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. **February 21, 2017**

Each Plaintiff in these five consolidated actions seeks compensation for injuries she sustained in connection with her use of Essure, a female birth control device. In a prior opinion in this case, McLaughlin v. Bayer, 172 F. Supp. 3d 804 (E.D. Pa. 2016), we considered a Motion for Judgment on the Pleadings with respect to Plaintiffs' First Amended Complaints and exhaustively analyzed Plaintiffs' claims, dismissing some claims with prejudice, dismissing others with leave to

amend, and denying the Motion as to the two remaining claims. Plaintiffs subsequently filed Second Amended Complaints, which assert seven claims for relief against Defendants Bayer Corp., Bayer Healthcare LLC, Bayer Essure, Inc., and Bayer Healthcare Pharmaceuticals (collectively, "Bayer"). Bayer has filed an identical Motion to Dismiss in each of the five cases, seeking dismissal of five of the seven Counts asserted in the Second Amended Complaints pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, we grant the Motion in part and deny it in part.

I. BACKGROUND[1]

The Second Amended Complaint in the McLaughlin case ("the SAC") alleges that Bayer manufactures, sells, distributes, markets and promotes Essure.[2] (SAC ¶ 46.) It describes Essure as metal coils, which are placed in a woman's fallopian tubes and are intended to block the tubes and prevent pregnancy. (Id. ¶¶ 34, 38.) The coils are inserted by a doctor using hysteroscopic equipment. (Id. ¶¶ 34-35.) The SAC alleges that, instead of working as intended, "the device migrates from the tubes, perforates organs, breaks into pieces, and/or corrodes." (Id. ¶ 16.) Each Plaintiff had Essure implanted and subsequently suffered serious consequences when the device migrated from her fallopian tubes to her uterus, rectum or colon. (See, e.g., SAC ¶¶ 100-104.)

Because Essure is classified as a Class III medical device, the Food and Drug

[1] As we write primarily for the parties, we do not repeat the extensive and familiar background information included in our prior Opinion. See McLaughlin, 172 F. Supp. 3d at 809-811.

[2] The Second Amended Complaints in the five cases are largely the same, although the McLaughlin SAC contains the most extensive lists of alleged fraudulent and/or negligent misrepresentations and breached warranties. For simplicity's sake, we will cite exclusively to the McLaughlin SAC, but our analysis of any specific alleged misrepresentation or warranty is pertinent only to the cases in which that specific misrepresentation or warranty is alleged.

Administration (the "FDA") evaluated Essure's safety and effectiveness prior to granting the product Conditional Premarket Approval ("PMA"), which authorized its commercial distribution. (Id. ¶¶ 18, 49; 11/4/02 PMA letter ("PMA Ltr.") at 1.[3]) Such approval was contingent upon the FDA's finding that there was "a 'reasonable assurance' of the device's 'safety and effectiveness.'" Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008) (quoting 21 U.S.C. § 360e(d)). At the same time, the PMA imposed certain conditions on Bayer's distribution of the product, including certain labeling requirements and restrictions on false and/or misleading advertising. (PMA Ltr. at 1.)

The SAC asserts seven causes of action, which seek to hold Bayer liable for the injuries Plaintiffs suffered as a result of their use of Essure. Count I asserts a claim of negligent training, alleging that Bayer undertook responsibility for training physicians how to implant Essure and then did so negligently. Count II asserts a claim for negligent risk management, alleging that Bayer failed to adequately track and review complaints about Essure's performance. Count III asserts a claim for breach of express warranty, grounded on various representations and promises about Essure made in promotional materials and on Essure's website. Counts IV and V assert claims of fraudulent misrepresentation and negligent misrepresentation, alleging that the same statements that constituted warranties about Essure, also constituted actionable misrepresentations. Count VI alleges that Bayer negligently manufactured Essure. Count VII asserts that Bayer negligently failed to warn Plaintiffs and the implanting physicians of the risks of the device and manufacturing defects. Bayer has moved to dismiss Counts I, II, III, IV, and VI, arguing both that certain claims are expressly preempted and that the SAC does not adequately

[3] We may consider the PMA letter in connection with the Motion to Dismiss, because it is referenced in the SAC and is a matter of public record. See 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)).

allege essential elements of the claims asserted.[4]

II. LEGAL STANDARDS

A. Motion to Dismiss Pursuant to Rule 12(b)(6)

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

[4] Bayer also argues that we should dismiss Count V, the negligent misrepresentation claim, as expressly preempted. At the same time, Bayer acknowledges that, in our prior opinion, we rejected its argument that the entire claim was expressly preempted and denied its request to dismiss the claim. See McLaughlin, 172 F. Supp. 3d at 826-830. Pursuant to Local Rule 7.1(g), a party may move for "reconsideration . . . within fourteen (14) days after the entry of the order concerned." E.D. Pa. L.R. Civ. P. 7.1(g). In order to prevail on such a request, the moving party must establish (1) "an intervening change in the controlling law;" (2) "the availability of new evidence that was not [previously] available;" or (3) "the need to correct a clear error of law or fact or to prevent manifest injustice." Max's Seafood Café v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999) (citation omitted). Here, Bayer's Motion to Dismiss as to the negligent misrepresentation claim constitutes a request for reconsideration that is not only untimely under Local Rule 7.1(g), but also fails to identify an approved basis for reconsideration. We therefore decline to reconsider our prior decision.

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) (alteration in original) (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. Express Preemption

The Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* (the "MDA"), expressly preempt 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 Riegel v. Medtronic, Inc, the Supreme Court set forth a two-step analysis for determining whether a claim is expressly preempted pursuant to the statute. 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. at 321. The Supreme Court concluded that any Class III device that receives premarket approval, which is specific to individual devices, satisfies this first prong of the § 360k(a) test. Id. at 322 ("Premarket approval . . . 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, 552 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. Id. at 330 (quoting and citing 21 U.S.C. § 360k(a)(1)). 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 Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996), and citing Lohr, 518 U.S. at 513).

III. DISCUSSION

As noted above, Bayer asks that we dismiss Count I (Negligent Training), Count II (Negligent Risk Management), Count III (Breach of Express Warranty), Count IV (Fraudulent

Misrepresentation), and Count VI (Negligent Manufacturing).

A. Count I – Negligent Training

In Count I, the SAC asserts a claim for negligent training, essentially alleging that Bayer undertook a duty to train Plaintiffs' physicians, breached that duty by failing to abide by FDA training guidelines and requirements, and thereby caused Plaintiffs' injuries. (See SAC ¶¶ 118, 120, 123-24.) We previously dismissed with leave to amend the negligent training claim that Plaintiffs asserted in their prior Complaints. See McLaughlin, 172 F. Supp. 3d at 816-818, 839-840. We explained that the claim was not expressly preempted under Riegel insofar as it alleged that Bayer failed to abide by FDA-approved training guidelines, but also observed that the claim, as pled in the prior Complaints, failed to state a claim upon which relief could be granted pursuant to Rule 12(b)(6) because it failed to specify how Bayer's training departed from such guidelines and also failed to articulate how any training failures caused any of the Plaintiffs' injuries. Id. at 816-818.

The SAC now alleges six ways in which Bayer allegedly failed to abide by FDA-approved training requirements:

1. Failing to ensure that doctors successfully completed five preceptorings during training.
2. Failing to ensure that doctors read and understood the training manual.
3. Failing to ensure that doctors monitored patients through recovery.
4. Failing to ensure that doctors were knowledgeable hysterosocopists prior to the time they enrolled in the training program.
5. Failing to ensure that doctors successfully completed Essure simulator training.
6. Failing to ensure that doctors were certified under the preceding requirements.

(SAC ¶¶ 122-123.) The SAC further alleges that these "departure[s] from the training guidelines caused the Essure coils to migrate from the fallopian tube and caused . . . specific injuries" because the coils were improperly placed in Plaintiffs' fallopian tubes due to the training failures. (Id. ¶ 124.) Bayer argues that Count I should be dismissed because certain aspects of this claim are

expressly preempted and the claim is otherwise subject to dismissal due to inadequate allegations of causation.

1. Express Preemption

Bayer argues that the negligent training claim is expressly preempted under Riegel insofar as it rests on allegations that Bayer failed to ensure that doctors (1) monitored their patients through recovery, (2) were knowledgeable hysteroscopists, and (3) were certified. As we discussed above, whether these aspects of the negligent training claim are, in fact, expressly preempted depends upon whether the alleged failings are violations of federal requirements or whether the claim seeks to impose requirements that are "'different from, or in addition to'" federal requirements. See Riegel, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)).

Plaintiffs maintain that all three of these alleged failings constitute violations of FDA-approved training requirements, which they assert are embodied in the Essure Physician Training Manual and Essure's Instructions for Use, and are conveyed to physicians, in part, during a didactic training course. Plaintiffs contend that the requirement that Bayer ensure that physicians be knowledgeable hysteroscopists is contained in Essure's Instructions for Use, which expressly state that Essure "should only be used by physicians who are knowledgeable hysteroscopists." (Request for Judicial Notice ("RJN") Ex. D at Bayer 0096.)[5] However, this

[5] Bayer's Request for Judicial Notice asks that we consider several documents, including Essure's Instructions for Use, the Physician Training Manual and the Essure Patient Information Booklet. Plaintiffs do not oppose our consideration of these documents or question their authenticity. We are permitted to take judicial notice of facts that are "not subject to reasonable dispute" because they "can be accurately and readily determined from sources who accuracy cannot be reasonably be questioned." Fed. R. Evid. 201(b). Moreover, on a Motion to Dismiss we may consider "matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." Mayer, 605 F.3d at 230 (citation omitted). Applying these standards, we conclude that we may consider the Instructions for Use, Physician Training Manual, and Essure Patient Information Booklet, because they are publicly available on the FDA website, they are indisputably authentic, and Plaintiffs' claims are based at

particular warning cannot reasonably be construed as requiring that Bayer ensure that doctors are knowledgeable hysteroscopists prior to their engaging in Essure training. Plaintiffs have not identified any other federal directive that arguably requires Bayer to ascertain a doctor's qualifications prior to permitting the doctor to participate in Essure training. Accordingly, the SAC fails to allege facts sufficient to support the assertion that Bayer's failure to confirm that doctors are knowledgeable hysteroscopists prior to training violated a federal requirement. Instead, this claim plainly seeks to impose a different or additional requirement. We therefore conclude that the negligent training claim is expressly preempted insofar as it is grounded on a failure to ensure that doctors are knowledgeable hysteroscopists prior to training.

Plaintiffs also contend that the requirement that Bayer ensure that physicians monitor their patients after implantation is contained in the Physician Training Manual, which directs that physicians conduct a follow-up with their patients three months after implantation of Essure. (See, e.g., RJN Ex. E § 8.) While the inclusion of this directive in the training manual may suggest that Bayer must train physicians to monitor their patients' conditions following implantation, it cannot reasonably be construed as requiring Bayer to police physician conduct after completion of training to ensure that the physicians are, in fact, monitoring their patients. Plaintiffs have not identified any other federal requirement that directs Bayer to monitor physician conduct post-training. Accordingly, we conclude that the SAC fails to support the assertion that Bayer's failure to monitor doctor conduct after the completion of training violated a federal

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least in part on these documents. See Starks v. Coloplast Corp., Civ. A. No. 13-3872, 2014 WL 617130, at *1 n.3 (E.D. Pa. Feb. 18, 2014) ("On a motion to dismiss, courts take judicial notice of documents that are matters of public record such as . . . FDA reports published on the FDA website." (citations omitted)); see also De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1096 n.5 (N.D. Cal. 2016) ("Judicial notice of the training materials approved by the FDA is appropriate inasmuch as they are matters of public record and appear on the FDA's website.")

requirement. We therefore conclude that Count I is expressly preempted insofar as it is grounded on an alleged failure to ensure that doctors monitor their patients after their completion of training.

Plaintiffs further assert that there is a federal requirement that Bayer "certify" that doctors have successfully completed simulator training and five preceptorings, have read and understood the training manual, are knowledgeable hysteroscopists, and have monitored their patients through recovery. They argue that Bayer, through its representatives, has admitted that this is a federal requirement. (See Pls.' Resp. to Mot. to Dismiss ("Pls.' Resp. Br.") Ex. A at 100; id. Ex. B at 16; id. Ex. C at 21.) However, Bayer's representatives simply stated that the company's didactic training includes signing off on a physician's capability. (See Pls.' Resp. Br. Ex. A at 100; id. Ex. B at 16; id. Ex. C at 21.) Plaintiffs have pointed to no federal requirement that specifically requires a formal certification process, much less certification that the trained physicians have met all of the requirements that Plaintiffs contend they must meet. Moreover, Plaintiffs have pointed to no authority for the proposition that we can find a federal certification requirement arising from statements made by Bayer representatives, when Plaintiffs are unable to identify a federally-approved document that sets forth such a certification requirement as a necessary component of Essure training. Accordingly, we conclude that the SAC fails to allege facts sufficient to support the assertion that Bayer's failure to certify doctors violated a federal requirement. We therefore conclude that Count I is expressly preempted insofar as it is grounded on Bayer's alleged failure to ensure that doctors are "certified."

2. Causation

Bayer argues that we should dismiss the remaining aspects of Plaintiffs' negligent training claim because the SAC does not adequately allege that Plaintiffs' injuries were caused by Bayer's alleged failure to ensure that physicians had completed five preceptorings, had read and

understood the training manual, and had successfully completed simulator training. See City of Philadelphia v. Beretta U.S.A. Corp., 277 F.3d 415, 422 n.9 (3d Cir. 2002) (noting that one element of a negligence claim is a causal connection between the breach of defendant's duty and plaintiff's resulting injury (citation omitted)). Specifically, Bayer contends that Plaintiffs' allegations of causation are boilerplate and do not suffice to plausibly link any alleged training failure to each Plaintiff's injuries.

The SAC alleges that Bayer undertook responsibility for physician training insofar as it created a simulator called Essure and organized training courses at which Bayer trainers observed physicians until they believed the physicians were competent. (SAC ¶ 119.) The Physician Training Manual provides that the training requirements include "[s]uccessful completion of a Physician's Didactic Training Course" and "Essure Simulator Training," as well as "[c]ompletion of the initial procedures under the observation of a [Bayer] designated preceptor until competency in performing Essure is established (typically expected to be achieved in 5 cases)." (RFJ Ex. E at 2.) It further provides that "[u]pon successful completion of the initial training program, [a] Physician Training Record will be completed by a [Bayer] representative" . . . and "the physician's name will be added to the list of those trained to perform the procedure." (Id.) The SAC alleges that Plaintiffs' implanting physicians did not complete the required preceptoring until competency, successfully complete the Essure Simulator Training, or understand the Physician Training Manual, and that Bayer negligently failed to ensure that these training requirements had been met. (Id. ¶ 123 (j)-(k), (n).) The SAC essentially alleges that, because Bayer departed from the required training by failing to ensure that physicians had successfully completed the required training, the physicians did not properly place the Essure device in Plaintiffs, and the device migrated from the fallopian tubes. (SAC ¶ 124.)

We conclude that these allegations plausibly allege causation. While the SAC does not contain specific allegations regarding the particular physicians who performed the Plaintiffs' procedures, including precisely how the implantations were negatively affected by the physicians' inadequate training, these are facts that can be developed in discovery. Accordingly, we deny Bayer's Motion to the extent that it seeks dismissal of Plaintiffs' claim that Bayer negligently trained doctors by negligently failing to ensure both that doctors successfully completed Essure simulator training and five preceptorings, and that they read and understood the training manual.

In sum, we conclude that the negligent training claim is expressly preempted insofar as it is grounded on Bayer's alleged failure to (1) confirm that doctors are knowledgeable hysteroscopists prior to training, (2) monitor doctors following their completion of training, or (3) ensure that doctors are "certified," and we grant the Motion to Dismiss as to Count I insofar as it relies on these alleged failures. However, we deny the Motion as to Count I insofar as it concerns Bayer's alleged failure to (1) ensure that doctors successfully completed five preceptorings during training, (2) ensure that doctors read and understood the training manual, and (3) ensure that doctors successfully completed Essure simulator training.

B. Count II – Negligent Risk Management

Count II of the SAC asserts a claim for negligent risk management. It alleges that Bayer is liable for breaching a "duty . . . to have in place a reasonable risk management procedure." (SAC ¶ 132.) In our earlier Opinion in this case, we dismissed Plaintiffs' prior version of this claim with leave to amend. McLaughlin, 172 F. Supp. 3d at 820-21, 840. We explained that a negligent risk management claim would not be expressly preempted under Riegel insofar as it alleged that Bayer violated federal risk management standards set forth in the Code of Federal Regulations, PMA and statutes. Id. at 820. We concluded, however, that we could not

determine whether Plaintiffs' claims were expressly preempted because the Complaint failed to identify with any precision what federal risk management standards had been violated. Id. at 820-21. We further concluded that the Complaint failed to state a negligent risk management claim upon which relief could be granted because it failed to allege any plausible and non-speculative causal connection between the alleged risk management inadequacies and each Plaintiff's injury. Id. at 821.

The SAC alleges that Bayer's breached its duties to have in place risk management plans that effectively provided for (1) identification and consideration of all adverse reports about Essure, including internal procedures to review complaints and event reports, (2) monitoring of Essure to identify additional complaints or adverse health consequences, (3) additional investigation of Essure's risks, and (4) comprehensive risk analysis. (SAC ¶ 132.) The SAC alleges that the duties to have such plans are embodied in federal requirements in the Code of Federal Regulations, federal statutes and the PMA, including requirements that a manufacturer "'establish and maintain adverse event files'" (id. ¶ 133(c) (quoting 21 C.F.R. § 803.1(a)); "'establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit,'" "'review and evaluate all complaints to determine whether an investigation is necessary,'" and investigate certain specified complaints (id. ¶ 133(o) (quoting 21 C.F.R. § 820.198(a)-(c)); "'conduct analysis, testing, or other evaluation'" to determine whether Essure "'may have . . . contributed to a death or serious injury,'" (id. ¶ 133(e) (quoting 21 C.F.R. § 803.50(a), (b)(1)(iii)); and "'conduct[] an investigation of each event [in which Essure may have contributed to death or serious injury] and evaluat[e] the cause of the event'" (id. (quoting 21 C.F.R. § 803.50(b)(3)).[6] The SAC alleges that the breaches of these duties caused Plaintiffs'

[6] The SAC also alleged that Bayer engaged in negligent risk management insofar as it

injuries because Bayer's negligent risk management resulted in its failure to report "thousands of adverse events and complaints for migrations, perforations, pregnancies, device failures and malfunctions" to the FDA, which, in turn, meant that the adverse events and complaints were never disclosed to Plaintiffs, who never would have had Essure implanted had they known of the full magnitude of adverse events and complaints. (See id. ¶ 136.) The SAC further alleges that the breaches caused Plaintiffs' injuries because Bayer should have withdrawn the product from the market once it properly identified and investigated all of the relevant adverse events and complaints. (Id.)

Bayer argues that the revised version of this claim should be dismissed for failure to state a claim upon which relief can be granted because certain aspects of the claim are expressly preempted and, in all other respects, the claim is indistinguishable from the failure to warn claim.

1. Express Preemption

Bayer argues that the negligent risk management claim is expressly preempted insofar as it rests on a theory of causation that Bayer "should have withdrawn Essure from the market prior to Plaintiff's implantation." (SAC ¶ 136.) It reasons that there was and is no federal requirement that Essure be withdrawn from the market and, thus, a claim that requires proof that Bayer had an obligation to withdraw the product from the market seeks to impose a duty that does not parallel federal requirements. See Riegel, 552 U.S. at 330. Bayer also specifically points out that the FDA publicly reaffirmed, in a February 2016 press release, that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," making clear that the

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failed to track non-conforming product and unilaterally update its labeling of Essure. (See SAC ¶¶ 132(7), 135.) However, on July 20, 2016, Plaintiffs withdrew those paragraphs of the SAC that alleged that these particular actions violated federal requirements. (Pls.' Notice of Withdrawal, ECF No. 93 (withdrawing SAC ¶¶ 133 (k)-(m) and (t)). Accordingly, we understand Plaintiffs to have abandoned any claim that Bayer engaged in negligent risk management insofar as it allegedly failed to track non-conforming product or failed to update labeling.

previously undisclosed adverse events and complaints about which Plaintiffs complain, which have since been reported to the FDA, did not result in an FDA finding that withdrawal was federally required. (RJN Ex. A at 1.[7])

Plaintiffs, however, respond that their assertion in Paragraph 136 of the SAC that Bayer "should have withdrawn Essure" "is an allegation, not a cause of action" and, thus, is not subject to preemption.[8] (Pls.' Resp. Br. at 17; Pls.' Sur-reply Br. at 10.) However, Plaintiffs' assertion makes no sense. To prevail on their negligent risk management claim, Plaintiff must allege and ultimately prove "a causal connection between the breach and the resulting injury." Beretta U.S.A. Corp., 277 F.3d at 422 n.9 (citation omitted). Here, Plaintiffs' theory of causation grounded on Bayer's required withdrawal of Essure from the market is dependent upon proof of a safety requirement that is "'different from, or in addition to'" the requirements imposed by federal law. Riegel, 552 U.S. at 323, 330 (quoting and citing 21 U.S.C. § 360k(a)). Thus, we conclude that the claim relying on that theory of causation is expressly preempted. Id. Indeed, we can perceive of no basis to distinguish between a negligence cause of action that alleges a breach of a duty that does not parallel a federal requirement and a negligence cause of action that relies on a theory of causation that is dependent upon proof that the defendant should have taken a subsequent

[7] We may consider the February 2016 news release because it is public document. Mayer, 605 F.3d at 230 (permitting consideration of matters of public record (citation omitted)); (see also SAC ¶ 76 (quoting news release at length)).

[8] Plaintiffs also suggest that, in spite of the phrasing in their Complaint that Bayer "should have withdrawn Essure," they are not asserting that Bayer was required to withdraw the product from the market but only that it would have voluntarily done so if it "had proper risk management procedures in place and were analyzing, investigating, and reporting the[] adverse events [of migrations and perforations]." (Pls.' Resp. Br. at 17.) However, the SAC itself does not allege that Bayer would have voluntarily withdrawn Essure from the market if it had conducted its risk management differently, much less any facts to support such a theory. Accordingly, we conclude that there is no such theory asserted in the SAC and do not consider such a theory to be part of Plaintiff's risk management claim.

safety action that is not required by federal law. Accordingly, we dismiss as expressly preempted that aspect of Plaintiffs' negligent risk management claim that rests on a theory that Bayer's negligent risk management caused Plaintiffs' injuries because Bayer did not withdraw Essure from the market when it should have done so.

2. Redundancy

Bayer argues that the remainder of Plaintiffs' negligent risk management claim should be dismissed pursuant to Rule 12(b)(6) because it is completely redundant of the failure to warn claim. Specifically, it argues that, to the extent that the claim asserts that, had Bayer reported adverse events to the FDA, Plaintiffs and their physicians would have learned of those events and Plaintiffs would have chosen not to have the device implanted, the claim is wholly redundant of the failure to warn claim and should be dismissed on that basis.[9] (Bayer Br. in Supp. of Mot. to Dismiss at 12-13 (citing Giannone v. Ayne Inst., 290 F. Supp. 2d 553, 566 (E.D. Pa. 2003) (dismissing duplicative negligence claims).) Bayer emphasizes that Plaintiffs "fail to allege any way in which their injuries could have been averted through better risk management protocols, other than by Bayer reporting additional adverse events." (Bayer Reply Br. at 9.) Accordingly, it maintains that Plaintiffs' risk management claim "collapses into their failure to warn claim." (Id.) Plaintiffs contend that, although the element of causation is "similar" in their negligent risk management and failure to warn claims, the two claims are distinct because they rest on breaches of different duties – the duty to engage in risk management versus the duty to warn. (Pls.' Resp. Br. at 16.)

[9] Bayer also argues, without any meaningful elaboration, that the SAC fails to allege a plausible and non-speculative causal connection between the alleged risk management breaches and Plaintiffs' injuries. However, at this stage, we conclude that Plaintiff's causation theory, while requiring many steps of proof, is sufficiently plausible and non-speculative to state a claim under the Rule 12(b)(6) standard.

As we have noted, Plaintiffs have latitude in labeling their claims. McLaughlin, 172 F. Supp. 3d at 820. We therefore deny Bayer's request that we dismiss Count II as duplicative of Count VII because Count II does, in fact, allege that Bayer breached certain duties that are not alleged to have been breached in Plaintiffs' failure to warn claim. Consequently, we deny Bayer's Motion to Dismiss the remainder of Plaintiffs' negligent risk management claim in Count II.

C. Count III – Breach of Express Warranty

Count III of the SAC asserts a claim for breach of express warranty. Specifically, Count III alleges that Bayer breached numerous express warranties it made to Plaintiffs, including:

- affirmations of fact on its website that erroneously stated that there were zero pregnancies in Essure's clinical trials, that "Physicians must be signed-off to perform Essure procedures," that Essure is "Worry free," that Essure is "more effective than tying your tubes or a vasectomy," that correct placement of Essure is "performed easily," that the Essure training program is "a comprehensive course designed to provide [physicians with] information and skills necessary to . . . perform competent procedures," and that Essure is "surgery-free;"

- affirmations of fact in brochures that erroneously stated that there were zero pregnancies in clinical trials, that physicians would not be "qualified" as Essure physicians unless they performed the Essure procedures at least once every 6-8 weeks, that Essure does not irritate the uterine lining, that Essure requires "no cutting, no pain, [and] no scars," that Essure users would "never have to worry about unplanned pregnancy again," and that Essure is "Worry free," stays secure, and is made "from the same silicon-free materials used in heart stents"; and

- an affirmation of fact in a commercial that falsely stated that the tip of Essure remains visible after implantation so that the physician can confirm proper placement.[10]

(See SAC ¶ 146.) The SAC alleges that these warranties "were specifically negotiated and expressly communicated to Plaintiff[s] . . . in such a manner that [they] understood and accepted

[10] The SAC alleges that this last misrepresentation was made in a commercial and then states that Plaintiffs encountered it in a brochure entitled "'When your family is complete, choose Essure,'" which was "given to her at her . . . physician's office." (SAC ¶ 146(m)(i)). For purposes of Bayer's Motion, it is immaterial whether the representation was made in a commercial or a brochure.

them" (id. ¶ 145 (emphases added)), that Plaintiffs relied on the warranties (id. ¶ 150), and that the warranties formed the "bases of the bargain between Plaintiff[s] and Defendants" (id. ¶ 146). The Complaint also alleges that, as a result of Plaintiffs' reliance on the warranties, Plaintiffs suffered damages, i.e., the device migrated and Plaintiffs suffered a variety of complications and other injuries. (Id. ¶ 150.)

In our prior Opinion, we dismissed with leave to amend the breach of express warranty claim that Plaintiffs asserted in their prior Complaints. McLaughlin, 172 F. Supp. 3d at 824, 840. We declined to find the breach of warranty claim to be expressly preempted because, as pled, it did not arise from state "requirements," but from alleged contracts between the parties. Id. at 822-23. However, we granted the Motion to Dismiss this claim because the Complaints did not allege facially plausible warranty claims because they did not allege facts that gave rise to a reasonable inference that each alleged warranty was an affirmation of fact or promise that formed the basis of the bargain between Bayer and each Plaintiff. Id. at 823-24.

Bayer argues in its current Motion that Count III should be dismissed because Plaintiffs have failed to remedy these critical deficiencies in their SACs by plausibly alleging that the warranties (1) formed the basis of the parties' alleged bargains, (2) were actionable affirmations of fact or promises, or (3) were even directed at Plaintiffs.[11] Bayer also argues that Count III should

[11] Bayer also asks us to revisit our conclusion that the express warranty claim is not expressly preempted, arguing that additional facts alleged in the SAC make clear that the claim is not based on negotiated contracts but, rather, is based on state requirements. Specifically, Bayer argues that, because the SAC does not plausibly allege that there were any identifiable contractual agreements between Bayer and Plaintiffs, the alleged warranties at issue actually arise solely by operation of the state common law rule that advertisements can give rise to express warranties. Noting that "a State's 'requirements' include its common-law duties," Riegel, 552 U.S. at 324, Bayer argues that Plaintiffs' warranty claim is subject to express preemption just like any other claim based on state requirements. However, we decline to deem Plaintiffs' express warranty claim under Pennsylvania law to be a non-contractual claim, merely because Bayer did not enter into any identifiable written contracts with Plaintiffs. Rather, we understand Pennsylvania law to

be dismissed because it does not plausibly allege that Bayer's breaches of the warranties caused Plaintiffs' injuries.

1. Basis of the Bargain

Bayer argues that the SAC fails to allege sufficient facts to give rise to an inference that the alleged misrepresentations constituted enforceable warranties that which formed the basis of the parties' bargains. Under Pennsylvania law, "express warranties are bargained, 'dickered,' individualized promises that the goods will perform up to the specific standards set forth in that warranty." Goodman v. PPG Indus., Inc., 849 A.2d 1239, 1245 (Pa. Super. Ct. 2004) (quoting 13 Pa. Cons. Stat. Ann. § 2313, Official Cmt. ¶ 1). A warranty "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, to state a cognizable claim for breach of express warranty, a plaintiff must allege both that defendant made "an actual affirmation of fact or a promise," and that the affirmation of fact or promise "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 v. I-Flow Corp., Civ. A. No. 10-3883, 2011 WL 5041374, at *6 (E.D. Pa. Oct. 24, 2011) (citations omitted). Where an express warranty claim is based on advertisements, a plaintiff must allege that she "actually saw or heard and believed the allegedly false advertisements" in order to satisfy her obligation to allege that advertisements formed the basis of the bargain. Jeter, 113 F. App'x at 469 (citing Weinberg v. Sun Co., 777 A.2d 442, 446 (Pa. 2001)); see also Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 752 (W.D. Pa.

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treat a breach of express warranty claim based on an advertisement as a contract claim and we do so as well.

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).

While Plaintiffs' prior version of their breach of express warranty claim failed to allege the circumstances under which each Plaintiff read or saw each particular warranty, and how each warranty came to be a basis of each Plaintiff's bargain with Bayer, the SAC adds these previously omitted allegations. The SAC now includes the date on which each Plaintiff encountered each warranty, where each Plaintiff was when she encountered the warranty, and the source of each warranty. (See SAC ¶ 146.) It further alleges that each warranty created the basis of the bargain because Plaintiff "wanted a reliable type of birth control" that would not migrate, would eliminate the risks and discomforts of other types of birth control, would be made of safe material, and would "not cause pain, cutting or scars"; wanted a reliable and properly trained implanting physician who was approved to perform the surgery; desired "a procedure that could be easily performed and ensure that placement of the devices were properly positioned;" and did not want to have to worry about her birth control working or causing her serious health problems. (See, e.g., SAC ¶ 146(a)(ii), (c)(ii), (f)(ii), (h)(ii), (k)(ii), (n)(ii), (o)(ii), (r)(ii), (t)(ii), (v)(ii).)

Under these circumstances, we conclude that the SAC alleges sufficient facts to support a reasonable inference that the warranties were the bases of the parties' bargains. We therefore deny Bayer's Motion insofar as it requests that we dismiss Count III on this basis.

2. Warranties Directed at Consumers

Bayer also argues that Count III should be dismissed insofar as it rests on two specific warranties because those two warranties, as alleged, were not directed to Plaintiffs. Under

Pennsylvania law, "an express warranty must be directed at consumers in order to induce purchases of the product." Sowers v. Johnson & Johnson Med., Inc., 867 F. Supp. 306, 314 (E.D. Pa. 1994) (quotation omitted); see also Esposito, 2011 WL 5041374, at *6 (citation omitted) (same); 3A Summ. Pa. Jur. Torts § 41:306 (2d ed.) (same). The two warranties that Bayer challenges are plainly directed only at physicians. The first, on the Essure website, addresses physician directly and states: "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 . . . ." (SAC ¶ 146(h).) The second, also on the Essure website, describes for physicians what they will gain from Essure training, stating "[T]he Essure Training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure . . . ."[12] (Id. ¶ 146(g).) We therefore grant the Motion to Dismiss Plaintiffs' express warranty claim insofar as the claim rests on these two warranties because the facts alleged in the SAC do not support a reasonable inference that the statements or promises or affirmations of fact were directed at Plaintiffs.

3. Affirmations of Fact or Promises

Bayer also argues that the following three additional statements are not actionable express warranties because they do not plausibly advance facts, promises or descriptions but, rather, merely offer opinions: (1) "[Y]ou never have to worry about unplanned pregnancy" (SAC ¶ 146(d)); (2) "You'll never have to worry about unplanned pregnancy again" (id. ¶ 146(l)); and (3)

[12] These two statements also appear in publications that are themselves directed to physicians -- the statement regarding the purpose of the Essure training program appears almost verbatim at the start of the Physician Training Manual and the warning that the device should only be used by knowledgeable hysteroscopists appears as an "Important" notice at the start of the detailed Instructions for Use. (RJN Ex. E at 2; RJN Ex. D at Bayer 0096.)

Essure is "Worry free" (id. ¶ 146(n)). As noted above, a warranty must be an "'affirmation of fact or promise.'" Starks, 2014 WL 617130, at *6 (quoting 13 Pa. Cons. Stat. § 2313). An "expression of the vendor's opinion" is not an express warranty. Madison-Kipp Corp. v. Price Battery Corp., 166 A. 377, 378 (Pa. 1933) (citations omitted); 3A Summ. Pa. Jur. 2d Torts § 41:305 (2d ed.) ("[A] statement purporting to be merely the opinion of the seller or commendation of the goods does not create a warranty." (citing 13 Pa. Cons. Stat. § 2313(b))). These three alleged warranties, which assure patients that they will not have to worry about the Essure device, are not, however, merely opinions. Rather, they are more properly characterized as promises, which are actionable under Pennsylvania law. See Goodman, 849 A.2d at 1245. We therefore deny the Motion to Dismiss Plaintiffs' express warranty claim in Count III insofar as it argues that these three statements are opinions, which cannot support an express warranty claim.

4. Causation

Bayer argues that we should dismiss Count III because the SAC fails to allege how each of the alleged warranty breaches was the proximate cause of Plaintiffs' injuries. The Pennsylvania Supreme Court has stated that "[t]o prevail on [a] breach of express warranty claim," a plaintiff must establish "that the breach was the proximate cause of the harm." Samuel-Bassett v. Kia Motors Am., Inc., 34 A.3d 1, 35 (Pa. 2011) (citing Price v. Chevrolet Motor Div., 765 A.2d 800, 809 (Pa. Super. Ct. 2000)). A breach is a proximate cause if it was a "'substantial factor'" in bringing about the plaintiff's harm. Bouriez v. Carnegie Mellon Univ., 585 F.3d 765, 771 (3d Cir. 2009) (quoting First v. Zem Zem Temple, 686 A.2d 18, 21 n.2 (Pa. Super. Ct. 1996)).

Here, the SAC alleges that "[a]s a result of [Bayer] warranties and Plaintiff's reliance on same, Plaintiff has suffered damages. Specifically, the Essure device did not perform as warranted and instead migrated from Plaintiff's fallopian tube," resulting in physical injuries.

(SAC ¶ 150.) The SAC further alleges that Bayer's "breaches of warranty" caused Plaintiffs to suffer physical and mental injuries, and have caused Plaintiffs monetary damages insofar as they have incurred medical expenses. (Id. ¶¶ 151, 153-54.) While these allegations, like other causation allegations in the SAC, are far from specific, we nonetheless conclude that they are sufficient to plausibly allege causation at this early stage of the proceedings. We therefore deny Bayer's Motion to Dismiss insofar as it seeks dismissal of Count III for failure to adequately allege causation.[13]

In sum, we grant Bayer's Motion to Dismiss Count III insofar as the claim rests on the two statements contained in Paragraphs 146(g) and 146(h) of the SAC, and which, on their face, were not directed to Plaintiffs, but we deny Bayer's Motion to Dismiss Count III in all other respects.

D. Count IV – Fraudulent Misrepresentation

Count IV of the SAC asserts a claim for fraudulent misrepresentation based on the exact same statements that are the subject of the express warranty claim in Count III. The alleged misrepresentations appeared on Bayer's website, in brochures, and in a commercial. (See SAC ¶ 158.) 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, (4) whether Essure effectively prevents pregnancy, (5)

[13] In addressing the sufficiency of the causation allegations, Bayer and Plaintiffs address the breach of warranty and misrepresentation claims together. In doing so, they fail to recognize that a breach of warranty claim requires different proof of causation than a misrepresentation claim, because a breach of warranty claim must allege that the breach caused the injury, whereas the misrepresentation claim must allege that the plaintiff's justifiable reliance on a false or misleading statement caused the injury. Compare Samuel-Bassett, 34 A.3d at 35 ("To prevail on [a] breach of express warranty claim," a plaintiff must establish "that the breach was the proximate cause of the harm") with Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994) (stating that a misrepresentation claim requires proof that the plaintiff's justifiable reliance on a misrepresentation was the proximate cause of her injury). Nevertheless, we are satisfied that the SAC plausibly alleges causation with regard to the breach of express warranty claim in Count III.

whether Essure stays secure, and (6) whether Essure is made from safe and trusted materials. (See id.)

In our previous opinion, we reject Bayer's argument that we should dismiss the fraudulent misrepresentation count as expressly preempted, but we also explicitly stated that we reached "no conclusion as to whether claims based on certain misrepresentations might be expressly preempted should the alleged misrepresentations prove to be consistent with FDA-approved statements." McLaughlin, 172 F. Supp. 3d at 828. At the same time, we dismissed the count with leave to amend, because it failed to state the circumstances of the alleged fraud with sufficient particularity, as required by Federal Rule of Civil Procedure 9(b), as the Complaint failed to inject any precision or measure of substantiation into the fraud allegations. Id. at 829, 840. Bayer argues in its current Motion that we should dismiss Plaintiffs' amended fraudulent misrepresentation claim either because it is expressly preempted or because the SAC does not adequately allege fraudulent intent.[14]

1. Express Preemption

Bayer argues that Count IV is expressly preempted under Riegel because each purported misrepresentation is indistinguishable from statements that were specifically approved by the

[14] As noted above, see supra note 13, Bayer also argues that we should dismiss the fraudulent misrepresentation claim because Plaintiffs have failed to plausibly allege a causal connection between their injuries and Bayer's statements. See Gibbs, 647 A.2d at 889 (stating that a plaintiff must establish that her reliance on the misrepresentation was the proximate cause of her injury). With respect to causation, the SAC alleges in Count IV that Plaintiffs would not have had Essure implanted had they known that the representations were false and that, as a result of the implantations, Plaintiffs suffered damages. (SAC ¶¶ 160, 162, and 164.) While Bayer contends that these allegations are insufficient, it conflates its argument with that concerning the breach of warranty claim, largely relies on law from other jurisdictions, and does not take into account that proximate causation in Pennsylvania is typically a jury question. See Ford v. Jeffries, 79 A.2d 111, 114 (Pa. 1977). In light of the SAC's allegations and in the absence of more persuasive argument, we deny Bayer's motion insofar as it requests that we dismiss Plaintiffs' fraudulent misrepresentation claims for failure to plausibly allege causation.

FDA. In support of this argument, Bayer presents a chart that lists the alleged misrepresentations and matches each to a specific FDA-approved statement in Essure's 2011 Instructions for Use ("IFUs") or 2012 Patient Information Booklet ("PIB"). Plaintiffs maintains, however, that (1) the misrepresentations are distinguishable from the FDA-approved statements upon which Bayer relies, providing its own chart attempting to explain how the misrepresentations deviate from the FDA-approved statements; and (2) Bayer does not address certain alleged misrepresentations.[15]

We stated in our prior Opinion that to state a misrepresentation claim that was not expressly preempted, Plaintiffs would need to "allege that Bayer made false or misleading statements in unapproved advertising or other promotional materials that were inconsistent with specific statements in approved FDA materials and that undermined the approved and required statements in those materials." McLaughlin, 172 F. Supp. 3d at 827 (citing Riegel, 552 U.S. at 330). As we explained, "[s]uch 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. at 827-28 (quoting Riegel, 552 U.S. at 330). Applying these standards to the alleged misrepresentations in the SAC, we conclude that the bulk of the alleged misrepresentations are not actionable because they are completely consistent with statements in FDA-approved materials and do not undermine -- or overstate -- the approved and/or required statements in those materials.

[15] Plaintiffs also emphasize that the PIB on which Bayer relies to establish that certain statements were federally-approved was published in 2012 and, thus, was not in effect when some of the Plaintiffs had their Essure devices implanted. They therefore argue that the federally-approved statements in the PIB are simply not relevant to whether the claims of those four Plaintiffs are expressly preempted. However, we do not follow Plaintiff's logic. Regardless of when the PIB was published, the statements therein articulate the federal requirements concerning Essure that are embodied in the PMA. We therefore reject Plaintiffs' argument, for which they cite no pertinent legal authority, that the statements in the PIB do not reflect federal requirements that are necessarily relevant to our express preemption analysis.

a. Zero Pregnancies

Plaintiffs seek to hold Bayer liable for a statement on the Essure website that Essure is the "[o]nly FDA approved female sterilization procedure to have zero pregnancies in the clinical trials" and two other statements, one on the website and one in a brochure, that state that there were "zero pregnancies" in clinical trials. (SAC ¶ 158 (a), (b), and (j).) Plaintiffs maintain that these statements are false and misleading because there were actually at least four pregnancies in clinical trials. (See, e.g., id. ¶ 158(j)(iii).) Bayer argues, however, that these statements are the equivalent of FDA-approved statements in the PIB that "[i]n five years of clinical trials, there have been no pregnancies among women who successfully completed all 3 steps of the Essure procedure" and that "[i]n Essure clinical studies, zero (0) pregnancies were reported in women who had the Essure inserts for up to five years." (RJN Ex. F at 10, 12.) In Plaintiffs' view, these statements in the PIB differ from the misstatements made on the Essure website and in the Essure brochure because they contain qualifiers that the alleged misstatements do not include. However, the FDA-approved PIB also contains the unqualified statement that "zero (0) pregnancies were reported during the Essure clinical trials." (Id. at 13.) We therefore conclude that Bayer's statements on the website and in a brochure that there were zero pregnancies in the clinical trials is completely consistent with at least one FDA-approved statement in the PIB. Accordingly, Plaintiffs' fraudulent misrepresentation claims based on statements that there were "zero pregnancies" are expressly preempted. Accord De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1098 (N.D. Cal. 2016) (concluding that claims based on statements that Essure had "zero pregnancies" in clinical trial were expressly preempted because such statement was approved and/or required by the FDA).

b. Physician Sign-Off

Plaintiffs also seek to hold Bayer liable for a statement on its website that "Physicians must be signed-off to perform Essure procedures," asserting that the statement is false because Bayer "failed to abide by the FDA guidelines when training the implanting physician[s] and 'signed-off' on [Plaintiffs'] implanting physician[s] who did not have the requisite training." (SAC ¶ 158(c)). Bayer argues that this alleged misrepresentation is virtually identical to an FDA-approved statement in the IFUs that the "device should only be used by physicians who . . . have successfully completed the Essure training program." (RJN Ex. D at 1.) Indeed, Bayer's statement on its website that physicians must be "signed-off" to perform Essure procedures is completely consistent with the FDA's statement that physicians should successfully complete the product training program before implanting the device. Accordingly, any assertion that Bayer fraudulently misrepresented the requirements imposed on physicians by stating that they must be "signed-off" is expressly preempted.[16] Accord Norman v. Bayer Corp., Civ. A. No. 16-253, 2016 WL 4007547, at *6 (D. Conn. July 26, 2016) (concluding that claim based on statement that Bayer would "'sign off' on hysteroscopy training for a physician before [the physician] would be permitted to implant [Essure] was expressly preempted because the statement was not "outside what was approved by the FDA").

c. Worry Free

Plaintiffs seek to hold Bayer liable for two statements on the Essure website and in a brochure that Essure is "Worry free," one of which adds that "Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy," and a third statement that

[16] At the same time, to the extent that Bayer may have failed to properly train physicians or "signed off" on their skills when the doctors had not successfully completed the required training, we are permitting Plaintiffs to pursue a claim based on such training deficiencies as a negligent training claim. See supra pp. 11-12.

"You'll never have to worry about unplanned pregnancy again." (SAC ¶ 158(d), (l), (n).) They primarily contend that these statements are false because some users became pregnant using Essure. (See id. ¶ 158(d)(iii), (l)(iii).) Bayer maintains that these statements are essentially indistinguishable from an FDA-approved statement in the PIB that "Essure may be right for you if . . . [y]ou would like to stop worrying about getting pregnant." (RJN Ex. F at 4.) Furthermore, the PIB says that "Essure may be right for you if . . . you are certain you do not want any more children" and "desire a permanent form of birth control." (Id.) We conclude that the FDA-approved statements in the PIB plainly convey that Essure users need not worry about getting pregnant and thus are the equivalent of the statements for which Plaintiffs seek to hold Bayer liable. We therefore further conclude that Plaintiffs seek to hold Bayer liable for what are, in essence, FDA-approved statements. The fraudulent misrepresentation claims based on these three statements are thus expressly preempted. Accord De La Paz, 159 F. Supp. 3d at 1098 (concluding that claims based on statement that Essure was "worry free" were expressly preempted because such statement was approved and/or required by the FDA).

d. Most Effective Birth Control

Plaintiffs seek to hold Bayer liable for a statement on the Essure website that "Essure is the most effective permanent birth control available – even more effective than tying your tubes or a vasectomy." (SAC ¶ 158(e)). This statement, however, is fully consistent with information in the PIB, which compares Essure with tubal ligation and vasectomy procedures and shows that the rate of failure for each is higher (i.e., the number of pregnancies is higher) than that of Essure. (RJN Ex. F at 15-16.) Accordingly, Plaintiffs' fraudulent misrepresentation claim based on this statement is expressly preempted. Accord Norman, 2016 WL 4007547, at *6 (concluding that claim based on statement that Essure "is the most effective form of birth control available" was

expressly preempted because statement was "materially identical" to statement in FDA-approved material (internal quotation omitted)).

e. Correct Placement

Plaintiffs assert that Bayer's statement on the Essure website that "[c]orrect placement . . . is performed easily because of the design of the micro-insert" is also a fraudulent misrepresentation because, in fact, it is not easy to place the product properly in the fallopian tubes. (SAC ¶ 158(f) (alteration in original).) This challenged statement, however, is completely consistent with, and does not overstate, the FDA-approved statement in the PIB that "Essure is a simple procedure that can be done in 10 minutes in your doctor's office." (RJN Ex. F at 5; see also id. at 4 ("Essure may be right for you if . . . [y]ou prefer a method or procedure that . . . [i]s simple and does not take a lot of time").) We therefore conclude that Plaintiffs' fraudulent misrepresentation claim based on this statement is expressly preempted. Accord De La Paz, 159 F. Supp. 3d at 1098 (concluding that claim based on statement that Essure's "correct placement . . . is easily performed" was expressly preempted because such statement was approved and/or required by the FDA (internal quotation omitted) (alteration in original)).

f. Surgery-Free and Permanent

Plaintiffs also seek to hold Bayer liable for statements made on the website and in brochures concerning the process of implanting Essure, including statements that the process is "surgery-free," "permanent," and "eliminates the risks, discomfort and recovery time associated with surgical procedures." (SAC ¶ 158 (i), (r), (s)). Plaintiffs contend that these statements are false because hysteroscopy is a surgical procedure, their birth control was not permanent, and the procedure does not eliminate all risks. (Id.) However, the PIB contains FDA-approved statements that Essure "[d]oes not require surgery or exposure to its potential risks," is

"permanent" and "Non-Surgical," and requires "No Downtime to Recover." (RJN Ex. F at 4-5.) Accordingly, we conclude that the statements at issue regarding the process of implanting Essure are consistent with, and largely equivalent to, FDA-approved statements and we find the fraudulent misrepresentation claims based these statements to be expressly preempted. Accord De La Paz, 159 F. Supp. 3d at 1098 (concluding that claim based on statement that Essure is "surgery free" was expressly preempted because such statement was approved and/or required by the FDA).

g. No Pain

Plaintiffs also seek to hold Bayer liable for a statement in a brochure that "there was no cutting, no pain, no scars." (SAC ¶ 158(v).) Plaintiffs contend that this statement is false insofar as it states that "there was . . . no pain," because they have experienced pain as a result of their use of Essure and, similarly, others have experienced pain in connection with the test used to confirm that their fallopian tubes are blocked. (Id. ¶ 158(v)(iii).) Without knowing the textual context of the alleged misrepresentation, we cannot discern precisely what it concerns, e.g., whether it reflects a single individual's account of her experience with Essure, whether it is a summary of the results of a clinical study for the product, and/or whether it concerns only the process of implanting Essure or, instead, concerns a woman's full experience with the product. Nevertheless, the statement that there "was . . . no pain" is arguably inconsistent with federally-approved statements in the PIB, including that there may be "mild to moderate pain" or a "little pain" associated with the Essure procedure. (RJN Ex. F at 7, 10.) Indeed, in spite of arguing that a claim based on this statement is expressly preempted, Bayer points to no federally-approved statement that is consistent with a statement that there is "no pain." We therefore reject Bayer's argument that Plaintiffs' fraudulent misrepresentation claim grounded on this statement is expressly preempted

h. Stays Secure, Visual Confirmation, and Irritation of Uterus

Plaintiffs seek to hold Bayer liable for additional statements made in brochures concerning how Essure functions, specifically that it "stays secure, forming a long protective barrier against pregnancy," and when implanted, "remains visible to [the] doctor, so proper placement can be confirmed" and that the "viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus." (SAC ¶¶ 158(m), (o), (u).) Plaintiffs contend that these statements are false because Essure does not allow for visual confirmation of proper placement during the procedure, and the device does not remain secure and does irritate the uterus. (Id. ¶ 158(m)(iii), (o)(iii), (u)(iii)) However, the IFUs specifically instruct the physician how to implant Essure and advise the physician to verify proper placement during implantation by assessing the "visible" portion of the device and the number of "visible" trailing coils. (RJN Ex. D at Bayer 0099-00100.) The PIB further states that "[a]fter 3 months, a doctor will administer the Essure Confirmation Test," "us[ing] contrast dye and a special type of x-ray," by which he or she "will verify that the inserts are in their correct location," and that, during confirmation, the radiologist will "look at your fallopian tubes to confirm that the inserts are properly placed." (RJN Ex. F at 6, 10 (emphasis added).) Furthermore, the PIB specifically states that the patient's "body will form tissue around the Essure inserts[, which] will develop a natural barrier within the fallopian tubes," and the IFUs state that the insert "acutely anchors itself in the fallopian tube." (RJN Ex. F at 6; RJN Ex. D at Bayer 0096 (emphasis added).) At the same time, Bayer points to no federally-approved statements that are the equivalent of the challenged statement that the visible part of the insert will not irritate the lining of the uterus, and we are aware of none. We therefore conclude that Plaintiffs' fraudulent misrepresentation claim based on the alleged misstatement in Paragraph 158(u) of the SAC that the visible portion of the micro-inserts does not irritate the uterus

is not expressly preempted. However, the statements in Paragraphs 158(m), and 1580(o), and the statement in Paragraph 158(u) that "the viewable portion of the micro-insert serves to verify placement" are consistent with, and equivalent to, FDA-approved statements and, thus, Plaintiffs' fraudulent misrepresentation claims grounded on those remaining statements are expressly preempted.

i. Safe, Trusted Material

Plaintiffs also assert that Bayer is liable for fraudulently asserting in brochures that the Essure inserts are made from "safe, trusted material," and that such material is the same material used in heart stents. (SAC ¶ 158(p), (t).) They contend that these statements are false because Essure contains PET fibers that trigger inflammation and scar tissue growth, which is not true for heart stents, and because the material is not, in fact, safe but rather, corrodes and breaks. (Id.) The FDA-approved PIB, however, states that "The inserts are made from . . . the[] same materials [that] have been used for many years in cardiac stents," which clearly conveys that the materials are safe and trusted. (RJN Ex. F at 11.) We therefore conclude that these two statements are consistent with FDA-approved statements and, as a result, the fraudulent misrepresentation claims based on those statements are expressly preempted.

j. Skilled Hysteroscopist

Finally, Plaintiffs argue Bayer should be held liable for a statement made on the Essure website that a physician must be a "skilled operative hysteroscopist" in order to be trained in Essure because Bayer signed off on physicians who were not skilled operative hysterocopists. (SAC ¶ 158(h).) However, the federally-approved IFUs specifically state that only skilled hysteroscopists should use Essure. (RJN Ex. D at 1.) Thus, Bayer's statement that a physician must be a skilled hysteroscopists to be trained to use Essure is completely consistent with that

federal requirement, and Plaintiffs' fraudulent misrepresentation claim based on this statement is expressly preempted.

In sum, we conclude that Plaintiffs' fraudulent misrepresentation claim is expressly preempted insofar as it rests on all of the statements in Paragraphs 158(a)-(f), (h)-(j), (l)-(p), and (r)-(t) of the SAC, and part of the statement in Paragraph 158(u). There are, however, three statements -- in Paragraphs 158(g), (k), and (q) of the SAC -- that Bayer has not challenged as being expressly preempted,[17] and we have found that a fourth statement in Paragraph 158(u) and a fifth statement in Paragraph 158(v) are not expressly preempted. Consequently, we do not find Plaintiffs' claim to be preempted insofar as it rests on those five statements, but we grant the Motion to Dismiss Plaintiffs' fraudulent misrepresentation claim in Count IV as expressly preempted with respect to all of the other statements.

2. Failure to Allege Elements of Cause of Action

Bayer also argues that we should dismiss Count IV for failure to state a claim upon which relief can be granted because it fails to plausibly allege two requirements for a federal misrepresentation claim: (1) that Bayer made the misrepresentations either with knowledge of their falsity or with reckless disregard of the truth, and (2) that Bayer made the statements with the intent to induce Plaintiffs' reliance.

a. Knowledge of Falsity or Reckless Disregard of Truth

To state a cognizable claim for fraudulent misrepresentation, a complaint must allege that

[17] These three statements are: (1) "The Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures, and manage technical issues related to the placement of Essure micro-inserts for permanent birth control" (SAC ¶ 158(g)); (2) "In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks" (id. ¶ 158(k)); and (3) "Step Two: 'pregnancy cannot occur'; Step Three: The Confirmation¨ (id. ¶ 158(q)).

the speaker had knowledge of the statement's falsity or was reckless as to whether the statement was true of false. Gibbs, 647 A.2d at 889. Pursuant to Federal Rule of Civil Procedure 9(b), "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

Plaintiffs maintain that they have satisfied this pleading standard, because the SAC alleges that Bayer made "fraudulent utterance[s]," that the alleged misrepresentations were false, and that Bayer concealed or "actively concealed" the truth regarding most of the statements at issue.[18] (See SAC ¶ 158.) While the SAC never explicitly alleges that Bayer knew that the statements were false or recklessly disregarded whether the statements were true or false, we conclude that the underlying facts alleged, read in the light most favorable to Plaintiffs, allow for a reasonable inference that Bayer knew that four of the five alleged misrepresentations that are not subject to express preemption were false. Specifically, the SAC alleges that Bayer represented that to be "identified as a qualified Essure physician," a physician must perform at least one Essure procedure every 6-8 weeks when, in fact, it "signed-off" on physicians who did not meet this criteria and then concealed its failure to enforce the this requirement from Plaintiffs. (Id. ¶

[18] Plaintiffs argue, in the alternative, that they need not plead knowledge of the statements' falsity or recklessness, relying on Pennsylvania law suggesting that a plaintiff can proceed on a claim based on an "innocent misrepresentation" that is material to the parties' transaction. (Pls.' Br. at 33 (citing Delahanty v. First Pa. Bank, N.A., 464 A.2d 1243, 1252 (Pa. Super. Ct. 1983); and Hughes v. Consol-Pennsylvania Coal Co., 945 F.2d 594, 614 (3d Cir. 1991)).) In this regard, the SAC explicitly asserts that "fraud may be established even where there is an innocently made misrepresentation so long as it relates to a material matter" and adds that "[p]leading the materiality of the misrepresentations substitutes for pleading the fraudulent utterance thereof." (SAC ¶ 159.) However, more recent authority in Pennsylvania makes clear that, to the extent a fraudulent misrepresentation claim may be brought based on an innocent misrepresentation under Pennsylvania law, it does not provide a basis for an award of monetary damages but, rather, only gives the plaintiff a right to equitable rescission. See Bortz v. Noon, 729 A.2d 555, 564 (Pa. 1999); Brimmeier v. Pa. Tpk. Comm'n, 147 A.3d 954, 963 (Pa. Commw. Ct. 2016) (citing Bortz, 729 A.2d at 564). Where, as here, Plaintiffs seek only monetary damages, we conclude that they cannot state a claim upon which the requested relief can be granted by alleging an innocent misrepresentation.

158(k).) Similarly, the SAC alleges that Bayer represented that "[t]he Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures, and manage technical issues related to the placement of Essure micro-inserts for permanent birth control" when, in fact, Bayer did not provide such training and concealed that information from Plaintiffs. (Id. ¶ 158(g).) In addition, the SAC alleges that Bayer described the steps of the Essure procedure, stating that "pregnancy cannot occur" at Step Two and that "The Confirmation" occurs at Step Three but, in fact, patients are warned that pregnancy can still occur before confirmation and Bayer affirmatively stated elsewhere that it is only after "The Confirmation" that pregnancy cannot occur. (Id. ¶ 158(q).) Finally, the SAC alleges that Bayer stated "there was . . . no pain," but at the same time described the test used to confirm the tubes are blocked as "painful" in its SEC filings, failed to report incidents of pain to the FDA, and altered the records of one trial participant to reflect less pain. (Id. ¶ 158(v)(iii). Accordingly, we reject Bayer's argument that we should dismiss Count IV insofar as it relies on these four alleged misrepresentations because Plaintiffs have failed to adequately allege that Bayer knew that its alleged misrepresentations were false or recklessly disregarded the truth or falsity of the statements. Instead, we conclude that the facts alleged support a reasonable inference that Bayer proceeded with such knowledge or recklessness.

We reach a different result with respect to the fifth alleged misrepresentation that is not subject to express preemption, i.e., that "the viewable portion of the micro-insert . . . does not irritate the lining of the uterus." (SAC ¶ 158(u)). The SAC does not explicitly allege that Bayer knew or recklessly disregarded that the viewable portion of the device does irritate the lining of the uterus. Moreover, instead of alleging facts that give rise to a reasonable inference that Bayer knew or recklessly disregarded that the device caused such irritation, it alleges only facts that

support an inference that Bayer knew, or recklessly disregarded, that the device migrated, broke into pieces and caused peritoneal perforations. (Id. ¶ 158(u)(iii)). Thus, with respect to the statement that "the viewable portion of the micro-insert . . . does not irritate the lining of the uterus," we conclude that the SAC has failed to allege, either generally or by way of supporting factual allegations, that Bayer knew that this statement was false or recklessly disregarded the truth or falsity of the statement. (Id. ¶ 158(u).) We therefore dismiss Count IV insofar as it is based on this particular statement because the SAC does not plausibly allege Bayer's knowledge of the statement's falsity or reckless disregard of its truth or falsity.

b. Intent to Induce Plaintiffs' Reliance

To state a cognizable claim for fraudulent misrepresentation under Pennsylvania law, a plaintiff must allege that the defendant made a misrepresentation "'with an intent to induce another to act on it." 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)); see also Kostryckyj v. Pentron Lab. Techs., LLC, 52 A.3d 333, 336 (Pa. Super. Ct. 2012) (citations omitted). As with the previously discussed knowledge element, this element of intent is a state of mind that need only be pled generally. See Fed. R. Civ. P. 9(b)(2).

Bayer argues that the SAC does not plead facts sufficient to support a plausible inference that it acted with an intent to induce reliance and instead rely on the bald and conclusory allegations that Bayer "intentionally made . . . statements so that Plaintiff[s] would be induced to have Essure implanted." (SAC ¶ 161.) We conclude, however, that whenever the SAC alleges that an alleged misrepresentation appeared in promotional brochures that were provided to prospective patients in their doctors' offices or in a commercial, it plausibly alleges facts that give rise to an inference that Bayer intended such representations to induce patients to purchase the

product and have Essure implanted. (See, e.g., id. 158(k), (q), (v).) There is, on the other hand, one website statement that we did not find to be subject to express preemption and that we have previously concluded was plainly directed to physicians, not patients, i.e., the statement describing physician training. (Id. ¶ 158(g).) With respect to this statement, we agree with Bayer that the SAC has failed to plausibly allege any facts that give rise to a reasonable inference that Bayer intended to induce Plaintiffs' reliance on the alleged misrepresentation because that statement, on its face, was not directed at prospective patients.[19] We therefore dismiss Count IV insofar as it is based on this particular misrepresentation in Paragraph 158(g) of the SAC.

In sum, we grant the Motion to Dismiss as to majority of the fraudulent misrepresentation claims in Count IV because they are expressly preempted, and we also grant the Motion to Dismiss as to the misrepresentation alleged in Paragraph 158(g) for failure to plausibly allege intent to induce reliance, and as to the alleged misrepresentation regarding the irritation of the uterus lining in Paragraph 158(u) for failure to plausibly allege knowledge or reckless disregard.[20] Thus, the only three alleged misrepresentations remaining in this claim are those in Paragraphs 158(k), 158(q), and 158(v). Moreover, only McLaughlin asserts a claim based on Paragraph 158(q), only McLaughlin, Stelzer and Strimel assert claims based on Paragraph 158(k), and only McLaughlin,

[19] Bayer also argue that a second statement -- the statement that physicians must be skilled hysteroscopists -- was plainly not intended to induce Plaintiffs' reliance because it was also directed to physicians, not patients. (See SAC ¶ 158(h).) However, because we have already concluded that the fraudulent misrepresentation claim grounded on this statement is expressly preempted, we need not address this alternative argument for its dismissal.

[20] We recognize that we did not dismiss Plaintiff's negligent misrepresentation claim grounded on these same misrepresentation in our prior Opinion. See McLaughlin 172 F. Supp. 3d at 830. However, Bayer did not argue in its prior Motion that the negligent misrepresentation claim did not plausibly allege (1) that Bayer intended to induce reliance on the statement in Paragraph 158(g) because the statement was not directed to patients, or (2) that Bayer knew or recklessly disregarded that the visible part of the micro-insert irritated the uterus. Thus, we never addressed these specific issues.

Stelzer, Strimel and Ruble assert claims based on Paragraph 158(v). Accordingly, we grant the Motion to Dismiss Walsh's fraudulent misrepresentation claims in its entirety.

E. Count VI – Negligent Manufacturing

Count VI of the SAC alleges that Bayer is liable for negligently manufacturing Essure in a manner inconsistent with the PMA and federal law, insofar as it used nonconforming materials, produced the product in nonsanitary conditions, and used misleading labeling. We dismissed Plaintiffs' prior version of this claim, explaining that the Complaint failed to plausibly allege that any particular manufacturing defect actually caused Plaintiffs' injuries and thus failed to allege an essential element of the negligent manufacturing claim. McLaughlin, 172 F. Supp. 3d at 835-36. At the same time, we deferred any ruling as to whether the claim was expressly preempted until Plaintiffs better defined their claim, so that we could determine whether the claim paralleled federal requirements or was seeking to impose different or additional safety requirement. Id. at 834-35. Bayer now argues that the SAC fails to remedy the pleading deficiency for which we dismissed the prior version of the Complaint, because the SAC does not plausibly allege that any negligent manufacturing caused Plaintiff's injuries.

The SAC asserts that Bayer had a duty to manufacture Essure consistent with the manufacturing standards set forth in six federal regulations, three federal statutes, and one provision of the PMA. (See SAC ¶ 183). It asserts that Bayer failed to comply with these standards – and thereby engaged in negligent manufacturing – insofar as it (1) used rejected or non-conforming materials in the Plaintiff's Essure device, (2) produced and provided to Plaintiff a product with misleading labeling, and (3) prepared the Plaintiff's Essure device in unsanitary conditions. (Id.) The SAC alleges no facts that could establish causation with respect to the latter two deficiencies, alleging only that "as a result of the use of nonconforming and rejected

materials in Plaintiff's Essure, it [sic] device did not perforrn as intended causing it to migrate leading to Plaintiff's hysterectomy." (Id. ¶ 184.)

Pennsylvania law 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 v. Zimmer, 474 F. Supp. 2d 737, 752 (E.D. Pa. 2007 (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)) (remaining citations omitted)). Other federal courts have similarly 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, as noted above, the SAC alleges no causal connection between the alleged mislabeling and unsanitary conditions, and Plaintiffs' injuries. Moreover, while it baldly alleges that nonconforming materials caused the device to migrate (SAC ¶ 184), it does not allege what material in the devices was allegedly non-conforming, or the manner in which such non-conforming material could have actually caused the device to migrate. Under these

circumstances, we conclude that Plaintiff's vague and non-specific allegations of causation do not "raise a right to relief above the speculative level," Twombly, 550 U.S. at 555, and thus, the SAC does not state a negligent manufacturing claim upon which relief can be granted.[21] We therefore grant the Motion to Dismiss as to the negligent manufacturing claim in Count VI, and dismiss Count VI in its entirety.

IV. CONCLUSION

For the foregoing reasons, we grant Bayer's Motion to Dismiss as to (1) Count VI (negligent manufacture); (2) Count I (negligent training), but only insofar as that Count rests on allegations that Bayer failed to confirm that doctors are knowledgeable hysteroscopists, ensure that doctors monitored their patients following their completion of training, and ensure that that doctors were certified; (3) Count II (negligent risk management) insofar as it rests on a theory that Bayer should have withdrawn Essure; (4) Count III (express warranty), but only insofar as it rest on the two statements in Paragraphs 146(g) and 146(h), which were directed to doctors, not patients, and (5) Count IV (fraudulent misrepresentation) except insofar as it rests on the specified alleged misrepresentations in Paragraphs 158(k), 158(q), and 158(v). In all other respects, we deny the Motion to Dismiss.

Accordingly, the claims that remain in this case are (1) Count I (negligent training) insofar as it rests on Bayer's alleged failure to ensure that physicians had completed five preceptorings, had read and understood the training manual, and had successfully completed simulator training; (2) Count II (negligent risk management) insofar as it rests on a causation theory grounded in a

[21] Furthermore, to the extent that the negligent manufacturing claim rests on a theory that the device was mislabeled, it is plainly expressly preempted as the FDA regulates the labeling of Essure and the SAC does not allege that the labeling departed from FDA standards. See, e.g., Riegel, 552 U.S. at 329 (stating that the MDA § 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").

failure to warn; (3) Count III (express warranty), except insofar as it rests on the alleged warranties in Paragraphs 146(g) and (h); (4) Count IV (fraudulent misrepresentation) insofar as it rests on three specific statements, i.e., (a) "there was . . . no pain," (b) to be "identified as a qualified Essure physician," a physician must perform at least one Essure procedure every 6-8 weeks, and (c) "Step Two: 'pregnancy cannot occur'; Step Three: The Confirmation." (SAC ¶ 158(k), (q), (v)); (5) Count V (negligent misrepresentation); and (6) Count VII (failure to warn).

An appropriate Order follows.

BY THE COURT:

/s/ John R. Padova, J.

John R. Padova, J.