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

ALEXANDRA DUNSTAN	:	CIVIL ACTION NO. 16-1458	
	:		
v.	:		
	:		
BAYER ESSURE, INC., et al.	:		
	:	NO. 16-1645 (Clarke)	NO. 16-3730 (Mantor)
	:	NO. 16-1921 (Souto)	NO. 16-3731 (O'Donnell)
	:	NO. 16-2166 (Bailey)	NO. 16-3732 (Gross)
	:	NO. 16-2154 (Campos)	NO. 16-3733 (Johnson)
	:	NO. 16-2717 (Morgan)	NO. 16-3766 (Summerlin)
And Related Actions	:	NO. 16-3049 (Tulgetske)	NO. 16-3767 (Rodvill)
	:	NO. 16-3409 (Abbey)	NO. 16-3768 (Bernal)
	:	NO. 16-3589 (Burgis)	NO. 16-3769 (Aponte)
	:	NO. 16-3710 (Donahue)	NO. 16-4081 (Bradford)
	:		NO. 17-2915 (Winstrom)

MEMORANDUM

Padova, J. **October 3, 2017**

Each female Plaintiff in these consolidated actions seeks compensation for injuries she sustained in connection with her use of Essure, a female birth control device. In two prior Opinions in five related cases ("the "McLaughlin cases"), McLaughlin v. Bayer, 172 F. Supp. 3d 804 (E.D. Pa. 2016) ("McLaughlin I"), and McLaughlin v Bayer, 2017 WL 697047 (E.D. Pa. Feb. 21, 2017) ("McLaughlin II"), we granted in part both a Motion for Judgment on the Pleadings and a Motion to Dismiss, and we thereby narrowed the claims on which the Essure plaintiffs could proceed to claims for negligent training, negligent risk management, breach of express warranty, fraudulent misrepresentation, negligent misrepresentation, and failure to warn. See McLaughlin II, 2017 WL 97697047, at *19. Thereafter, Plaintiffs in the instant cases (the "Dunstan Cases") filed new complaints, which only assert claims that we allowed the McLaughlin plaintiffs to pursue and, in four cases, added loss of consortium claims. Defendants Bayer Essure, Inc., and Bayer Healthcare Pharmaceuticals, Inc. (collectively, "Bayer") have now filed an identical Motion to Dismiss the amended complaints in each of the Dunstan Cases pursuant to Federal Rule of Civil

Procedure 12(b)(6).[1] For the following reasons, we grant the Motion in part and deny it in part. Specifically, we grant the Motion insofar as it seeks to dismiss the bulk of the negligent misrepresentation claim, but deny it in all other respects.

I. BACKGROUND[2]

The Amended Complaint (the "Complaint") in Dunstan v. Bayer Essure, Inc., Civ. A. No. 16-1458, alleges that Bayer manufactures, sells, distributes, markets and promotes Essure.[3] (Compl. ¶ 54.) 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. ¶¶ 40, 42.) The coils are inserted by a doctor using hysteroscopic equipment. (Id. ¶¶ 42-43.) The Complaint alleges that, instead of working as intended, "the device migrates from the tubes, perforates organs, breaks into pieces, and/or corrodes." (Id. ¶ 24.) Each Plaintiff had Essure implanted and, as a result, suffered "severe and permanent injuries." (See, e.g., id. ¶¶ 108-16.)

Because Essure is classified as a Class III medical device, the Food and Drug Administration (the "FDA") evaluated Essure's safety and effectiveness prior to granting the product Conditional Premarket Approval ("PMA"), which granted permission to market the

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[1] Bayer filed an "Omnibus Motion to Dismiss" in all of the cases except Winstrom v. Bayer, Inc., Civil Action No. 17-2915, which was filed on June 29, 2017, after the Omnibus Motion was filed. As a result, Bayer filed a separately-captioned Motion to Dismiss in Winstrom. The body of the Winstrom Motion, however, is identical in all material respects to the Omnibus Motion. We therefore refer in this Opinion to the Omnibus Motion and the Winstrom Motion as a single Motion.

[2] Because we write primarily for the parties, we do not repeat the extensive and familiar background information included in McLaughlin I. See McLaughlin, 172 F. Supp. 3d at 809-11.

[3] The complaints in the Dunstan Cases are largely the same. For ease of reference, we will cite exclusively to the Dunstan Complaint unless otherwise noted.

device. (Id. ¶¶ 26, 54, 57, 59; 11/4/02 PMA letter ("PMA Ltr.") at 1.[4]) 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.)

Each Complaint asserts either five or six 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 asserts a claim of negligent misrepresentation, alleging that the same statements about Essure that constituted warranties also constituted actionable negligent misrepresentations. Count V asserts a claim for negligent failure to warn, alleging that Bayer negligently failed to warn Plaintiffs and the implanting physicians of the risks of the device and manufacturing defects. In Campos, Morgan, Tulgetske, and Winstrom, the complaints also include a Count VI, which asserts a loss of consortium claim on behalf of the husbands of certain female Plaintiffs.

Bayer has moved to dismiss Counts III and IV pursuant to Rule 12(b)(6). With respect to

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[4] We may consider the PMA letter in connection with the Motion to Dismiss, because it is referenced in the Complaint 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)).

Count III, it argues that that the breach of warranty claim fails to satisfy the pleading standards that we required for such claims in McLaughlin I. With respect to Count IV, it argues that the negligent misrepresentation claim is expressly preempted for the same reasons that we found the fraudulent misrepresentation claims to be expressly preempted in McLaughlin II.[5]

II. LEGAL STANDARD

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

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[5] Bayer also argues that we should dismiss Counts I (negligent training), II (negligent risk management), and V (failure to warn), resting on the same arguments that it made in seeking dismissal of those claims in the McLaughlin cases, i.e., that the claims are expressly preempted and otherwise fail to state valid claims. Bayer acknowledges, however, that we rejected those very arguments in our prior Opinions in McLaughlin I and McLaughlin II, concluding that the plaintiffs had alleged sufficient facts to state non-preempted and cognizable claims. McLaughlin I, 172 F. Supp. 3d at 816-18, 820-21, 836-38; McLaughlin II, 2017 WL 697047, at *3-8. Bayer therefore states that it reasserts its arguments for dismissal of those claims solely for the purpose of preserving its arguments for the record. (Bayer Mem. in Supp. of Omnibus Mot. at 2; Bayer Reply Br. at 2.) Accordingly, we will not revisit our prior analysis with respect to these claims and simply reject Bayer's arguments regarding Count I, II, and V for the same reasons we rejected those arguments in McLaughlin I and McLaughlin II.

Bayer also argues that we should dismiss the loss of consortium claims because the husbands cannot recover for loss of consortium unless their wives have a right to recover and, according to Bayer, the wives assert no cognizable claims. See Nationwide Mut. Ins. Co. v. Consenza, 258 F.3d 197, 206 (3d Cir. 2001) (stating that loss of consortium is a "derivative claim" that is "'always dependent upon the injured spouse's right to recover'" (quoting Scattaregia v. Shin Shen Wu, 495 A.2d 552, 554 (Pa. Super. Ct. 1985)). However, we do not dismiss the female Plaintiffs' claims in their entirety and, thus, we also do not dismiss the male Plaintiffs' loss of consortium claims.

"'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) (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).

III. DISCUSSION

As noted above, Bayer moves to dismiss Count III (Breach of Express Warranty), and Count IV (Negligent Misrepresentation), asserting, inter alia, that the express warranty claim does

not comply with the pleading standards that we set forth in McLaughlin I and McLaughlin II and that the bulk of the negligent misrepresentation claim is preempted for the same reasons that we found the bulk of plaintiffs' fraudulent misrepresentation claims preempted in McLaughlin II.

A. Count III – Breach of Express Warranty

Count III of the Complaint 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," 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.

(Compl. ¶ 197.) The Complaint alleges that these warranties "were specifically negotiated, directed, intended, and expressly communicated to Plaintiffs in such a manner that Plaintiffs understood and accepted them" (id. ¶ 199); that Plaintiffs relied on the warranties (id. ¶ 201); and that the warranties "formed the bases of the bargain between Plaintiffs and Defendants" (id. ¶ 197).

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. Ann. § 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. Ann. § 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 saw or heard, and also believed, the allegedly false advertisements in order to satisfy her obligation to allege that advertisements formed the basis of the bargain. Weinberg v. Sun Co., 777 A.2d 442, 446 (Pa. 2001) (cited in Jeter, 113 F. App'x at 469); 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. 504 (1992).

We previously addressed the sufficiency of the breach of express warranty claim of Essure users in McLaughlin I and McLaughlin II. In McLaughlin I, we dismissed the plaintiffs' breach of express warranty claim with leave to amend, concluding that the complaint did not allege facially plausible claims because it 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. 172 F. Supp. 3d at 823-24. Thereafter, the McLaughlin

plaintiffs amended their breach of warranty claim, and Bayer moved to dismiss the claim. Bayer argued that we should dismiss the amended breach of warranty claim, because the McLaughlin plaintiffs' new complaint again failed to allege sufficient facts to give rise to an inference that the alleged misrepresentations constituted enforceable warranties, which formed the basis of the parties' bargains. However, we rejected that argument and denied Bayer's request that we dismiss the amended breach of warranty claim. We explained: "[W]hile 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 new complaint remedied this deficiency. McLaughlin II, 2017 WL 697047, at *10. Specifically, we observed that the new complaint "include[d] the date on which each Plaintiff encountered each warranty, where each Plaintiff was when she encountered the warranty, and the source of each warranty." Id. We likewise observed that the new complaint alleged "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." Id. (quotations omitted)

Bayer now argues that the Dunstan Complaint suffers from the same deficiencies as the complaint we considered in McLaughlin I in that it fails to allege sufficient facts concerning each individual Plaintiff so as to render the breach of warranty claims plausible. Bayer focuses on the Complaint's failure to allege the date on which each Plaintiff encountered each warranty or the

precise location of each Plaintiff when she encountered each warranty. It further contends that the individual Dunstan complaints, taken together, implausibly allege that each of the hundreds of Plaintiffs encountered the exact same brochures and website pages, and relied on the same 20 statements, in deciding to have Essure implanted, even though they had their Essure devices implanted at different times over the span of a decade.

We conclude, however, that the Complaint meets the standards that we set forth in McLaughlin I and McLaughlin II. While the amended complaint that we considered in McLaughlin II alleged the precise date on which each plaintiff encountered each warranty and the precise location where she encountered it, and we found that such factual allegations satisfied plaintiffs' obligation to allege the circumstances under which each plaintiff read or saw each particular warranty, we did not hold that allegations of precise dates and locations were necessary to state a plausible claim. Rather, we required only "sufficient facts to support a reasonable inference that the warranties were the bases of the parties' bargains." McLaughlin II, 2017 WL 697047, *10.

Here, the Complaint, unlike the complaint at issue in McLaughlin I, alleges with respect to each warranty: (1) that the Plaintiffs saw and read the warranty when they were researching birth control options, (2) the type of publication (print or internet) in which the warranty appeared and often the name of the publication, and (3) that the warranty became the basis of the bargains between Plaintiffs and Bayer because the Plaintiffs wanted a reliable and safe type of birth control that complied with the various representations in the warranties. (See generally Compl. ¶ 197.) We therefore conclude that the Complaint sufficiently pleads the essential elements of a breach of express warranty claim. See McLaughlin II, 2017 WL 697047, at *10 (stating that complaint must "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"). Moreover, we find this conclusion to be consistent with our Opinions in McLaughlin I and McLaughlin II.[6]

In sum, we conclude that the Complaint alleges sufficient facts to support a reasonable inference that the warranties were the bases of the parties' bargains and thereby states a plausible claim for breach of express warranty. We therefore deny Bayer's Motion insofar as it requests that we dismiss Count III.[7]

D. Count IV – Negligent Misrepresentation

Count IV of the Complaint asserts a claim for negligent misrepresentation based on the same statements that are the subject of the express warranty claim in Count III. (See Compl. ¶ 208.) Bayer argues that we should dismiss the bulk of this claim as expressly preempted based on the same analysis we employed in dismissing the bulk of plaintiffs' fraudulent misrepresentation claim in McLaughlin II.

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[6] We note that the complaints in the Dunstan Cases present special challenges because of the parties' agreement to proceed – at least initially – on complaints that have as many as 90 individual Plaintiffs joined in a single action. Each complaint in the five McLaughlin Cases had just one plaintiff and, thus, could realistically allege the plaintiff's personal circumstances that gave rise to her express warranty claim. In contrast, such factual specificity is not practical in the Dunstan complaints, each of which asserts the claims of as many as 94 Plaintiffs, already contains upwards of 400 paragraphs, and already spans as many as 107 pages in length. See, e.g., Compl. in Burgis v. Bayer Corp., Docket No. 32, Civ. A. No. 16-3589 (asserting the claims of 94 Plaintiffs in 397 paragraphs). Indeed, due in part to the inherent difficulties of proceeding with such collective complaints, the parties have agreed that Plaintiffs will complete detailed fact sheets that, among other things, will specifically identify all written or electronic information regarding Essure that each Plaintiff reviewed prior to her procedure as well as the dates on which she received and reviewed the information. Accordingly, we observe that, to the extent that Bayer continues to perceive deficiencies in the factual allegations in the Dunstan complaints, it will obtain the factual detail it desires in Plaintiffs' fact sheets.

[7] Bayer argues, alternatively, that we should dismiss Count III because it is expressly preempted but, at the same time, it recognizes that we previously rejected that same argument in McLaughlin I. 172 F. Supp. 3d at 822-23. We likewise reject that argument now for the reasons set forth in McLaughlin I. Id.

1. 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 MDA. 552 U.S. at 321-22. First, we must ascertain whether the federal government has established requirements applicable to the medical device at issue and, in this regard, the Supreme Court has concluded that all Class III devices are subject to requirements that satisfy this first step in the analysis. 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)). Our express preemption inquiry thus focuses on the second step, which requires us to 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 (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).

2. Our Prior Opinions

In McLaughlin I, we considered Bayer's arguments in a motion for judgment on the pleadings that the negligent and fraudulent misrepresentation claims in the McLaughlin cases were expressly preempted and also failed to state claims pursuant to Rule 12(b)(6). We denied the motion with regard to Bayer's express preemption arguments, rejecting Bayer's argument that the McLaughlin plaintiffs' misrepresentation claims were necessarily expressly preempted, because misrepresentation claims, as a class, seek different or additional warnings regarding the safety of Essure than those required by the FDA. McLaughlin, 172 F. Supp. 3d at 826-28. We also stated, however, that we had 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." Id. at 828. We also denied Bayer's motion insofar as it sought dismissal of the negligent misrepresentation claim for failure to state a claim upon which relief can be granted, concluding that the negligent misrepresentation claim met Rule 12(b)(6)'s pleading standards. Id. at 830. However, we granted the motion insofar as it sought dismissal of the fraudulent misrepresentation claim, because we found that the fraudulent misrepresentation claim had not been plead with the particularity required by Federal Rule of Civil Procedure 9(b). Id. at 829.

After the plaintiffs in the McLaughlin cases filed amended complaints, Bayer again moved

to dismiss the misrepresentation claims on express preemptions grounds. In McLaughlin II, we rejected that argument with respect to the negligent misrepresentation claim, noting that we had permitted that claim to proceed in McLaughlin I and, thus, Bayer's motion to dismiss that claim amounted to an untimely motion for reconsideration. 2017 WL 697047, at *2 n.4. However, we addressed Bayer's express preemption argument with respect to the fraudulent misrepresentation claim. In doing so, we explained that to assert a misrepresentation claim that was not expressly preempted, the plaintiffs were required 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.'" 2017 WL 697047, at *12 (quoting McLaughlin I, 172 F. Supp. 3d at 827). We stated that a claim based on such a statement "'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 McLaughlin I, 172 F. Supp. 3d at 827-28).

We then exhaustively compared each alleged misrepresentation in the McLaughlin complaint to statements in FDA-approved materials, and carefully analyzed whether each statement was consistent with an FDA-approved statement. Id. at *12-15. Upon doing so, we concluded that claim was expressly preempted under Riegel insofar as it was grounded on the great bulk of the alleged misrepresentations. Id. We also dismissed the plaintiffs' fraudulent misrepresentation claim insofar as it was grounded on a statement regarding the scope of the Essure training program, concluding that the statement about training was directed to physicians, not plaintiffs and, thus, the complaint did not plausibly allege that Bayer intended to induce Plaintiff's reliance on the statement, which is a required element of a misrepresentation claim under prevailing law. Id. at *17.

3. Negligent Misrepresentation Claims in the Dunstan Cases

Bayer now argues that we should apply the same express preemption analyses to the negligent misrepresentation claim in the Dunstan Cases that we employed with respect to the fraudulent misrepresentation claim in McLaughlin II, and that we should therefore dismiss the bulk of the negligent misrepresentation claim as expressly preempted.[8] It also argues that we should dismiss the negligent misrepresentation claim insofar as it is grounded on the statement regarding the scope of training, which we concluded in McLaughlin II was not an actionable misrepresentation because it was directed at physicians. At the same time, Bayer does not argue that there is any basis on which to dismiss the negligent misrepresentation claim insofar as it is based on the statements in Paragraphs 208(w), (cc), (gg), and (hh).[9]

Plaintiffs do not address Bayer's argument that, employing the analysis in McLaughlin II, we must dismiss the bulk of the negligent misrepresentation claim for the same reasons we dismissed the bulk of the fraudulent misrepresentation claim. Rather, they simply argue, as they

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[8] There is no dispute that the statements giving rise to the fraudulent misrepresentation claim in the McLaughlin Cases are the same statements as those giving rise to the negligent misrepresentation claim in the Dunstan Cases.

[9] In McLaughlin II, we denied Bayer's motion to dismiss the fraudulent misrepresentation claim insofar as it was based on three of these alleged misstatements: (1) "In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks" (Compl. ¶ 208(w)); (2) "Step Two: 'pregnancy cannot occur'; Step Three: the Confirmation" (id. ¶ 208(cc)); and (3) "there was . . . no pain" (id. ¶ 208(hh)). McLaughlin II, 2017 WL 697047, at *19. Thus, Bayer does not seek to dismiss the negligent misrepresentation claim to the extent that it is grounded on these statements.

Bayer also does not seek to dismiss the negligent misrepresentation claim based on a fourth statement, i.e., that "[t]he viewable portion of the microinsert . . . does not irritate the lining of the uterus." See Compl. ¶ 208(gg). In McLaughlin II, we dismissed the fraudulent misrepresentation claim based on that statement for failure to allege that Bayer knew of, or recklessly disregarded, that the device cause such irritation, which is an element that was particular to the fraudulent misrepresentation claim. 2017 WL 697047, at *17; see Gibbs v. Ernst. 647 A.2d 882, 889 (Pa. 1994). Accordingly, Bayer acknowledges that, under our prior reasoning, Plaintiff can still pursue a negligent misrepresentation claim grounded on that same statement.

did in McLaughlin II, that the alleged misrepresentations "run counter to FDA approved labeling" and thus, are not consistent with that labeling and are not subject to express preemption. (Pls.' Opposition to Defs.' Omnibus Mot. to Dismiss, at 10.)

We will not, however, revisit our conclusion in McLaughlin II that misrepresentation claims are expressly preempted if they are based on statements that are "completely consistent with statements in FDA-approved materials and do not undermine – or overstate – the approved and/or required statements in those materials," and that certain statements on which the McLaughlin II, 2017 WL 697047, at *12. Moreover, we will not revisit our conclusion that certain alleged misstatements upon which the McLaughlin plaintiffs relied in their fraudulent misrepresentation claim – and on which the Dunstan Plaintiffs now rely in their negligent misrepresentation claim – are, in fact, "completely consistent with statements in FDA-approved materials and do not undermine – or overstate – the approved and/or required statements in those materials." Id. at *12-15; (see Compl. ¶¶ 208(m)-(r), (t)-(v), (x)-(z), (aa)-(bb), (dd)-(ff).) We therefore conclude that the Dunstan Plaintiffs' negligent misrepresentation claim is expressly preempted insofar as it is based on the statements in Paragraphs 208(m)-(r), (t)-(v), (x)-(z), (aa)-(bb), and (dd)- (ff) of the Dunstan Complaint.

We likewise will not revisit our conclusions in McLaughlin II that Bayer's statement describing physician training is directed to physicians and, thus, is not an actionable misrepresentation under Pennsylvania law. Id. at *17. We therefore conclude that the negligent misrepresentation claim fails to state a claim upon which relief can be granted insofar as it rests on the statement in Paragraph 208(s) of the Dunstan Complaint, because the Complaint does not plausibly allege that Bayer made that statement with the intent to induce Plaintiffs' reliance.

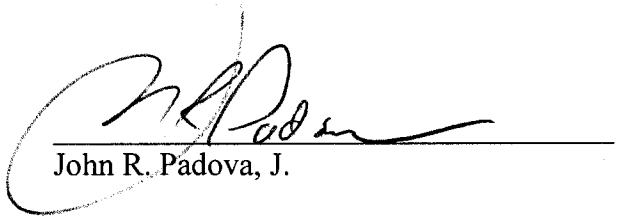
Consequently, we grant Bayer's Motion to the extent that it asks us to dismiss the negligent misrepresentation claim insofar as it is grounded on the statements set forth in Paragraphs 208(m)-(v), (x)-(z), (aa)-(bb), and (dd)- (ff).

IV. CONCLUSION

For the foregoing reasons, we grant Bayer's Motion to Dismiss insofar as it seeks to dismiss Count IV, the negligent misrepresentation claim, except insofar as that claim rests on the specified misrepresentations in Paragraphs 208(w), (cc), (gg), and (hh). In all other respects, we deny the Motion to Dismiss.

An appropriate Order follows.

BY THE COURT:



John R. Padova, J.