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

ROY R. COGSWELL and NANCY COGSWELL,	)	
Plaintiffs,	)	Case No. 15-295
v.	)	Judge Cathy Bissoon
WRIGHT MEDICAL TECHNOLOGY, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

For the reasons stated below, the Wright Medical Technology Group's ("Defendant's") Motion to Dismiss (Doc. 4) will be GRANTED IN PART and DENIED IN PART.

I. MEMORANDUM

BACKGROUND

Roy Cogswell ("Plaintiff" or "Mr. Cogswell")[1] alleges that on July 11, 2007, he underwent a right total hip replacement surgery, whereby his right hip was replaced with the Wright Hip System, designed, manufactured, and/or sold by Wright Medical Technology[2] ("Defendant"). Compl. (Doc. 1, Ex. A) ¶¶ 5-7. On March 31, 2008, Plaintiff underwent a left

[1] This action is additionally brought by the wife of Roy Cogswell, Nancy Cogswell ("Mrs. Cogswell"). Compl. at ¶ 1. Mrs. Cogswell brings only the loss of consortium claim, which is not directly at issue in this Motion to Dismiss. As Mr. Cogswell is the primary plaintiff, the Court will refer to him as "Plaintiff."

[2] Plaintiffs' initial Complaint (Doc. 1) was directed against both Wright Medical Technology, Inc. and Wright Medical Group, Inc. On March 13, 2015, Plaintiffs filed a Motion to Dismiss Defendant Wright Medical Group (Doc. 2) which was granted (Doc. 7). In light of the dismissal of Defendant Wright Medical Group, Inc. from the instant action, the Court construes the Complaint as against Defendant Wright Medical Technology, Inc. only, even where language pertaining to multiple defendants is used.

total hip replacement where he once again received the Wright Hip System. Id. at ¶¶ 8-9. Following these surgeries, Plaintiff alleges that he experienced pain in his right hip and underwent a revision surgery of his right hip, during which elements of the Wright Hip System were replaced with new parts. Id. at ¶¶ 10, 13-14. Following the revision surgery, Plaintiff alleges that he experienced further pain in his right hip and underwent a relocation surgery of the right hip, as the replacement had become dislocated. Id. at ¶¶ 17-18. Thereafter, Plaintiff alleges that he experienced additional complications for which he was hospitalized on several occasions. Id. at ¶ 19. Plaintiff alleges that Defendant's development and marketing of the defective Wright Hip System caused Plaintiff to undergo multiple hip operations and suffer serious medical complications. Id. at ¶ 36, 41.

Plaintiff and his wife, Nancy Cogswell (together, "Plaintiffs"), filed a ten-count Complaint in the Court of Common Pleas of Lawrence County on February 5, 2015, asserting causes of action in strict liability for manufacturing defect, failure to warn, and design defect (Counts I-III), as well as causes of action for negligence (Count IV), breach of express and implied warranties (Counts V-VI), fraudulent misrepresentation and fraudulent concealment (Counts VII-VIII), negligent misrepresentation (Count IX), and loss of consortium (Count X). The case was removed to this Court on March 3, 2015, on the basis of diversity jurisdiction. Notice of Removal (Doc. 1) ¶ 4. Defendant filed this Motion to Dismiss Counts I, II, III, V, VI, VIII, and IX on March 13, 2015, pursuant to Federal Rule of Civil Procedure 12(b)(6). Def.'s Mot. (Doc. 4).

ANALYSIS

A. *Strict Liability – Manufacturing Defect (Count I)*

Defendant contends that Plaintiff's strict liability claims for his medical device are barred by Pennsylvania law. Def.'s Br. in Supp. (Doc. 5), 3. Although the Pennsylvania Supreme Court has not explicitly held this to be the case, the Court is inclined to agree.

The Pennsylvania Supreme Court has held that, where a prescription drug is at issue, Comment k of the Restatement (Second) of Torts bars strict liability claims. Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996). Comment k, titled "Unavoidably unsafe products," provides that:

> [t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis in original). The Pennsylvania Supreme Court later returned to its holding in Hahn and again declined to hold prescription drug manufacturers strictly liable, consistent with the language of Comment k. Lance v. Wyeth, 85 A.3d 434, 438 (Pa. 2014). The Pennsylvania Superior Court has outlined the policy reasons for this position, explaining that prescription drugs are both inherently dangerous and greatly beneficial to society. Hahn v. Richter, 628 A.2d 860, 871 (Pa. Super. Ct. 1993) aff'd, 673 A.2d 888 (Pa. 1996). To hold manufacturers of prescription drugs liable for "unforeseeable reactions to their products . . . would stifle the incentive to produce new products." Id.

Plaintiff argues that although Comment k applies to prescription drugs, it does not apply to the product at issue here, which is a medical device. Pl.'s Br. in Opp'n (Doc. 11) at 4. Plaintiff argues that the Wright Hip System is distinguishable from prescription drugs, which are

unavoidably unsafe, because the risks alleged in this case could have been avoided. Id. at 5. Such a distinction, according to Plaintiff, weighs in favor of declining to read Comment k as applicable in the instant case. This particular argument is unpersuasive, as the law in Pennsylvania requires the Court to determine the application of Comment k categorically, not to conduct a case-by-case analysis of each particular product. Lance, 85 A.3d at 442 n. 11, 452 n. 21; see Kee v. Zimmer, Inc., 871 F. Supp. 2d 405, 410 (E.D. Pa. 2012).

Although the Pennsylvania Supreme Court has not yet decided whether the application of Comment k extends to medical devices, the Superior Court of Pennsylvania explained that there is "no reason why the same rational [*sic*] applicable to prescription drugs may not be applied to medical devices." Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (affirming the trial court determination that the plaintiffs' strict liability claim for a medical device was barred by Comment k). Several federal district courts applying Pennsylvania law have similarly extended the application of Comment k to medical devices. See, e.g., Terrell v. Davol, Inc., No. 13-5074, 2014 WL 3746532, at *4 (E.D. Pa. July 30, 2014); Gross v. Stryker Corp., 858 F. Supp. 2d 466, 482 (W.D. Pa. 2012); Horsmon v. Zimmer Holdings, Inc., No. 11-1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011).

Plaintiff also argues that a product is only covered by Comment k if it fulfills the "caveats" that it is "properly prepared, and accompanied by proper directions and warning." Pl.'s Br. in Opp'n at 5. However, the courts in Lance and Hahn did not recognize such "caveats," instead barring strict liability for *all* prescription drug cases. See Lance, 85 A.3d at 453 (holding that, "for policy reasons this Court has declined to extend strict liability into the prescription drug arena"); Hahn, 673 A.2d at 891 (holding that "where the adequacy of warnings associated with prescription drugs is at issue . . . the manufacturer's negligence, is the only

recognized basis of liability"). In Horsmon, 2011 WL 5509420, at *2, this Court noted that "while other jurisdictions might recognize caveats to Comment k's exclusion of strict liability claims, this Court must apply Pennsylvania law, which does not recognize such caveats." Thus, Plaintiff's argument that exceptions be made is unpersuasive, and the Court will apply Comment k to medical devices.

Plaintiff argues that even if Comment k applies in the instant case, it does not bar strict liability for the manufacturing defect claim. Pl.'s Br. in Opp'n 8. Plaintiff relies on Doughtery v. C.R. Bard, Inc., No. 11-6048, 2012 WL 2940727 (E.D. Pa. July 18, 2012), which states that Comment k does not intend to shield a seller from liability for products which have been "mismanufactured." Id.

There is currently a split among federal district courts applying Pennsylvania law on the application of strict liability to manufacturing defect claims. Some have reasoned that strict liability claims for manufacturing defect are not barred under Hahn, which they believe applies only to failure to warn cases. E.g., Kline v. Zimmer Holdings, Inc., No. 13-513, 2013 WL 3279797, at *5 (W.D. Pa. June 27, 2013); Killen v. Stryker Spine, No. 11-1508, 2012 WL 4498865, at *4 (W.D. Pa. Sept. 28, 2012); Doughtery, No. 2012 WL 2940727, at *4-5. Strict liability for manufacturing defects may also rightly incentivize sellers to ensure quality control. Doughtery, 2012 WL 2940727, at *5. However, other courts have dismissed all alleged strict liability claims, including manufacturing defect, using the reasoning in Hahn, Lance, and Comment k. E.g., Terrell, 2014 WL 3746532, at *5 ("[I]n the case of prescription drugs and devices, strict liability claims based on all three defective conditions, including manufacturing defects, are barred in Pennsylvania."); Rowland v. Novartis Pharm. Corp., 34 F. Supp. 3d 556, 568-69 (W.D. Pa. 2014). In Terrell, for example, that court reasoned that allowing strict liability

for manufacturing defects may stifle a seller's incentive to produce new, useful products. Terrell, 2014 WL 3746532, at *4.

Plaintiff cites the Superior Court of Pennsylvania in Lance v. Wyeth, 4 A.3d 160 (Pa. Super. Ct. 2010) to support his argument that a manufacturer of prescription drugs may still be held strictly liable for a manufacturing defect. Pl.'s Br. in Opp'n 8. However, the Pennsylvania *Supreme Court* in Lance declined to hold prescription drug manufacturers strictly liable and did not include an exception for manufacturing defects. Lance, 85 A.3d at 438. Had the Pennsylvania Supreme Court intended an exception to the strict liability rule, it presumably would have articulated one. Although the Pennsylvania Supreme Court has not spoken directly to the issue of whether a strict liability manufacturing defect claim encompassed by Comment k is barred by Pennsylvania law, precedent indicates that it would reach the conclusion that such a claim is barred. And, because medical devices fall within the bounds of Comment k, just as prescription drugs do, Plaintiff's manufacturing defect claim will be dismissed for failure to state a claim.

B. *Strict Liability – Failure to Warn (Count II)*

Plaintiff asserts that a strict liability claim for failure to warn should be permitted because Comment k does not apply to the medical device at issue here. Pl.'s Br. in Opp'n at 4. As discussed above, Comment k applies to medical devices, and thus, Plaintiff's claim is barred by the holding in Hahn, 673 A.2d 888. Hahn itself was a failure to warn case and the Court relies on that decision to bar Plaintiff's failure to warn claim here. Plaintiff's strict liability claim for failure to warn will be dismissed.

C. *Strict Liability – Design Defect (Count III)*

Plaintiff contends that even if Comment k applies, the strict liability design defect claim is viable because Plaintiff has set forth a feasible alternative design. Pl.'s Br. in Opp'n 6-7. However, this argument is unpersuasive. The Pennsylvania Supreme Court has made clear that strict liability does not extend to manufacturers of prescription drugs, Lance, 85 A.3d at 453, and by extension, to manufacturers of medical devices. Whether Plaintiff could potentially conceive of an alternative design is immaterial. Thus, the Court will dismiss Plaintiff's strict liability claim for design defect.

D. *Breach of Express Warranty (Count V)*

Defendant argues that Plaintiff's express warranty claim is barred by Pennsylvania law. Def.'s Reply (Doc. 12) at 4. Federal courts in Pennsylvania are split on the viability of an express warranty claim for a medical device. Killen, 2012 WL 4498865, at *4. Plaintiff once again relies on Doughtery 2012 WL 2940727, which held that breach of express warranty claims against manufacturers of prescription drugs and medical devices are not barred under Pennsylvania law because of their contractual nature. Pl.'s Br. in Opp'n at 12. The court in Doughtery additionally explained that barring all non-negligence claims would extend the holding of Hahn beyond its scope. 2012 WL 2940727, at *9; see also Kee, 871 F. Supp. 2d at 410 n. 4.

Numerous other courts, however, have barred express warranty claims, relying on the statement in Hahn that "where the adequacy of warnings associated with prescription drugs is at issue . . . the manufacturer's negligence, is the only recognized basis of liability." 673 A.2d at 891; see also Rowland, 34 F. Supp. 3d at 569 (dismissing an express warranty claim because "[c]ourts have interpreted Hahn broadly to bar all non-negligence based claims asserted against a

manufacturer of prescription drugs"); Salvio v. Amgen, Inc., 810 F. Supp. 2d 745, 755-56 (W.D. Pa. 2011); Leonard v. Taro Pharm. USA, Inc., No. 10CV1341, 2010 WL 4961647, at *5 (W.D. Pa. Dec. 2, 2010); Aaron v. Wyeth, No. 2:07CV927, 2010 WL 653984, at *11 (W.D. Pa. Feb. 19, 2010) (dismissing an express warranty claim because "Hahn requires that this Court dismiss all claims that do not rest on a theory of negligence"); Kline v. Pfizer, Inc., No. 08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008). This Court will follow the majority of Pennsylvania federal courts and dismiss Plaintiff's claim for breach of express warranty for failure to state a claim as a matter of law.

E. *Breach of Implied Warranty (Count VI)*

Defendant asserts that Plaintiff's breach of implied warranty claim is barred by Pennsylvania law. Def.'s Br. in Supp. 14. The Superior Court of Pennsylvania addressed this issue for prescription drugs, explaining that "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes', as each individual for whom they are prescribed is a unique organism." Makripodis by Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374 at 377 (Pa. Super. Ct. 1987). A number of Pennsylvania federal courts have extended this reasoning to preclude implied warranty of fitness and merchantability claims for medical devices as well. E.g., Terrell, 2014 WL 3746532, at *7; Horsmon, 2011 WL 5509420, at *3; Kester v. Zimmer Holdings, Inc., No. 210-CV-00523, 2010 WL 2696467, at *11 (W.D. Pa. June 16, 2010) (invoking the same logic for implied warranties that bars strict liability for medical devices); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 752 (E.D. Pa. 2007) (dismissing both implied warranty of fitness and merchantability claims); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 753 (W.D. Pa. 2004) (noting that "there is no basis in law or logic to treat prescription drugs differently than prescription medical devices").

Plaintiff argues that the implied warranty claim is not barred because, unlike the prescription drug in Makripodis, the Wright Hip System is not an "unavoidably unsafe" product under Comment k. Pl.'s Br. in Opp'n at 13. However, this Court has determined, both in this case and in previous cases, that medical devices fall under the umbrella of Comment k. See Horsmon, 2011 WL 5509420, at *2. Thus, Plaintiff's claim for breach of implied warranties will be dismissed.

F. *Fraudulent Misrepresentation (Count VII) and Fraudulent Concealment (Count VIII)*

Plaintiff voluntarily dismisses his claim for fraudulent misrepresentation and fraudulent concealment. These claims will be dismissed.

G. *Negligent Misrepresentation (Count IX)*

Defendant contends that a heightened pleading standard under Federal Rule of Civil Procedure 9(b) applies to negligent misrepresentation claims. Def.'s Br. in Supp. at 10 (citing Kester, 2010 WL 2696467; Hanover Ins. Co. v. Ryan, 619 F. Supp. 2d 127, 142 (E.D. Pa. 2007)). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The majority of district courts within the Third Circuit have declined to apply this heightened pleading standard to claims of negligent misrepresentation. See, e.g., Keybank Nat'l Ass'n v. Voyager Grp., LP, No. 09-1238, 2010 WL 441464, at *10 (W.D. Pa. Feb. 4, 2010); Sims v. Viacom, Inc., No. 09-3521, 2009 WL 3856667, at *2 (E.D. Pa. Nov. 17, 2009) ("While fraud falls squarely within the heightened pleading standard required by Rule 9(b), claims of negligent misrepresentation are subject to notice pleading under Rule 8(a)."); Bionix Dev. Corp. v. Sklar Corp., No. 07-CV-4465, 2009 WL 3353154, at *3 (E.D. Pa. Oct. 14, 2009); see also Shapiro v. UJB Fin. Corp., 964 F.2d 272, 288 (3d Cir. 1992) (noting that the 9(b) standard applies to claims grounded in fraud

rather than negligence). This Court will follow the majority of Third Circuit courts and decline to apply a heightened pleading standard to claims of negligent misrepresentation.

Defendant then argues that Plaintiff's allegations do not even meet the lower pleading requirements of Rule 8(a) and the standards established in Twombly and Iqbal. Rule 8(a) requires that pleadings contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). The complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Mere '"labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Ashcroft, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 555). Although Defendant claims that Plaintiff's allegations do not have the requisite level of particularity, Plaintiff does, in fact, allege a series of specific misrepresentations made by Defendant about the safety and performance of the Wright Hip System. Compl. ¶ 40(a)–(j). Plaintiff additionally alleges that Defendant intended Plaintiff to rely on its misrepresentations, which Plaintiff indicates he did. Id. at ¶ 39, 41, 106. Thus, Plaintiff's allegations are sufficient under the Rule 8(a) standard to place Defendant on notice of the misconduct charged.

Defendant questions Plaintiff's use of "collective references" in the Complaint, citing Kester, 2010 WL 2696467. Def.'s Br. in Supp. 12. However, in Kester, the plaintiff failed to allege that any one of the *seven* defendants even manufactured the drug at issue, 2010 WL 2696467, at *7, whereas here, Plaintiff clearly has assigned responsibility for the manufacture of the Wright Hip System. Additionally, here, there is only one defendant remaining in the case, and the remaining defendant is a subsidiary of the defendant who was dismissed. See Compl. ¶ 3. Thus, Defendant's reliance on Kester is misplaced, and making all inferences in the light most

favorable to Plaintiff, it can be inferred that Plaintiff intends all allegations against the remaining Defendant.

Defendant additionally argues that "Plaintiffs' purported fraud-based claims appear to be allegations of fraud on the FDA," not Plaintiff, and thus, these claims are not actionable. Def.'s Br. in Supp. at 13. However, Plaintiff alleges that misrepresentations "were communicated to the medical community and the general public, *including Plaintiff*, with the intent that the medical community and general public, *including Plaintiff*, would rely." Compl. ¶ 39 (emphasis added). The explicit inclusion of Plaintiff in these allegations makes clear that Plaintiff alleges misrepresentations were made to him personally. Therefore, the motion to dismiss Plaintiff's negligent misrepresentation claim will be denied.

II. ORDER

For the reasons stated above, Defendant Wright Medical Technology's Motion to Dismiss (Doc. 4) is **GRANTED IN PART and DENIED IN PART**. With respect to Plaintiff's claim of negligent misrepresentation, the Motion to Dismiss is DENIED. In every other respect, the Motion to Dismiss is GRANTED.

Specifically, the following claims are hereby **DISMISSED WITH PREJUDICE**: Plaintiff's strict liability claim for manufacturing defect (Count I), strict liability claim for failure to warn (Count II), strict liability claim for design defect (Count III), claim for breach of express warranty (Count V), claim for breach of implied warranty (Count VI), claim for fraudulent misrepresentation (Count VII), and claim for fraudulent concealment (Count VIII).

IT IS SO ORDERED.

July 16, 2015

s\Cathy Bissoon
Cathy Bissoon
United States District Judge

cc (via ECF email notification):

All Counsel of Record