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

CATHLEEN CARSON,	)	
	)	
Plaintiff,	)	Case No. 15-830
	)	
v.	)	Judge Cathy Bissoon
	)	
ATRIUM MEDICAL CORPORATION, *et al.*,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM ORDER

For the reasons stated below, the Atrium Medical Corporation, Maquet Cardiovascular US Sales, LLC,[1] Maquet Cardiovascular, LLC and Maquet Medical System USA's Motion to Dismiss (Doc. 17) will be GRANTED IN PART and DENIED IN PART.

I. MEMORANDUM

BACKGROUND[2]

On May 27, 2009, Cathleen Carson ("Plaintiff" or "Ms. Carson") underwent a repair to a right inguinal hernia. Am. Compl. (Doc. 15) at ¶ 26. The hernia was repaired by physicians at Jefferson Regional Medical Center using a polypropylene mesh. Id. The mesh implanted in

[1] Maquet Cardiovascular US Sales, LLC appears to have been incorrectly identified in the caption of this case as "Maquest Cardiovascular US Sales, LLC." Because it is evident from both the Amended Complaint and the pending motion that this is a typographical error, the Court will refer to this Defendant by its correct name. The parties should, at their earliest convenience, file a motion to correct the caption of this case.

[2] The following background facts are taken from Plaintiff's Amended Complaint (Doc. 15). Because the case presently is before this Court on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court accepts as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom. See Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir. 1989). In addition, the Court views all well pleaded factual averments and reasonable inferences in the light most favorable to Plaintiff.

Plaintiff was manufactured, promoted, marketed, distributed and sold by Defendants. Id. at 27. Following the surgery, Plaintiff suffered from a variety of complications, including "severe abdominal pain, inability to eat solid food, difficulty ambulating and severe leg pain due to nerve damage. Id. at 33. Plaintiff has undergone additional surgical procedures, which would be unnecessary but for the complications caused by the mesh implant. Id. at 34. Plaintiff suffers from chronic neuropathic pain, constipation, decreased sensation in her rectal area, pain radiating into her right leg, abdominal pain after eating, right lower quadrant pain, abdominal distention, weight loss, weakness and cramps, all as a result of the injuries she suffered due to the polypropylene mesh. Id. at 35. Plaintiff has been told by her physicians, that the mesh implant cannot safely be removed. Id. at 36-37. Accordingly, Plaintiff will continue to suffer from this harm and take medication for the pain and discomfort for the remainder of her life. Id. at 37-38.

On June 24, 2015, Plaintiff filed a complaint against Atrium Medical Corporation, Does 1-20, Getinge Group, Getinge USA, Inc., Maquet Cardiovascular US Sales, LLC, Maquet Cardiovascular, LLC, Maquet Medical Systems USA, and Premier Healthcare Alliance L.P.. Compl. (Doc. 1). Plaintiff voluntarily dismissed Premier Healthcare Alliance on August 5, 2015. (Doc. 3). On September 8, 2015, Defendant Atrium Medical Corporation Filed a Motion to Dismiss for Failure to State a Claim. (Doc. 6). Plaintiff subsequently filed an Amended Complaint against Atrium Medical Corporation, Does 1-20, Getinge Group, Getinge USA, Inc., Maquet Cardiovascular US Sales, LLC, Maquet Cardiovascular, LLC, and Maquet Medical Systems USA. (Doc. 15). Plaintiff's six-count Amended Complaint, filed on October 30, 2016, asserts causes of action in strict liability for failure to warn, (Counts I), as well as causes of action for negligence (Count II), breach of express and implied warranties (Counts III-IV), fraud (Count V), and negligent misrepresentation (Count VI). Defendants Atrium Medical

Corporation, Maquet Cardiovascular US Sales, LLC, Maquet Cardiovascular, LLC, and Maquet Medical Systems USA (hereinafter "Defendants") filed this Motion to Dismiss the Complaint on November 23, 2015, pursuant to Federal Rules of Civil Procedure 8, 9 and 12(b)(6). Def.'s Mot. (Doc. 17).

ANALYSIS

A. *Strict Liability – Failure to Warn (Count I)*

Defendants contend that Plaintiff's strict liability claim is barred by Pennsylvania law. (Doc. 18) at 5-7. Although the Pennsylvania Supreme Court has not explicitly held this to be the case, many courts, including this Court, have so held. See e.g., Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006); Cogswell v. Wright Medical Tech., Inc., 2015 WL 4393385, at *5(W.D. Pa. July 16, 2015); Gross v. Stryker Corp., 848 F. Supp. 2d 466, 482 (W.D. Pa. 2012); Horson v. Zimmer Holdings, Inc., 2011 WL 5509420, at *2 (W.D. Pa. Nov 10, 2011); Kee v. Zimmer, Inc., 871 F. Supp. 2d 405, 409 (E.D. Pa. 2012).

The central issue is whether Comment k of the Restatement (Second) of Torts bars strict liability claims for medical devices. 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). 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, 903 A.2d at 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., 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 2011 WL 5509420, at *2.

Plaintiff argues that, if Comment k applies, a product is only covered by Comment k if it meets the definition that it is "properly prepared, and accompanied by proper directions and warning." (Doc. 19) at 6. However, the Pennsylvania Supreme Court has rejected this exception as it applies to prescription drugs. See Lance v. Wyeth, 85 A.3d 434, 453 (Pa. 2014)(holding that, "for policy reasons this Court has declined to extend strict liability into the prescription drug arena"); Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996)(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, and Cogswell, 2015 WL 4393385, at *3, 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, without exceptions, to medical devices. Accordingly, Plaintiff's strict liability claim for failure to warn will be dismissed.

E. *Negligence (Count II)*

Plaintiff makes a number of negligence related claims without specifically stating on which theory or theories of negligence she premises her claims. Defendants argue first, that to the extent Plaintiff is asserting a negligent failure to test claim, the theory fails as a matter of law, as Pennsylvania law imposes no affirmative duty to test. (Doc. 18) at 7-8. Next, Defendants argue that to the extent that Plaintiff is asserting a negligent marketing claim, that claim is likewise not recognized by Pennsylvania law. Id. Defendants also argue that Plaintiff's manufacturing defect claim is really a *res ipsa loquitor* claim that fails to meet the necessary elements of such a claim. (Doc. 21) at 3. Finally, Defendants argue that to the extent Plaintiff argues a negligent failure to warn claim, it too must fail due to Pennsylvania's learned intermediary doctrine. (Doc. 18) at 8-9

Plaintiff concedes that Pennsylvania law prohibits her negligent marketing and negligent testing claims. However, she asserts her negligence claims for manufacturing defect and failure to warn are plausible. The manufacturing defect claim should proceed, she argues, because it reasonably can be inferred, based on the allegations in the complaint, that the product was manufactured in such a way that it was unreasonably safe and that lack of safety led to Plaintiff's health problems. As to the negligent failure to warn claim, Plaintiff argues that she has put forth sufficient facts in the Amended Complaint to establish that the physicians in this case were not adequately informed, thus overcoming Pennsylvania's learned intermediary doctrine.

As to the manufacturing defect claim, the Court agrees with Defendants that the allegations in Plaintiff's complaint are conclusory statements insufficient to overcome the pleading standard established by the United States Supreme Court in Iqbal and Twombly. 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). Plaintiff does not point to specific facts to support negligence in the manufacturing process; she simply makes general statements that Defendants were negligent in the manufacturing process. See (Doc. 15) at ¶¶ 52 and 52(b). Under Iqbal and Twombley, that is not enough. Accordingly, Plaintiff's manufacturing defect claim will be dismissed without prejudice.

As to Plaintiff's failure to warn claim, it is well established that a "manufacture's duty to warn is directed toward physicians," not to the patient or general public. Lance, 85 A.3d at 438 n.6; Kline v. Pfizer, 2008 WL 4787577, *3 (E.D. Pa. Oct. 31, 2008) (citing Baldino v. Castagna, 478 A.2d 807, 812 (Pa. 1984)). Plaintiff makes multiple allegations that not only did Defendants fail to provide adequate warning of the risks associated with the polypropylene mesh to her, but Defendants likewise failed to inform Plaintiff's physicians. See (Doc. 15) at ¶¶ 25, 45(a)-(t), 46-47 and 53. Specifically, she alleges:

> Despite the abundance of scientific and medical information published in the literature relating to the dangerous properties of polypropylene mesh, Defendants made a deliberate decision to ignore these dangers and to aggressively promote polypropylene mesh to healthcare providers and consumers. Defendants misrepresented and concealed from Plaintiff, her physicians and consumers, the serious risks, damages and defects enumerated in this complaint.

(Doc. 15) at ¶ 25. Thus, after reading the Amended Complaint as a whole and in the light most favorable to Plaintiff, the Court finds Plaintiff has alleged sufficient facts to establish that Defendants failed to exercise reasonable care in informing Plaintiff's doctors of the alleged defects of polypropylene mesh, thereby depriving Plaintiff of advice from a fully informed

physician. See Wilson v. Synthes USA Products, LLC, 116 F. Supp. 3d 463, 469 (E.D. Pa. 2015) (finding a negligent failure to warn claim could proceed where plaintiff alleged that physicians were not adequately warned of storage and handling requirements, of manufacturing defects and that the device could fail). Defendants Motion will be denied as to Plaintiff's negligent failure to warn claim.

C. *Breach of Implied Warranty (Count III)*

Defendants assert that Plaintiff's breach of implied warranty claim is barred by Pennsylvania law. (Doc. 18) at 10-11. Plaintiff does not make any specific argument in support of her implied warranty claim. 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, 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., 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").

In a claim for breach of implied warranty of merchantability, "[t]he essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such

goods are used." Makripodis v. Merrell–Dow Pharms., Inc., 523 A.2d 374, 376 (Pa.Super.Ct.1987) (citing Wisniewski v. Great Atl. & Pac. Tea Co., 323 A.2d 744, 746–47 (Pa.Super.Ct.1974); 13 Pa.C.S. § 2314(b)(3)). Since this Court has determined, both in this case and in previous cases, that medical devices fall under the umbrella of Comment k, and thus are unavoidably unsafe products, there can be no breach of implied warranty. See Cogswell 2015 WL 4393385, at *5; Horsmon, 2011 WL 5509420, at *2. Thus, Plaintiff's claim for breach of implied warranty will be dismissed.

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

Defendants argue that Plaintiff's express warranty claim is similarly 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 v. Stryker Spine, 2012 WL 4498865, at *4 (W.D. Pa. Sept. 28, 2012). This Court has previously held such a claim to be barred under Pennsylvania law, Cogswell, 2015 WL 4393385, at *4, and will so find in this case. Plaintiff's claim for breach of express warranty will dismissed.

F. *Fraud (Count V)*

Plaintiff concedes that her fraud claim is barred due to precedential case law. This claim will be dismissed.

G. *Negligent Misrepresentation (Count VI)*

Defendants argue that Plaintiff's allegations as to her negligent misrepresentation count do not meet the pleading requirements of Rule 8(a) and the standards established in Twombly and Iqbal. Defendants argue that the Amended Complaint "fails to aver the statements that are allegedly false, by whom those specific statements were made, in what manner they were

allegedly false, and how the allegedly false nature of the statements induced reliance by Plaintiff and her physicians." (Doc. 18) at 15-16.

Although Defendant claims that Plaintiff's allegations do not have the requisite level of particularity, Plaintiff does, in fact, allege that Defendants marketed the product as "safe, fit and effective for use in hernia repair." (Doc. 15) at ¶ 74. Plaintiff additionally alleges that Defendant intended Plaintiff to rely on its misrepresentations, which Plaintiff indicates she did. Id. at ¶ 77-78. Reading the Amended Complaint as a whole and taking into account Plaintiff's allegations regarding Defendants inadequate warnings, Defendants' misrepresentations and Defendants' failure to provide adequate information to consumers, including Plaintiff, and physicians, id. at ¶ 45(a)-(t), Plaintiff has met the Rule 8(a) standard to place Defendants on notice of the misconduct charged. Moreover, the facts alleged are sufficient to state a claim for negligent misrepresentation.

Therefore, the motion to dismiss Plaintiff's negligent misrepresentation claim will be denied.

II. ORDER

For the reasons stated above, Defendants Atrium Medical Corporation, Maquet Cardiovascular US Sales, LLC, Maquet Cardiovascular, LLC, and Maquet Medical Systems USA's Motion to Dismiss (Doc. 17) is **GRANTED IN PART and DENIED IN PART**. With respect to Plaintiff's claims of negligent failure to warn and 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 failure to warn (Count I), claim for breach of express warranty (Count III), claim for breach of implied warranty (Count IV), and claim for fraud (Count V).

Additionally, the following claims are hereby **DISMISSED WITHOUT PREJUDICE**: Plaintiff's negligence claims for negligent failure to test (Count II), negligent marketing (Count II), and manufacturing defect (Count II).

IT IS SO ORDERED.

June 8, 2016

s\Cathy Bissoon
Cathy Bissoon
United States District Judge

cc (via ECF email notification):

All Counsel of Record