factual circumstances alleged. However, we need not reach this argument as we find Plaintiffs' negligent entrustment claim to be expressly preempted.

[13] "A court granting a motion for judgment on the pleadings should freely grant leave to amend pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure, unless amending the complaint would be futile." Bloomfield v. Wissinoming Volunteer Trust Aid Corps, Inc., Civ. A. No. 15-1013, 2015 WL 4077048, at *6 (E.D. Pa. July 6, 2015) (citation omitted); see also Phillips v. Cty. of Allegheny, 515 F.3d 224, 245 (3d Cir. 2008) ("[I]f a complaint is subject to Rule 12(b)(6) dismissal, a district court must permit a curative amendment, unless such an amendment would be inequitable or futile." (citing Alston v. Parker, 363 F.3d 229, 235 (3d Cir. 2004)).

[14] The Complaint also alleges that Bayer breached a duty to have a risk management procedure that ensured that adverse reports were made to the FDA. However, Plaintiffs do not

¶ 162.) Bayer argues that this claim should be dismissed as expressly preempted pursuant to Riegel, because all risk management is plainly and comprehensively regulated by the FDA insofar as the PMA specifically requires the reporting of events involving safety and efficacy and any state law concerning risk management would add to those federal requirements. Bayer further argues that Count IV fails to state a claim upon which relief can be granted because Plaintiffs do not identify any state law that creates a tort for negligent risk management and there is, in fact, no parallel state law that provides for liability for violations of the FDA risk management protocols.

Pennsylvania law, however, permits plaintiffs considerable latitude in labeling their negligence claims, and we conclude that it would recognize a claim for negligent risk management. As the Pennsylvania Supreme Court has made clear, plaintiffs are the "master[s] of [their] own claim[s]." Lance v. Wyeth, 85 A.3d 434, 460 (Pa. 2014). Moreover, the Pennsylvania Supreme Court has quoted with apparent approval an amicus brief which states that:

> "A manufacturer's negligent conduct can occur at any stage of the marketing process: in the initial design of the [product], in the failure to investigate information about the risks the [product] poses, and in its decision to continue to sell the [product] despite those unreasonable risks. The defendant's unreasonable behavior at any point in this process should be sufficient to give rise to negligence liability when that conduct results in injury."

Id. at 458 (emphases added) (quoting Br. for *Amici* Am. & Pa. Ass'ns for Justice at 3). As such, we reject Bayer's argument that Pennsylvania would not recognize a claim for negligent risk management.

Moreover, while Bayer maintains that any such claim is expressly preempted because Plaintiffs seek to impose different or additional standards from those imposed by the FDA, as we

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explain how this alleged failure to report gives rise to a negligent risk management claim, and instead simply refer us to their argument regarding failure to report in connection with their failure to warn claim in Count XII of the Complaint. Accordingly, we do not separately consider failure to report in connection with Plaintiffs' negligent risk management claim in Count IV, but rather address the failure to report, as Plaintiffs do, only in connection with Count XII.

read the Complaint, Plaintiffs only seek to hold Bayer to federal risk management standards as articulated in the Code of Federal Regulations, the PMA, and federal statutes. Accordingly, at this time, we cannot conclude that Plaintiffs are seeking to pursue anything other than a permissible parallel claim.

Nevertheless, the scope of the parallel claim that Plaintiffs seek to pursue and the elements of that claim are insufficiently pled and we therefore dismiss this claim on that basis. As an initial matter, we observe that it is impossible to discern from the Complaint precisely what federal standards are allegedly violated by each alleged violation of risk management standards, because Count IV simply includes a laundry list of over twenty-five federal "requirements," and then alleges over twenty alleged breaches of Bayer's risk management duties, without giving any indication as to what federal requirement was violated by each alleged breach. (See Compl. ¶¶ 162(a)-(z), 163(a)-(w).) Moreover, certain of the alleged breaches do not appear to have any identifiable relation to "risk management," such as allegations that Bayer issued untruthful warranties, failed to use pre-sterile and post-sterile cages during manufacturing, and required physicians to purchase two Essure kits a month. (Id. ¶ 163(e), (j), (v).)

Most importantly, however, Plaintiffs have failed to allege any identifiable causal connection between the alleged risk management breaches and Plaintiffs' resulting injuries. See Beretta U.S.A. Corp., 277 F.3d at 423 (requiring plaintiff to allege "some direct relation between the injury asserted and the injurious conduct alleged" (citation and internal quotation marks omitted)). For example, the Complaint appears to allege that Bayer violated state and federal risk management standards in 2003 by failing to follow manufacturing procedures to control products that did not conform to specifications, and by failing to identify existing and potential causes of non-conforming product. (Compl. ¶ 163(t), (u).) The Complaint then baldly alleges that all

identified risk management breaches caused Plaintiffs' damages insofar as the Essure device migrated from Plaintiff's fallopian tubes. (Id. ¶ 170.) Given the lack of allegations that in any way link Bayer's failure to follow procedures in 2003 with the migration of any of Plaintiffs' Essure devices between 2008 and 2013, we can only conclude that Plaintiffs' claims are based entirely on speculation. Indeed, we are unable to discern any plausible and non-speculative causal connection between any of Bayer's alleged risk management failings and the migration of Plaintiffs' Essure devices. See Twombly, 550 U.S. at 678 (requiring complaint to set forth "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face" (quotation omitted)). Accordingly, we conclude that the negligent risk management claim, as currently pled, does not set forth a plausible claim for relief, and we dismiss Count IV on that basis.

D. Count V – Breach of Express Warranty

Count V of the Complaint alleges that Bayer is liable for breaching express warranties. Specifically, the Complaint alleges that Bayer breached numerous express warranties with Plaintiffs, including:

- warranties on its website that erroneously stated, inter alia, that Physicians "must be signed-off to perform Essure procedures," that Essure is "Worry free," and that Essure is "more effective than tying your tubes";
- warranties in its advertisements that erroneously stated that physicians would not be "qualified" as Essure physicians unless they performed the Essure procedures at least once every 6-8 weeks;
- a marketing warranty that Essure allows for "visual confirmation of each insert's proper placement," when it does not;
- warranties in brochures that erroneously state, inter alia, Essure is "Worry free," stays secure and remains visible outside a user's tubes, so that a doctor can confirm its proper placement, and is made from the same silicon-free materials used in heart stents;

- warranties in the Essure booklet that Essure is painless, and does not irritate the uterine lining.

(See Compl. ¶¶ 103-115.)[15] The Complaint alleges that all of these warranties "were specifically negotiated and expressly communicated to Plaintiff[s] in such a manner that [they] understood and accepted them" (id. ¶ 182 (emphases added)), and that Plaintiffs relied on the warranties prior to implantation (id. ¶ 102). Finally, the Complaint alleges that, as a result of Plaintiffs' reliance on the warranties, they suffered damages, i.e., the device migrated and Plaintiffs suffered a variety of complications and other injuries. (Id. ¶ 183.) Bayer argues that this claim should be dismissed as expressly preempted because Plaintiffs seek to impose requirements that are different from federal requirements. It also argues that the claim fails to state a plausible claim for relief under the requisite pleading standards.

1. Express Preemption

Pursuant to Riegel's express preemption analysis, we must consider whether Plaintiffs' breach of warranty claim relies on state requirements that are "different from, or in addition to"

[15] Prior to oral argument on the pending Motions, the Complaint alleged that there were forty separate warranties and misrepresentations on which Plaintiffs relied in deciding to have Essure implanted. We asked Plaintiffs' counsel at oral argument whether it was actually Plaintiffs' intention to allege that each of the five Plaintiffs read or saw each and every one of the forty warranties and that each of the five Plaintiffs relied on each and every one of the forty warranties in deciding to have Essure implanted. (N.T. 1/11/16 at 12-13.) At the time, counsel reiterated that this was, in fact, Plaintiffs' position. (Id. at 13.) However, following oral argument, Plaintiffs withdrew their allegations concerning seventeen of the forty warranties and misrepresentations and clarified that seven of the remaining twenty-three warranties and misrepresentations pertained only to Plaintiff McLaughlin. (See Post-Argument Jt. Submission Concerning Pls.' Warranty Claims at 2-3.) Accordingly, Plaintiffs are now alleging that Bayer breached sixteen warranties with respect to Plaintiffs Ruble, Strimel, Stelzer, and Walsh (Compl. ¶¶ 103(c), (e)-(g), (i)-(k), 104(b), 110, 111(a)-(c), (g), 113, 115(a)-(b)), and breached those same warranties and seven others with regard to Plaintiff McLaughlin. (Id. ¶¶ 103(a)-(b), 104(a), (c)-(d), 107, 111(f).) We note that the warranties on which only Plaintiff McLaughlin is basing her claim are various warranties regarding the risk of pregnancy, including website and advertising warranties that there were zero pregnancies in clinical trials, a warranty by "Defendants' CEO" that Essure frees users of their constant worry about unplanned pregnancy, and a warranty in the Essure booklet that pregnancy "cannot occur." (Id. ¶¶ 103(a)-(b), 104(a), 107, 111(f).)

federal requirements. Riegel, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). Plaintiffs argue that their claim is not expressly preempted because it is not based on state requirements but, rather, is grounded on voluntary contractual promises made by Bayer.

Plaintiffs are correct that "[e]xpress warranties, as distinguished from implied warranties, do not independently arise by operation of state law." Bentzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 454 (E.D. Pa. 2011). Pennsylvania law provides that an express warranty is "specifically negotiated," Goodman v. PPG Indus., 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004), and "is created by a seller through '[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain.'" Starks v. Coloplast Corp., Civ. A. No. 13-3872, 2014 WL 617130, at *6 (E.D. Pa. Feb. 18, 2014) (quoting 13 Pa. Cons. Stat. § 2313). Thus, "the parties, not the state, 'define[] the substantive obligations of the contract and hence any express warranties.'" Bentzley, 827 F. Supp. 2d at 454-55 (alteration in original) (quoting Michael v. Shiley, Inc., 46 F.3d 1316, 1325 (3d Cir. 1995)), abrogated on other grounds by Lohr, 510 U.S. 470. Consequently, a "claim for breach of express warranty does not involve a state 'requirement' and is not preempted by MDA." Id.; see also Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009) ("Because express warranties 'arise from the representations of the parties and are made on the basis of the bargain between them,' a 'state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA' and therefore may not be preempted." (quoting Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997))). In accordance with this analysis, we conclude that Plaintiffs' breach of warranty claim is not expressly preempted because, as pleaded, it does not arise from state "requirements," but rather arises from alleged contracts between the parties.

2. Plausibility

Bayer argues in the alternative that the breach of warranty claim should be dismissed for failure to state a plausible claim because the Complaint does not include allegations as to "the source of the statements, when the statements were made, in what manner the statements were made, the Defendants' alleged intended recipient, when Plaintiffs became aware of the statements," or "how the alleged warranties ended up as the basis for an alleged and unspecified bargain between the parties." (Bayer's Reply Br. at 45-46.)

As stated above in Section II.A, supra, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows a court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (citation omitted). "[A] plaintiff cannot make a conclusory recitation of the elements of a cause of action and assume that it is sufficient to establish the existence of an express warranty." Esposito v. I-Flow Corp., Civ. A. No. 10-3883, 2011 WL 5041374, at *6 (E.D. Pa. Oct. 24, 2011) (citation and internal quotation marks omitted). Rather, a plaintiff must allege that defendant made "an actual affirmation of fact or a promise, [which] formed the basis of the bargain between the [defendant] and the plaintiff." Jeter v. Brown & Williamson Tobacco Corp., 113 F. App'x 465, 468 (3d Cir. 2004) (citing 13 Pa. Cons. Stat. § 2313 and Goodman, 849 A.2d at 1243); see also Esposito, 2011 WL 5041374, at *6 (citations omitted). Moreover, where a breach of warranty claim is based on advertisements, the plaintiff can only establish reliance if he "'actually saw or heard and believed the allegedly false advertisements.'" Jeter, 114 F. App'x at 469 (quoting Weinberg v. Sun Co., Inc., 777 A.2d 442, 446 (Pa. 2001)); see also Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004) (stating that, in order to meet the basis of the bargain requirement, a plaintiff must "prov[e] that she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise"

(quoting Cipollone v. Liggett Group, Inc., 893 F.2d 541, 567 (3d Cir. 1990)), rev'd on other grounds, 505 U.S. 503 (1992).

Here, the Complaint pleads the substance of the alleged warranties, explicitly quoting most of them. (See Compl. ¶¶ 103-15.) It also alleges the mode of communication for each warranty (e.g., advertisement, website, brochure) (see id.), and suggests that Plaintiffs encountered the warranties either on the internet, in their physicians' offices, on Bayer's website, or through Bayer's advertising (see id. ¶ 102). However, the Complaint fails to allege any of the circumstances under which each Plaintiff read or saw each particular warranty, or how that warranty came to be a basis of each Plaintiff's bargain with Bayer. Instead, it includes only the wholly conclusory allegations that warranties were "specifically negotiated and expressly communicated to Plaintiff[s] in such a manner that Plaintiff[s] understood and accepted them," and that the affirmations of fact or promises in the warranties "created a basis of the bargain" between Plaintiffs and Bayer. (Id. ¶¶ 181-82.)

The following examples illustrate the Complaint's insufficiencies. While the Complaint alleges that certain warranties appeared in advertisements and marketing, it does not allege whether the advertisements appeared in magazines, newspapers or other publications, on posters, on the internet, or on the television. (Id. ¶¶ 104, 110.) In addition, insofar as it alleges that other warranties came from Bayer's brochures (id. ¶ 111), it does not allege the titles of, or any other identifying information for, the alleged brochures. The Complaint also fails to allege how or when each Plaintiff encountered each warranty beyond alleging the general time frame of "prior to implantation," which covers a period of many years. (Id. ¶ 102.) The Complaint also does not allege sufficient facts concerning the sources of many warranties, so as to support a reasonable inference that all of the warranties were actually directed to, and intended for, patients such as

Plaintiffs. Indeed, one of the alleged warranties on Bayer's website states that "In order to be trained in Essure you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy . . ." (id. ¶ 103(j)), which, on its face, does not appear to be directed to patients such as Plaintiffs. In addition, at least one warranty, on its face, does not appear to be an affirmation of fact or promise that could give rise to an express warranty. (Id. ¶ 104(d) ("I don't want to worry about an unexpected pregnancy.").)

In short, the Complaint fails to allege facts that give rise to a reasonable inference that each alleged warranty was an affirmation of fact or promise that formed a "basis of the bargain" between Bayer and each Plaintiff. See Starks v. Coloplast Corp., Civ. A. No. 13-3872, 2014 WL 617130, at *7 (E.D. Pa. 2014) (dismissing breach of warranty claim pursuant to Rule 12(b)(6), in part because it did not allege "any details regarding . . . how the warranty was made, that it became the basis of the bargain, or that it was directed to [plaintiff]"). Indeed, there are no meaningful allegations concerning the circumstances under which the alleged warranties were "specifically negotiated" with Bayer, and "expressly communicated" to each Plaintiff (id. ¶ 179), such that we can reasonably infer that the warranties became a matter of contract between each Plaintiff and Bayer. See Bentzley, 827 F. Supp. 2d at 454-55 ("[T]he parties . . . define[] the substantive obligations of the contract and hence any express warranties." (quotation omitted)). We therefore conclude that the bald allegation that the warranties "created a basis of the bargain" is nothing more than a "conclusory recitation" of an element of the cause of action, which is insufficient to plead the existence of an express warranty. Esposito, 2011 WL 5041374, at *6.

Under these circumstances, we conclude that the Complaint does not contain "'sufficient factual matter to show that the [breach of express warranty] claim is facially plausible,' thus enabling '[us] to draw the reasonable inference that the defendant is liable for [the] misconduct

alleged.'" Warren Gen. Hosp., 643 F.3d at 84 (quoting Fowler, 578 F.3d at 210). We therefore conclude that Count V fails to allege a plausible breach of express warranty claim, and we dismiss it on that basis.

E. Count VII – Fraudulent Concealment

Count VII of the Complaint alleges that Bayer is liable for fraudulent concealment because it actively concealed adverse events involving Essure, as well as manufacturing irregularities and complaints about the product, from both Plaintiffs and their physicians to induce Plaintiffs to have Essure implanted. Specifically, the Complaint alleges that Bayer had a duty to make certain disclosures pursuant to federal law and the Essure PMA and that it intentionally breached those duties. (Compl. ¶¶ 205-07.) Bayer argues, inter alia, that Count VII should be dismissed as impliedly preempted under Buckman. Specifically, Bayer argues that the fraudulent concealment claim is actually a preempted "fraud-on-the-FDA" claim, because Bayer's alleged duty to disclose is a federal duty to disclose information to the FDA.

As discussed in Section II.B.2, supra, the Supreme Court held in Buckman that "fraud-on-the-FDA" claims, which "exist solely by virtue of FDCA disclosure requirements," are solely within the authority of the FDA to punish and deter. 531 U.S. at 348, 350, 353. Thus, where a plaintiff sues "*because* the conduct violates the FDCA," it is impliedly preempted under Buckman. Sprint Fidelis, 623 F.3d at 1204 (emphasis in original) (quotation omitted).

In order to state a cognizable claim for fraudulent concealment under Pennsylvania law, a plaintiff's claim must rest on a duty to disclose, as "there can be no liability for fraudulent concealment absent some duty to speak."[16] City of Rome v. Glanton, 958 F. Supp. 1026, 1038

[16] A fraudulent concealment claim under Pennsylvania law has the same underlying elements as a fraudulent or intentional misrepresentation claim, see infra n. 19 and accompanying text, but "'in the case of intentional non-disclosure, a party intentionally conceals a material fact

(E.D. Pa. 1997) (citing Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 611–12 (3d Cir. 1995); Gibbs v. Ernst, 647 A.2d 882, 889 n.12 (Pa. 1994); and In re Estate of Evasew, 584 A.2d 910, 913 (Pa. 1990)); see also Restatement (Second) of Torts § 551(2) (providing that omissions can give rise to valid claims of fraud only when the defendant had a duty to disclose the omitted information). "Moreover, [under Pennsylvania law], a duty to disclose does not typically arise unless there is a confidential or fiduciary relationship between the parties." Protica, Inc. v. iSatori Techs., Inc., Civ A. No. 11-1105, 2012 WL 1071223, at *5 (E.D. Pa. Mar. 30, 2012) (citation omitted).

The Complaint in this case alleges only that federal law and the PMA imposed a duty to speak by requiring Bayer to disclose certain information to the FDA. (See, e.g., Compl. ¶ 205(a), (b), (c), (d), (e), (f), (k), (l), (v), and (w) (referencing federal law mandating disclosures to the FDA).) It does not allege that Pennsylvania law imposed any duty on Bayer to disclose the allegedly undisclosed information, much less a duty to disclose such information to Plaintiffs and/or their physicians. As such, Plaintiffs' fraudulent concealment claim, as pled, exists "solely by virtue of FDCA requirements." Buckman, 531 U.S. at 353.

Plaintiffs argue that their fraudulent concealment claim is not subject to implied preemption for the same reasons that their negligent failure to warn claim is not subject to such preemption, see infra, Section III.J., thereby suggesting that their fraudulent concealment claim is partially grounded on a state law duty to warn. However, as noted above, the Complaint itself alleges only violations of federal duties to disclose. Moreover, to the extent that Plaintiffs intended to ground their fraudulent concealment claim on a state law duty to warn that parallels the federally-imposed disclosure duties, it would fail to state a claim upon which relief can be granted

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rather than making an affirmative misrepresentation.'" Boortz v. Noon, 729 A.2d 555, 560 (Pa. 1999) (quoting Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994)).

because "negligence is the sole theory upon which a plaintiff may recover against a prescription drug [or medical device] manufacturer for a failure to warn." Kline v. Pfizer, Inc., Civ. A. No. 08-3238, 2009 WL 32477, at *4 (E.D. Pa. Jan. 6, 2009) (citing Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996)); see also Runner v. C.R. Bard, 108 F. Supp. 3d 261, 268-69 (E.D. Pa. 2015); Kester v. Zimmer Holdings, Inc., Civ. A. No. 10–523, 2010 WL 4103553, at *4 (W.D. Pa. Oct. 18, 2010) (citing Kline v. Pfizer, Inc., Civ. A. No. 08-3238, 2009 WL 32477, at *4-5 (E.D. Pa. Jan. 6, 2009)); and Parkinson, 315 F. Supp. 2d at 747-48 (stating that "'the manufacturer's negligence[] is the *only* recognized basis of liability'" for failure to warn in connection with a medical device (quoting Hahn, 673 A.2d at 891; additional citations omitted)).

Accordingly, we conclude that Count VII is grounded exclusively on federal duties to disclose and exists "solely by virtue of FDCA requirements." Buckman, 531 U.S. at 353. We therefore dismiss the fraudulent concealment claim as impliedly preempted under Buckman.[17] Moreover, because the claim is impliedly preempted and Plaintiffs have identified no state law duty to disclose that could give rise to a claim for fraudulent concealment under Pennsylvania law, we deny Plaintiffs leave to amend this claim as we conclude that amendment would be futile.

F. Counts VIII and IX – Fraudulent and Negligent Misrepresentation

Count VIII of the Complaint asserts that Bayer is liable for fraudulent misrepresentation based on the misrepresentations contained in the warranties that are the subject of the express

[17] Plaintiffs also argue that Buckman preemption does not apply to claims that concern non-disclosures that occur after PMA approval. They rely on Knipe v. Smithkline Beecham, 583 F. Supp. 2d 553 (E.D. Pa. 2008), which held that the state law failure-to-warn claims of the plaintiffs in that case, which were premised on certain post-approval omissions, were not impliedly preempted pursuant to Buckman because they did "not exist by virtue of FDCA disclosure requirements, but rather [were] premised entirely on state tort theories." Id. at 597-98. However, as explained above, Plaintiffs' fraudulent concealment claim is based entirely on alleged violations of federal disclosure requirements. Accordingly, Knipe is readily distinguishable from the instant case and in no way alters our analysis here.

warranty claim in Count V. Meanwhile, Count IX asserts that Bayer is liable for negligent misrepresentation based on those same misrepresentations. As we discussed in Section III.D., the alleged misrepresentations appeared on Bayer's website, in advertisements, in brochures, and in the Essure booklet. They concern matters such as (1) whether Essure is painless, and/or "worry free," (2) the qualifications of physicians implanting Essure, (3) whether it is possible to secure visual confirmation of Essure's proper placement, and (4) Essure's composition (e.g., whether it is made from silicon-free materials used in heart stents). (See Compl. ¶¶ 103-04, 107, 110-111, 113, 115.)

Bayer argues that Plaintiffs' misrepresentation claims should be dismissed as expressly preempted because Plaintiffs seek different or additional warnings regarding the safety of Essure from those required by the FDA.[18] It argues, in the alternative, that we should dismiss the claims for failure to satisfy the pleading standards in Rule 12(b)(6) or Rule 9(b).

1. Express Preemption

As noted above, pursuant to Riegel's express preemption analysis, we must consider whether Plaintiffs' misrepresentation claims seek to impose state requirements that are "different from, or in addition to" federal requirements applicable to Essure. Riegel, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). Where Plaintiffs' claims seek to enforce state requirements that parallel federal requirements, however, there is no express preemption. Id.

[18] Bayer also argues the Plaintiffs' misrepresentation claims are impliedly preempted under Buckman because they are based on alleged intentional misrepresentations to the FDA and, thus, are essentially fraud-on-the FDA claims. However, Bayer relies on paragraphs of the Complaint that concern reports to the FDA, which are neither included in the misrepresentation counts nor referenced in them. As noted above, the misrepresentation claims are based on the non-withdrawn "Facts and Warranties" set forth in paragraphs 103-115 of the Complaint, none of which appear to involve statements made to the FDA. Accordingly, we conclude that Bayer's arguments in this regard misconstrue Plaintiffs' claims.

Plaintiffs' misrepresentation claims are based on Pennsylvania law that imposes liability for "'a misrepresentation of a material fact . . . made . . . with an intent to induce another to act on it . . . [,] which results in injury to a party acting in justifiable reliance on the misrepresentation.'" Bilt–Rite Contractors, Inc. v. The Architectural Studio, 866 A.2d 270, 277 (Pa. 2005) (quoting Bortz v. Noon, 729 A.2d 555, 561 (Pa. 1999); and Gibbs, 647 A.2d at 889 (citations omitted)).[19] Moreover, Pennsylvania law recognizes a cause of action based on a medical manufacturer's misrepresentations that, in effect, overpromote the manufacturer's product and "nullify otherwise adequate warnings." Baldino v. Castagna, M.D., 478 A.2d 807, 810 (Pa. 1984) (citing Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971)); Wolfe v. McNeil-PPC, Inc., 773 F. Supp. 2d 561, 570-71 (E.D. Pa. 2011) (stating that "[a] plaintiff can bring a claim that the manner in which a drug is promoted negated otherwise-adequate warnings" (citing Baldino, 478 A.2d at 810)).

In this case, one of the conditions imposed by the PMA is that the sale and distribution of Essure may not violate 21 U.S.C. § 352(q), which prohibits the use of false or misleading advertising. (See PMA Ltr. at 1.) Moreover, federal regulations prohibit a device from being labeled, advertised, or distributed in a manner inconsistent with any condition of approval in the PMA. See 21 C.F.R. 814.80 (prohibiting a device from being labeled, advertised, or distributed in a manner inconsistent with any condition of approval in the PMA). Under these circumstances, we conclude that Plaintiffs can potentially allege cognizable and parallel misrepresentation claims at least insofar as they allege that Bayer made false or misleading statements in unapproved advertising or other promotional materials that were inconsistent with specific statements in

[19] To state a cognizable claim for negligent misrepresentation, the plaintiff must also plead that the misrepresenter ought to have known of the statement's falsity. Bilt–Rite Contractors, 866 A.2d at 277 (citations omitted). To state a cognizable claim for fraudulent misrepresentation, the plaintiff must also plead that the speaker had knowledge of the statement's falsity or was reckless as to whether the statement was true or false. Gibbs, 647 A.2d at 889 (citations omitted).

approved FDA materials and that undermined the approved and required statements in those materials. See Riegel, 552 U.S. at 330 (stating that state law claims that parallel federal requirements are not expressly preempted). Such claims would not appear to impose standards that are "different from, or in addition to" PMA requirements but, rather, would appear to be consistent with PMA requirements. Id. (quoting 21 U.S.C. § 360k(a)(1)). We therefore deny Bayer's Motion insofar as it argues that we should dismiss the misrepresentation claims on express preemption grounds because all misrepresentation claims are necessarily expressly preempted.[20] However, we reach no conclusion as to whether claims based on certain misrepresentations may be expressly preempted should the alleged misrepresentations prove to be consistent with FDA-approved statements.[21]

2. Plausibility and Rule 9(b)

Bayer argues that the misrepresentation claims in Counts VIII and IX should be dismissed

[20] Bayer argued in its briefing that many of the representations on which Plaintiffs relied were identical to representations in FDA-approved material, but it did not specify which representations appeared in FDA-approved materials or precisely where they appeared. We therefore asked Bayer during oral argument on January 11, 2016 to submit a chart that specifically identifies the FDA-approved material in which these alleged misrepresentation appeared, and the page on which the alleged misrepresentation appeared. Thereafter, the parties prepared a joint submission in which Bayer provided the information requested for each alleged misrepresentation and Plaintiffs provided a "response." (See Ex. B to Post-Argument Jt. Submission Concerning Pls.' Warranty Claims ("Ex. B. to Jt. Submission").) While we had anticipated that this submission would simplify matters (and, indeed, it apparently prompted Plaintiffs to withdraw certain aspects of their warranty and misrepresentation claims, see supra n. 15), it also appears to have opened the door to considerable additional argument. Accordingly, we will not parse the additional submissions at this stage of the proceedings.

[21] In spite of reaching no conclusion as to the express preemption of this claim, we note that, at least with respect to the alleged misrepresentations in the Essure booklet (Compl. ¶ 115(a)-(b)), Plaintiffs appear to concede that the misrepresentations appear, verbatim, in FDA-approved materials, and thus only give rise to a potential breach of express warranty claim. (See Ex. B to Jt. Submission at 21.) Indeed, if, in fact, the alleged misrepresentations appear verbatim in FDA-approved materials, it seems apparent that any misrepresentation claim based on those statements would be expressly preempted under the legal framework set forth above.

because they fail to state claims upon which relief may be granted pursuant to the pleading standards in Federal Rules of Civil Procedure 12(b)(6) and 9(b).

Bayer contends that we should analyze both the fraudulent and negligent misrepresentation claims pursuant to the heightened pleading standard for fraud claims in Rule 9(b). As noted above, in order to state a claim upon which relief may be granted pursuant to Rule 12(b)(6), a complaint must contain "'sufficient factual matter to show that the claim is facially plausible,' thus enabling 'the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged.'" Warren Gen. Hosp., 643 F.3d at 84 (quoting Fowler, 578 F.3d at 210). Rule 9(b) imposes a more strict pleading standard by requiring that the plaintiff "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b) (emphasis added). In order to satisfy Rule 9(b), a complaint "must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the 'precise conduct with which [it is] charged.'" Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007) (alteration in original) (quoting Lum v. Bank of Am., 361 F.3d 217, 223–24 (3d Cir. 2004)), abrogated on other grounds by Twombly, 550 U.S. 544. A plaintiff can meet this requirement "by pleading the 'date, place or time' of the fraud, or through 'alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud.'" Lum, 361 F.3d at 224 (quoting Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984)).

"There is currently a disagreement among district courts in the Third Circuit regarding whether Rule 9(b) applies to claims based on negligent misrepresentation." Schmidt v. Ford Motor Co., 972 F. Supp. 2d 712, 720 n.3 (E.D. Pa. 2013) (comparing Hanover Ins. Co. v. Ryan, 619 F. Supp. 2d 127, 142 (E.D. Pa. 2007), with Brandow Chrysler Jeep Co. v. DataScan Techs., 511 F. Supp. 2d 529, 537 (E.D. Pa. 2007)). Some courts have held that the "particularity

requirement of Rule 9(b) applies to claims of negligent misrepresentation." Hanover Ins. Co., 619 F. Supp. 2d at 142. Other courts have stated that "Rule 9(b) does not govern claims of negligent misrepresentation." Brandow Chrysler, 511 F. Supp. 2d at 537. Still "[o]ther courts, although declining to apply Rule 9(b), have held that a plaintiff must nonetheless plead negligent misrepresentation with a degree of specificity." Scott v. Bimbo Bakeries, USA, Inc., Civ. A. No. 10–3154, 2012 WL 645905, at *5 (E.D. Pa. Feb. 29, 2012) (citations and internal quotation marks omitted). Given this lack of consensus, we will not apply the pleading standards in Rule 9(b) to the negligent misrepresentation claim but, instead, only hold Plaintiffs' negligent misrepresentation claim to the pleadings standard of Rule 12(b)(6) as we have done with negligent misrepresentation claims in the past. See, e.g., HCB Contractors v. Rouse & Assocs., Civ. A. No. 91-5350, 1992 WL 176142, at *6 (E.D. Pa. July 13, 1992) (stating that, "because a claim of negligent misrepresentation is distinct from a claim of fraud under Pennsylvania law, Rule 9(b) does not apply to the former according to its terms").

Here, Plaintiffs' allegations with respect to the alleged negligent and fraudulent misrepresentation claims are virtually identical. Indeed, the only distinction between Plaintiffs' negligent misrepresentation claim and fraudulent misrepresentation claim is that the Complaint alleges in the fraudulent misrepresentation claim that the misrepresentations were "fraudulently utter[ed]" and/or material, and that Bayer "intentionally made the statements so that Plaintiff[s] would be induced to have Essure implanted." (Compl. ¶¶ 217-20.) With respect to the fraud claim, the Complaint makes no effort to "inject[] precision" by either pleading the date, place or time of the alleged fraud or by using any alternative means to substantiate the allegations. Lum, 361 F.3d at 224. As discussed above in connection with the breach of express warranty claim, see supra Section III.D.2., the Complaint alleges the mode of communication for each alleged

misrepresentation, but fails to include any allegations as to (1) the date on which each misrepresentation was made, (2) the precise source of certain of the misrepresentations, or (3) the circumstances under which each Plaintiff encountered each misrepresentation prior to having Essure implanted. Moreover, the Count only baldly alleges that Plaintiffs "justifiably relied on the misrepresentations" and "would have never had Essure implanted had [they] been aware of the falsity of the representations." (Compl. ¶ 221.) We therefore conclude that the Complaint fails to "inject precision and some measure of substantiation into [the] allegations of fraud," and thus fails to "state the circumstances of the alleged fraud with sufficient particularity" as required by Rule 9(b). Lum, 361 F.3d at 224 (quotation omitted); Fed. R. Civ. P. 9(b). Consequently, we dismiss Count VIII for failure to satisfy the requirements of Rule 9(b).[22]

The pleading requirements of Rule 12(b)(6), which we apply to the negligent misrepresentation claim in Count IX, are less strict that those in Rule 9(b) and require only that the complaint contain "sufficient factual matter to show that the claim is facially plausible." Warren Gen. Hosp., 643 F.3d at 84 (quotation omitted). As noted above, to state a negligent misrepresentation claim upon which relief can be granted, a complaint must allege a material misrepresentation "made under circumstances in which the [defendant] ought to have known its falsity," that the defendant intended to induce plaintiff to act on the misrepresentation, and that the

[22] We also note that in each Complaint, the misrepresentation claims allege that the Plaintiff did not discover the misrepresentations until September 29, 2014. (See, e.g., Compl. ¶ 229.) However, all five Plaintiffs are alleged to have suffered considerable and painful complications due to the migration of Essure no later than January 30, 2014. (See, e.g., id. ¶ 89 (alleging that Plaintiff McLaughlin had her fallopian tubes removed on October 31, 2013, at which time only one Essure coil was located).) Thus, at least insofar as the misrepresentation claims are grounded on Bayer's alleged misrepresentations that Essure is "painless" and "worry-free," and "stays secure," it is difficult to comprehend how Plaintiffs would not have been alerted to the fact of the alleged misrepresentations well prior to September 29, 2014. While we do not rest our dismissal of the fraudulent misrepresentation claim on our inability to understand this aspect of Plaintiffs' pleading, this aspect of the pleading is nevertheless illustrative of the Complaint's lack of precision, which has made it difficult for us to comprehend some of Plaintiffs' claims.

plaintiff "act[ed] in justifiable reliance on the misrepresentation." Bilt-Rite Contractors, 866 A.2d at 277 (quotation omitted). Here, the Complaint alleges the substance of the alleged misrepresentations, which primarily appeared on Bayer's website and in Essure brochures (Compl. ¶¶ 103-115); that Bayer "intentionally made the statements so that Plaintiff[s] would be induced to have Essure implanted" (id. ¶ 220); and that Plaintiffs "justifiably relied" on those misrepresentations prior to implantation, and never would have had Essure implanted had they been aware that the representations were false (id. ¶¶ 230-31). We conclude that these allegations are sufficient to state a plausible negligent misrepresentation claim under the circumstances of this case. We therefore deny Bayer's Motion insofar as it seeks dismissal of Plaintiffs' negligent misrepresentation claim in Count IX for failure to set forth a plausible claim for relief under the governing standard in Rule 12(b)(6).[23]

G. Count VI – UTPCPL Claim

Count VI of the Complaint asserts that Bayer is liable under the UTPCPL for unfair and deceptive practices based on the same allegedly false and misleading warranties on which Plaintiffs base their breach of warranty and misrepresentation claims, as well as on Bayer's failure to disclose adverse events, and Bayer's marketing and selling of a misbranded and adulterated product. (Compl. ¶ 194.) Bayer argues, inter alia, that this claim should be dismissed pursuant to Pennsylvania's learned intermediary doctrine, because the doctrine prevents Plaintiffs from establishing the chain of causation and justifiable reliance required under the UTPCPL.

"The UTPCPL grants a private right of action to consumers harmed by deceptive business

[23] Although we do not dismiss the negligent misrepresentation claim based on either express preemption or failure to state a claim, we encourage Plaintiffs to consider amending Count IX if they file amended complaints to omit any allegations concerning misrepresentations that they have decided not to pursue, see supra n.15, as well as allegations concerning misrepresentations that they may decide they will only pursue as warranty claims, see supra n.21.

practices." Baynes v. George E. Mason Funeral Home, Inc., Civ. A. No. 09-153, 2011 WL 2181469, at *4 (W.D. Pa. June 2, 2011) (citing 73 Pa. Stat. Ann. § 201-9.2(a)). To state a plausible claim under the UTPCPL, a complaint must allege that: "(1) [plaintiff] purchased or leased goods or services primarily for a personal, family, or household purpose; (2) [plaintiff] suffered an ascertainable loss of money or property; and (3) the loss occurred as a result of the use or employment by a person of a method, act, or practice declared unlawful by the UTPCPL."[24] Id. (citing 73 Pa. Stat. Ann. § 201-9.2(a)). The complaint must also allege that the plaintiffs justifiably relied on the defendant's fraudulent or deceptive conduct. See Hunt v. U.S. Tobacco Co., 538 F.3d 217, 221-22 (3d Cir. 2008) (stating that plaintiffs pursuing claims under the UTPCPL must prove justifiable reliance).

Under Pennsylvania law, a medical device manufacturer has a duty to warn implanting physicians about the dangers of a medical device, but has no duty to warn patients directly. Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971), abrogated on other grounds by Kaczkowski v. Bolubasz, 421 A.2d 1027 (Pa. 1980); see also Pa. Suggested Standard Jury Instruction (Civ.) 23.10. This duty to warn only the prescribing physician renders the prescribing physician the "learned intermediary," and "'it is . . . the duty of the prescribing physician to communicate any risks or other information about [a prescription medical device] to the patient.'" In re Avandia Marketing, Sales Practices & Prods. Liab. Litig., No. 07-MD-1871, 2013 WL 3486907, at *2 (E.D. Pa. July 10, 2013) (emphasis added) (quoting Zafarana v. Pfizer, Inc., 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010)).

Because a medical device manufacturer "do[es] not have a duty to disclose information

[24] In this case, Plaintiffs allege that Bayer's unlawful conduct under the UTPCPL was "fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 Pa. Stat. Ann § 201–2(4)(xxi). (See N.T. 1/11/16 at 63.)

directly to [the] consumer[]" under Pennsylvania law, "a consumer does not have a cause of action under the UTPCPL against the manufacturer [of a medical device]." Kee v. Zimmer, Inc., 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012). This is because the UTPCPL "requires proof of justifiable reliance and causation, and such requirements cannot be present when the defendant is a [medical device manufacturer] that did not sell its product directly to the patient" or have a duty to warn the patient directly. Kee, 871 F. Supp. 2d at 411 (citing Kester v. Zimmer Holdings, Inc., Civ. A. No. 10–523, 2010 WL 2696467, at *14 (W.D. Pa. June 16, 2010)). As one court has further explained, the "learned intermediary [i.e., the doctor] breaks the chain in terms of reliance, since the patient cannot obtain [a] prescription [device] without the physician no matter what [the patient] believe[s] about [the device]." Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 384 (D.N.J. 2004) (applying Pennsylvania law). Thus, it is only the "prescribing physician who [can] provide[] the grounds for justifiable reliance" under the UTPCPL. Avandia, 2013 WL 3486907, at *2 (quoting Zafarana, 724 F. Supp. 2d at 557).

Plaintiffs make two arguments as to why we should not apply the learned intermediary doctrine to bar their UTPCPL claim. First, they argue that Lance v. Wyeth, 85 A.3d 434 (Pa. 2014), overruled the longstanding application of the learned intermediary doctrine to medical device cases. Plaintiffs rely on the Lance court's observation that "some of the underpinnings of the principle have come into question in light of changed practices in the prescription drug industry[, including] the emergence of direct-to-consumer advertising." Id. at 457. However, the Lance court also specifically stated that it did not "consider the wisdom of modifications or exceptions to the doctrine" because that case involved a situation in which no warning would be sufficient and, thus, the learned intermediary doctrine simply did not apply. Id. at 457-58 (citation omitted). Accordingly, we conclude that Lance in no way altered existing Pennsylvania

law as to the application of the learned intermediary doctrine in UTPCPL cases.

Second, Plaintiffs argue that we should not apply the learned intermediary doctrine here because they have alleged that Bayer withheld information from the physicians and, thus, they have functionally alleged the physicians were not actually "learned." (See, e.g., Compl. ¶ 125.) However, whether or not the physicians were appropriately "learned" does not affect our conclusion that Plaintiffs cannot prevail on their UTPCPL claim against Bayer because, as patients, they were required to rely on the advice and counsel of their doctors. Avandia, 2013 WL 3486907, at *2 (stating that it is the doctor's duty to communicate any risks to the patient (citing Zafarana, 724 F. Supp. 2d at 558)). Where, as here, Plaintiffs allege only that they relied on information that they received from Bayer directly (see id. ¶ 194), Pennsylvania law dictates that they have not stated a cognizable UTPCPL claim. Zafarana, 724 F. Supp. 2d at 558 ("[A] patient in Pennsylvania cannot justifiably rely on the prescription drug manufacturer."); see also Avandia, 2013 WL 3486907, at *2 (rejecting plaintiff's argument that a prescription drug manufacturer's alleged provision of deceptive information to plaintiff's prescribing physician subverted the learned intermediary doctrine because the physician was not "learned").

For the foregoing reasons, we dismiss the UTPCPL claim in Count VI for failure to state a claim upon which relief can be granted. Moreover, because the learned intermediary doctrine precludes a plaintiff from establishing the justifiable reliance element of a UTPCPL claim against a medical device manufacturer, we deny Plaintiffs leave to amend Count VI as we conclude that amendment would be futile.

H. Count X – Strict Liability

Count X of the Complaint alleges that Bayer is liable on a strict liability claim. Pennsylvania law recognizes the following types of strict liability claims: "design defect,

manufacturing defect and failure to warn." Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995) (citation omitted). Count X asserts both a strict liability-manufacturing defect claim and a strict liability-failure to warn claim, which essentially allege that Essure is a defective and unreasonably dangerous product due to manufacturing defects and inadequate warnings.[25] (See Compl. ¶ 242.) Bayer argues, inter alia, that Count X should be dismissed because it fails to state a claim upon which relief can be granted under well-settled Pennsylvania law, which does not recognize strict liability claims involving medical devices.

The Pennsylvania Supreme Court has adopted section 402A of the Restatement (Second) of Torts, which imposes strict liability for products sold "in 'a defective condition unreasonably dangerous to the user or consumer.'" Phillips, 665 A.2d at 1170 (quoting § 402A and citing Webb v. Zern, 220 A.2d 853, 854 (Pa. 1966)). However, Comment k limits liability for "Unavoidably Unsafe Products," such as prescription drugs, stating:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous.

Restatement (Second) of Torts, § 402A cmt. k. The Pennsylvania Supreme Court has adopted Comment k and has explicitly relied upon it to exclude prescription drugs from strict liability-failure to warn claims. Hahn v. Richter, 673 A.2d 888, 889-91 (Pa. 1996) (stating that "negligence[] is the only recognized basis of liability" for failure to warn claims involving prescription drugs (citing Mazure v. Merck & Co., Inc., 964 F.2d 1348, 1353 (3d Cir. 1992))). The Pennsylvania Superior Court subsequently held that "[w]ith our Supreme Court's adoption of

[25] Count X of the Complaint initially asserted a strict liability-design defect claim as well, but Plaintiffs asked to withdraw that aspect of their claim without prejudice, and we issued an Order dismissing that aspect of Count X without prejudice on January 14, 2016.

comment k, a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs." Lance v. Wyeth, 4 A.3d 160, 165 (Pa. Super. Ct. 2010), rev'd in part on other grounds, 85 A.3d 434 (Pa. 2014).

While Hahn and Lance both concerned prescription drugs, not medical devices, the Pennsylvania Superior Court and numerous judges in the Eastern District of Pennsylvania have predicted that the Pennsylvania Supreme Court would extend Comment k to exclude medical devices from strict liability as well. See, e.g., Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (stating that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices"); Wilson v. Synthes USA Prods., LLC, 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015); Runner v. C.R. Bard, 108 F. Supp. 3d 261, 265-66 (E.D. Pa. 2015); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 749-750 (E.D. Pa. 2007); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 441-42 (E.D. Pa. 2004); Murray v. Synthes (U.S.A.), Inc., Civ. A. No. 95-7796, 1999 WL 672937, at *6-8 (E.D. Pa. Aug. 23, 1999). We agree with the reasoning of these cases and conclude that Comment k's prohibition of strict liability-design defect and strict liability-failure to warn claims for prescription drugs should also apply to medical devices.

Plaintiffs argue that, even if Comment k applies to medical devices, it does not bar their strict liability-manufacturing defect claim, because Comment k only precludes claims against products that are properly prepared, and they have alleged that Essure was not properly prepared. Indeed, there is some authority that supports Plaintiffs' position. In Dougherty v. C.R. Bard, Inc., Civ. A. No. 11-6048, 2012 WL 2940727 (E.D. Pa. July 18, 2012), one district court noted that the Pennsylvania Supreme Court has not addressed Comment k's "properly prepared" requirement, and found, based largely on the requirement's language, that strict liability-manufacturing defect

claims against manufacturers of prescription drugs and devices were not barred. Id. at *4-6. More recently, however, in Lance v. Wyeth, 85 A.3d 434 (Pa. 2014), the Pennsylvania Supreme Court stated, without qualification, that "for policy reasons this Court has declined to extend strict liability to the prescription drug arena." Id. at 453. Courts in this district that have considered the viability of strict liability-manufacturing defect claims involving medical devices after Lance have found that they are not cognizable under Pennsylvania law. See Terrell v. Davol, Civ. A. No. 13-5074, 2014 WL 3746532, at *5 (E.D. Pa. July 30, 2014); Wilson, 116 F. Supp. 3d at 466-67 (citing Terrell, 2014 WL 3746532, at *5).

We conclude that Terrell and Wilson both accurately state the present law regarding the viability of strict liability-manufacturing defect claims in Pennsylvania. Accordingly, we further conclude that Plaintiffs' strict liability claims concerning Essure, a medical device, are not cognizable under Pennsylvania law and, thus, we dismiss Count X for failure to state a claim upon which relief can be granted. For this same reason, we deny Plaintiffs leave to amend Count X, because we conclude that any amendment would be futile.

I. Count XI – Negligent Manufacturing

Count XI of the Complaint alleges that Bayer is liable for negligently manufacturing Essure in a manner inconsistent with its PMA and federal law, and thereby producing an adulterated and misbranded product that caused Plaintiffs' injuries. Specifically, Count XI cites to eighteen federal regulations, three federal statutes, and five provisions of Essure's PMA (see Compl. ¶¶ 268(a)-(z)), as the applicable federal law, and alleges that Bayer violated these provisions in seven different ways (id. ¶ 269).[26] Specifically, Plaintiffs allege that Bayer engaged

[26] The Complaint alleges that Bayer violated the listed provisions in twenty different ways, but many of the alleged violations, on their face, have nothing to do with manufacturing. We questioned Plaintiffs as to this factual disconnect at oral argument on January 11, 2016, and

in negligent manufacturing insofar as it (1) used non-conforming materials in manufacturing Essure (id. ¶ 269(g) (citing Ex. C)); (2) failed to use pre-sterile and post-sterile cages in the manufacturing of Essure (id. ¶ 269(h) (citing Ex. D)); (3) manufactured Essure at an unlicensed facility (id. ¶ 269 (i) (citing Ex. D)); (4) manufactured Essure for three years without a license (id. ¶ 269(j) (citing Ex. D)); (5) failed to document the use of non-conforming materials (id. ¶ 269(q) (citing Ex. F)); (6) failed to analyze the potential causes of non-conforming product in the manufacturing process (id. ¶ 269(r) (citing Ex. G)); and (7) failed to "follow[] procedures used to control products which did not confirm [sic] to specifications" (id. ¶ 269(s) (citing Ex. G)). However, the Complaint does not specify which of the twenty-six regulations, statutory provisions and/or PMA provisions allegedly prohibited this particular conduct.

Bayer argues that Count XI should be dismissed as expressly preempted because it seeks to impose manufacturing requirements that are different from the federal requirements. It argues, in the alternative, that the claim should be dismissed for failing to state a plausible negligent manufacturing claim because, inter alia, the allegations do not support the reasonable inference that any device with a manufacturing defect reached the market, much less that a defective device was implanted in any Plaintiff and caused the Plaintiff's injuries.

1. Express Preemption

Pursuant to Riegel's express preemption analysis, we must consider whether Plaintiffs' negligent manufacture claim seeks to impose state requirements that are "different from, or in addition to" federal requirements applicable to Essure, in which case the claim is expressly preempted, or whether it seeks to enforce state requirements that parallel federal requirements and, thus, is not expressly preempted. Id. at 330 (quoting 21 U.S.C. § 360k(a)(1)). Plaintiffs argue

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Plaintiffs advised us that their negligent manufacturing claim is actually only based on the seven alleged violations that we now address. (N.T. 1/11/16 at 95-96.)

that their negligent manufacturing claim is not expressly preempted because it is a cognizable state law claim that is parallel to federal requirements.

As noted above, in order to state a claim for negligence under Pennsylvania law, a complaint must allege: (1) a duty owed to the plaintiff by the defendant; (2) a breach of that duty; (3) a causal connection between the breach and the resulting injury; and (4) actual loss or damages. Beretta U.S.A. Corp., 277 F.3d at 422 n.9 (citing Martin, 711 A.2d at 461). Plaintiffs assert that Bayer had a state law duty to manufacture Essure in a non-negligent fashion so as to avoid exposing others to reasonably foreseeable risks and that it breached that duty insofar as it violated various federal manufacturing standards.[27] Indeed, the Complaint identifies a whole host of specific federal requirements and alleges that the conduct that forms the basis of its negligence claim violated these requirements.

Given Plaintiffs' identification of several specific federal requirements on which their state law negligent manufacturing claim rests, we cannot conclude at this juncture that Plaintiffs' claim seeks to impose state requirements that are "different from, or in addition to" federal requirements and, thus, is expressly preempted. Id. at 330 (quoting 21 U.S.C. § 360k(a)(1)). At the same time, because Plaintiffs have not specified which federal requirements have been violated by each alleged incident of negligent conduct, we are unable to discern whether their state law negligent manufacture claim actually rests on violations of federal requirements and, thus, is a parallel claim. Accordingly, we deny Bayer's Motion insofar as it requests that we dismiss the negligent

[27] Bayer also argues that that Plaintiffs have failed to identify the applicable state law on which they are entitled to pursue a claim of negligent manufacturing. Plaintiffs, however, have pointed to Harsh v. Petroll, 840 A.2d 404 (Pa. Commw. Ct. 2003)). Id. at 415 (acknowledging claim of negligent manufacturing); see also Soufflas, 474 F. Supp. 2d at 752 (recognizing claim of negligent manufacture under Pennsylvania law). Indeed, we read Pennsylvania law to recognize a claim for negligent manufacturing, at least in cases such as this one, which do not give rise to cognizable claims of strict liability. See Harsh, 840 A.2d at 415 and n.8.

manufacturing claim as expressly preempted at this time, and we defer ruling on this question of express preemption until Plaintiffs have better defined their negligent manufacturing claim and we can determine whether it parallels federal requirements.

2. Plausibility

Bayer argues, in the alternative, that Count XI fails to plausibly allege a negligent manufacturing claim because the Complaint does not sufficiently allege causation. Pennsylvania law clearly requires that a negligence claim allege a causal connection between a defendant's allegedly negligent conduct and the plaintiff's resulting injury. Beretta U.S.A. Corp., 277 F.3d at 422 n.9 (citation omitted); Soufflas, 474 F. Supp. 2d at 752 (stating that, to establish negligent manufacture under Pennsylvania law, a plaintiff must show that the breach of the duty owed by the manufacturer to the plaintiff was the proximate cause of plaintiff's injuries (citing, e.g., Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003))). Moreover, federal courts have observed that a cognizable negligent manufacturing claim involving a medical device requires "allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury." Bass v. Stryker Corp., 669 F.3d 501, 511-12 (5th Cir. 2012) (citations omitted); see also Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301-02 (11th Cir. 2001) (stating that a negligent manufacturing claim is adequately pled if it "set[s] forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged" (quotation omitted)); Funk v. Stryker Corp., 631 F.3d 777, 782 (5th Cir. 2011) (requiring complaint to specify "a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury" (citations omitted)).

Here, the Complaint alleges that "Plaintiffs' injuries were caused by the manufacturing of Essure inconsistent with the [PMA] and Federal law, [and the] manufacturing [of] an 'adulterated'

and 'misbranded' product." (Compl. ¶ 267.) The Complaint does not allege, however, that a product that was negligently manufactured was implanted in any of the Plaintiffs and does not clearly allege that any alleged manufacturing defects actually caused any of the Plaintiffs' injuries. For instance, while the Complaint alleges that Bayer used non-sterile cages and that certain devices were made with "non-conforming materials" (id. ¶ 269(g), (h)), it does not allege that any device affected by these errors was implanted in any of the Plaintiffs, much less that any such manufacturing errors actually caused Plaintiffs' injuries. Likewise, the Complaint does not allege that Bayer's alleged failure to properly document certain manufacturing issues actually resulted in the products having manufacturing defects; that devices with defects that resulted from documentation errors were actually implanted in Plaintiffs; or that such defects caused the devices to migrate from Plaintiffs' fallopian tubes or otherwise caused any of Plaintiffs' alleged injuries. Finally, it is not even plausible that certain alleged manufacturing deficiencies -- i.e., the manufacture of a device in an unlicensed facility or without a valid manufacturing license -- could have been the cause of Plaintiffs' Essure injuries, as they are not violations that, in their own right, would cause a product abnormality. We therefore conclude that the Complaint fails to plausibly allege that any particular manufacturing defect actually caused Plaintiffs' injuries and thus fails to allege an essential element of the negligent manufacturing claim.

For the above stated reasons, we decline to hold at this stage of the proceedings that the negligent manufacturing claim is expressly preempted, but we nevertheless dismiss Count XI for failure to state a claim upon which relief can be granted because it does not plausibly allege an essential element of a cause of action for negligent manufacturing under Pennsylvania law.

J. Count XII – Negligent Failure to Warn

Count XII asserts that Bayer is liable on a claim for negligent failure to warn. Specifically, it alleges that Bayer had a state law duty to warn Plaintiffs and their implanting physicians, which was "consistent with Federal law and [the PMA]," and that Bayer breached that duty by, inter alia, failing to notify the FDA of adverse reactions to Essure, including perforations, as well as other complaints regarding the device, including complaints that the Essure device had migrated. (Compl. ¶ 278(a), (c)-(e), (k).) The Complaint alleges that Plaintiffs would not have had Essure implanted if Bayer had disclosed the withheld information and that, as a result of Bayer's negligence, Plaintiffs have sustained various permanent injuries and had to undergo numerous surgical procedures. (Id. ¶¶ 282-83.) Bayer argues that Count XII should be dismissed as expressly preempted because the gravamen of the claim is that Bayer should have issued different or additional warnings about Essure from those approved by the FDA. See Riegel, 552 U.S. at 329 (stating that § 360k(a) "[s]urely . . . would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings").

Plaintiffs, however, clarify in their responsive brief that their failure to warn claim is "based primarily" on Bayer's alleged "failure to advise the FDA of thousands of adverse events, which in turn were never reported to the public database or the implanting physician." (Pls.' Resp. Br. at 63.) They rely on a recent en banc decision of the United States Court of Appeals for the Ninth Circuit in Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013), which found no federal preemption of a failure to warn claim asserted pursuant to Arizona law, where the claim was premised on a medical device manufacturer's failure to report complaints about the device to the FDA. Id. at 1233. The Stengel court explained that Arizona law provided a cause of action

for negligent failure to warn and expressly permitted the duty to warn to be satisfied by a warning to a third party as long as there was "reasonable assurance that the information will reach those whose safety depends on their having it." Id. Thus, it concluded that the plaintiff's failure to warn claim was a parallel and independent state law claim that was consistent with federal law and not subject to express preemption.

Plaintiffs also rely on the decision of the United States Court of Appeals for the Fifth Circuit in Hughes v. Boston Scientific Corp., 631 F.3d 762, 768 (5th Cir. 2011), which determined that a failure to warn claim was not preempted where the plaintiff claimed that a manufacturer "failed to provide adequate warnings or sufficiently communicate information about the risks associated with [a medical device] to the extent that the claim is predicated on [the manufacturer's] failure to report 'serious injuries' and 'malfunctions' of the device as required by the applicable FDA regulations." Id. at 769. The Hughes court "assum[ed] that a [negligent] failure to warn claim may be pursued under [the applicable] Mississippi law as [the plaintiff] argue[d]," and stated that it was "clear that such a claim is preempted only to the extent that it purports to impose liability despite [the manufacturer's] compliance with FDA regulations." Id. (citing Riegel, 552 U.S. at 325; Gomez v. St. Jude Medical Daig Div., Inc., 442 F.3d 919, 933 (5th Cir. 2006)). The Fifth Circuit concluded that "[t]o the extent that [plaintiff] asserts a failure to warn claim based only on [the manufacturer's] failure to comply with FDA regulations, . . . such a claim is not expressly preempted." Id.; see also Beavers-Gabriel v. Medtronic, Inc., Civ. A. No. 13–686, 2015 WL 143944, at *11-12 (D. Haw. Jan. 9, 2015) (finding no preemption of failure to warn claim grounded on failure to report adverse events to FDA).

Bayer maintains that Stengel was incorrectly decided and, in any event, is not binding here. Bayer suggests that we instead look to In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab.

Litig., 623 F.3d 1200 (8th Cir. 2010). In Sprint Fidelis, the United States Court of Appeals for the Eighth Circuit rejected a failure to warn claim grounded on allegations that the defendant failed to provide the FDA with sufficient information and did not timely file adverse reports, as required by federal regulations, concluding that that "these claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in Buckman." 623 F.3d at 1205-06 (citing Buckman, 531 U.S. at 349, and Hughes v. Boston Scientific Corp., 669 F. Supp. 2d 701, 710-12 (S.D. Miss. 2009)). Bayer also argues that this claim should be dismissed because Plaintiffs have failed to identify Pennsylvania law that imposed a duty to extend warnings to third parties like the Arizona law applied in Stengel (or the Mississippi law "assum[ed]" in Hughes), and which permits such duty to be satisfied by reporting adverse events to the FDA.

Plaintiffs have, however, identified Pennsylvania law that imposes such a duty. Plaintiffs rely on Phillips v. A.P. Refractories Co., 630 A.2d 874 (Pa. Super. Ct. 1993), which adopted Section 388 of the Restatement (Second) of Torts, including Comment n to that Section, which is entitled "Warnings given to third person." Id. at 882, aff'd sub nom. Phillips v. A-Best Products Co., 665 A.2d 1167 (Pa. 1995). Like the Arizona law on which Stengel relied, Comment n provides that

> a supplier's duty to warn is discharged by providing information about the product's dangerous propensities to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product or those who may be exposed to its hazardous effects.

Id. at 882 (citing Restatement (2d) of Torts § 388 cmt. n). Thus, while Bayer is correct that Plaintiffs have not pointed to a case that explicitly imposes a duty to file adverse reports with the FDA, Plaintiffs have cited to Pennsylvania law that is essentially indistinguishable from the Arizona law that the Ninth Circuit found sufficient to create a parallel and independent state claim in Stengel. Accordingly, we follow the reasoning of the en banc decision in Stengel and conclude

that Plaintiffs' failure to warn claim, as stated, is not expressly preempted, at least insofar as it is premised upon Bayer's alleged failure to report adverse events to the FDA. We therefore deny Bayer's Motion insofar as it seeks dismissal of Plaintiffs' negligent failure to warn claim in Count XII.

K. Count III – Pharmacovigilance

Count III of the Complaint asserts that Bayer is liable on a claim entitled "Pharmacovigilance," which sounds in negligence. The Complaint alleges that Bayer "had a duty to distribute, promote, and report adverse events regarding Essure in a reasonably safe manner," and that these duties are reflected in federal regulations and conditions in the PMA. (Compl. ¶ 149.) The Complaint alleges that Bayer violated these duties by violating manufacturing standards; failing to report adverse events to the FDA; issuing false and misleading warranties; engaging in false and misleading advertising; engaging in an unreasonably dangerous distribution plan that required physicians to purchase two Essure kits a month, even if the physicians did not use the kits and even if the physicians were not qualified to implant the device; and promoting Essure through hysteroscopic equipment companies that were not qualified to promote the device. (Id. ¶¶ 150, 153-154; see also id. ¶¶ 100-01.) According to the Complaint, these individual acts combined to create an "unreasonably dangerous and negligent distribution, advertising, promotion and reporting plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff[s]." (Id. ¶ 151.) It further alleges that Bayer's breach of these combined duties caused Plaintiffs' damages insofar as the Essure devices migrated and caused Plaintiffs' related physical injuries. (Id. ¶ 155.)

Bayer argues that the "Pharmacovigilance" claim should be dismissed because it is expressly preempted, impliedly preempted and otherwise fails to state a claim upon which relief

may be granted. Plaintiffs maintain that their claim is not expressly or impliedly preempted because it is based on Pennsylvania law, which imposes "a duty, in any situation, not to place others at risk as it pertains to those risks that are reasonably foreseeable," as well as "a duty of reasonable care with respect to marketing, promotion and distribution," and which parallels federal regulations. (Pls.' Resp. Br. at 81 (citing Burman v. Golay & Co. Inc., 616 A.2d 657 (Pa. Super. Ct. 1992); Lance, 85 A.3d 434; and Widdoss v. Huffman, No. 7340 Civ. 2002, 2003 WL 22512092 (C.C.P. Monroe Cty. June 10, 2003)).) They also maintain that their claims are exhaustively and adequately pled and, thus, state a claim upon which relief can be granted.

While Plaintiffs insist that Pennsylvania law recognizes a claim for "pharmacovigilance," they have cited (and we have found) no Pennsylvania authority that suggests the existence of such a claim. Moreover, it is apparent that Plaintiffs' claim, as alleged, overlaps considerably with other claims, all of which we have addressed at length above. Specifically, insofar as the claim rests on negligent advertising, it is grounded on the same representations that provide the bases for the breach of express warranty claim (Count V), the fraudulent misrepresentation claim (Count VIII), the negligent misrepresentation claim (Count IX), and the UTPCPL claim (Count VI). Meanwhile, insofar as the claim asserts negligent distribution of devices with manufacturing defects, it rests on the same essential allegations as the negligent manufacturing claim (Count XI). Likewise, insofar as it rests on a negligent failure to report adverse events, it is essentially indistinguishable from the negligent failure to warn claim (Count XII).

Accordingly, the only distinctive allegations in this claim are that Bayer negligently distributed and/or promoted Essure insofar as it "compelled implanting physicians to sell two (2) [Essure] devices per month at the expense of Plaintiff's safety and well-being," and "promot[ed] Essure through representatives of hysteroscopic equipment companies who were not qualified to

do the same." (Compl. ¶¶ 153-54.) These latter aspects of the claim are not cognizable in their own right as they plainly concern the safety of Essure and Plaintiffs have identified no federal regulations or requirements addressing these matters, on which they could ground a parallel state law negligence claim. See Riegel, 552 U.S. at 330 (requiring express preemption of claims grounded on state safety requirements that are different from or in addition to federal safety requirements.)

In sum, aside from the above-referenced non-cognizable assertions of negligent distribution and/or promotion, the "pharmacovigilance" claim is nothing more than an amalgamation of the other claims in the Complaint, which Plaintiffs piece together in order to allege an elaborate, coordinated scheme "aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff[s]." (Compl. ¶ 151.) We are aware of no Pennsylvania legal authority that recognizes such an over-arching cause of action for so-called "pharmacovigilance." We therefore dismiss the pharmacovigilance claim in Count III for failure to state a claim that is recognized by Pennsylvania law, and we deny Plaintiffs leave to amend this claim as we conclude that amendment to assert a cause of action that does not exist in Pennsylvania would be futile.

IV. CONCLUSION

For the foregoing reasons, we grant Bayer's Motion for Judgment on the Pleadings, insofar as is seeks dismissal of Count II (negligent entrustment), and Count X (strict liability) on express preemption grounds; Count VII (fraudulent concealment) on implied preemption grounds; and insofar as it seeks dismissal of Count I (negligent training), Count III (pharmacovigilance), Count IV (negligent risk management), Count V (breach of express warranty), Count VI (UTPCPL), Count VIII (fraudulent misrepresentation), and Count XI (negligent manufacture) for failure to

state a plausible claim pursuant to the pleading standards of Rule 12(b)(6) or the heightened pleading standards of Rule 9(b). We deny the Motion insofar as it seeks dismissal of Count IX (negligent misrepresentation) and Count XII (negligent failure to warn).

For the reasons set forth above, we conclude that Plaintiffs' negligent entrustment (Count II), Pharmacovigilance (Count III), UTPCPL (Count VI), fraudulent concealment (Count VII), and strict liability (Count X) claims are futile and, thus, we do not afford Plaintiffs leave to amend those Counts. We cannot, however, state with certainty that Plaintiffs' other dismissed Counts – Count I (negligent training), Count IV (negligent risk management), Count V (breach of express warranty), Count VIII (fraudulent misrepresentation), and Count XI (negligent manufacture) – are necessarily futile, and we thus grant Plaintiffs leave to amend these Counts.

We nevertheless caution Plaintiffs to consider carefully the legal and pleading principles that we have set forth at length in this opinion and urge them to set forth with greater clarity the facts on which each individual Plaintiff's claims are based, as well as the precise federal requirements that are allegedly violated by each individual instance of alleged misconduct (i.e., the federal requirements that Plaintiffs contend give rise to a parallel claim under state law). We also urge Plaintiffs to make clear in any amended complaints if they are pleading claims in the alternative.

An appropriate Order follows.

BY THE COURT:

/s/John R. Padova
John R. Padova, J.