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

PAUL WAGNER, Individually and as Executor of the ESTATE OF REGINA WAGNER, Deceased,	:	
	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	
	:	**NO. 16-4209**
KIMBERLY-CLARK CORPORATION,	:	
Defendant.	:	

MEMORANDUM

STENGEL, J. **December 1, 2016**

I. INTRODUCTION

This is a wrongful death and survival action under Pennsylvania law. The plaintiff's product liability claims against Kimberly-Clark Corporation relate to the defendant's design and manufacture of a feeding tube. The feeding tube was placed in Regina Wagner's body prior to her death. Kimberly-Clark filed a motion to dismiss plaintiff's strict liability claim (Count II) and breach of warranty claim (Count III).[1] I will grant Kimberly-Clark's motion to dismiss the breach of warranty claim, but I will deny Kimberly-Clark's motion to dismiss the manufacturing defect claim.

[1] Kimberly-Clark has not moved to dismiss plaintiff's negligence claim (Count I). Kimberly-Clark indicates that it will file an Answer with respect to that claim "once a determination has been made on this Motion." (Doc. No. 5 at 1 n.1).

II. BACKGROUND[2]

The decedent, Regina Wagner, suffered from Amyotrophic Lateral Sclerosis ("ALS"), commonly known as Lou Gehrig's disease. (Compl. ¶ 5). Due to her ALS, Ms. Wagner experienced dysphagia: difficulty or discomfort in swallowing. (Id.). Because of these complications, she arranged to have a percutaneous gastrostomy tube (*i.e.*, a feeding tube) placement procedure. (Id.)

In 2014, Ms. Wagner went to Hershey Medical Center to have the feeding tube installed. (Id.) While her anesthesia was being administered, she suffered an adverse reaction that caused her to stop breathing. (Id. ¶ 6). After she recovered, Ms. Wagner made arrangements to come back to Hershey Medical Center at a later date for the procedure. (Id. ¶ 7). Ms. Wagner returned to Hershey Medical Center on March 26, 2014, for placement of the feeding tube. (Id. ¶ 8). During this procedure, a part of the feeding tube—the dilator—"popped into [Ms. Wagner's] stomach and was un-retrievable." (Id. ¶ 9). The medical staff determined that they could retrieve the dilator from Ms. Wagner's stomach. (Id.) Nevertheless, they determined that to do so would be unsafe "given the stiffness of the overlapping dilators." (Id.)

Medical staff performed an upper endoscopy for the purpose of removing the dilator from Ms. Wagner's stomach. (Id. ¶ 10). The dilator was able to be dislodged. (Id.) However, during this upper endoscopy, Ms. Wagner's oxygen saturations dropped

---

[2] Because this is a motion to dismiss for failure to state a claim, I will "accept all [plaintiff's] factual allegations as true" and "construe the complaint in the light most favorable to the plaintiff." Bruni v. City of Pittsburgh, 824 F.3d 353, 360 (3d Cir. 2016). However, my acceptance of all allegations as true does not apply to "legal conclusions." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

multiple times. (Id. ¶ 11). The medical staff "felt that the size of the object and the lack of flexibility" would have caused damage had they attempted to remove the dilator through Ms. Wagner's throat. (Id. ¶ 10). Therefore, the emergency general surgery department was consulted to perform an exploratory laparotomy to remove the dilator. (Id. ¶ 12). Dr. Quac Thai Vu was ultimately able to remove the dilator by performing this procedure. (Id. ¶¶ 13–14). During this procedure, Dr. Vu had to create a "new open gastrostomy feeing [sic] tube." (Id. ¶ 15).

After this surgery, Ms. Wagner stayed in the hospital for four days, and was discharged on March 30, 2014. (Id. ¶ 16). Following her discharge, Ms. Wagner's ALS "progressed rapidly." (Id. ¶ 17). Ms. Wagner died on June 13, 2015. (Id. ¶ 18). Ms. Wagner's husband, Paul Wagner, commenced this action, as Executor of Ms. Wagner's estate, by filing a complaint in the Court of Common Pleas of Philadelphia on July 12, 2016. Kimberly-Clark removed the action to this Court on August 3, 2016. One week later, Kimberly-Clark filed this motion to dismiss.

III. LEGAL STANDARD

Under Rule 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). In Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), the United States Supreme Court recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555. Subsequently, in Ashcroft v. Iqbal, 556 U.S. 662

(2009), the Supreme Court defined a two-pronged approach to a court's review of a motion to dismiss. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 678. Thus, while "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era . . . it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Id. at 678–79.

Second, the Supreme Court emphasized that "only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 679. "Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.; see also Phillips v. Cnty. of Allegheny, 515 F.3d 224, 232–34 (3d Cir. 2008) (holding that: (1) factual allegations of complaint must provide notice to defendant; (2) complaint must allege facts suggestive of the proscribed conduct; and (3) the complaint's "'factual allegations must be enough to raise a right to relief above the speculative level.'" (quoting Twombly, 550 U.S. at 555)).

The basic tenets of the Rule 12(b)(6) standard of review have remained static. Spence v. Brownsville Area Sch. Dist., No. Civ.A.08-626, 2008 WL 2779079, at *2 (W.D. Pa. July 15, 2008). The general rules of pleading still require only a short and plain statement of the claim showing that the pleader is entitled to relief and need not

contain detailed factual allegations. Phillips, 515 F.3d at 233. Further, the court must "accept all factual allegations in the complaint as true and view them in the light most favorable to the plaintiff." Buck v. Hampton Twp. Sch. Dist., 452 F.3d 256, 260 (3d Cir. 2006). Finally, the court must "determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Pinkerton v. Roche Holdings Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002).

IV. DISCUSSION

Kimberly-Clark contends that Pennsylvania law does not recognize strict liability claims against medical device manufacturers. Kimberly-Clark makes the same argument on the breach of warranty claim and argues that plaintiff's express warranty claim is insufficiently pled.

A. Strict Liability Claim (Count II)

The issue here is whether Pennsylvania recognizes a cause of action for strict liability against manufacturers of medical devices. The Pennsylvania Supreme Court has not yet ruled on this issue. A resolution of this motion requires a prediction of how the Pennsylvania Supreme Court would rule on this issue. Barrier v. Simplicity Mfg., Inc., 563 F.3d 38, 45–46 (3d Cir. 2009) ("In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state's substantive law must predict how Pennsylvania's highest court would decide this case."). A federal district court in this position should consider "relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." Id. at 46 (quoting

McKenna v. Ortho Pharm. Corp., 622 F.2d 657, 663 (3d Cir. 1980)). From the sources available, it appears that the Pennsylvania Supreme Court would permit a cause of action against medical device manufacturers under a "manufacturing" defect theory of strict liability. Accordingly, I will deny Kimberly-Clark's motion to dismiss plaintiff's strict liability claim.[3]

1. Pennsylvania Law

Pennsylvania has adopted the Restatement (Second) of Torts § 402A in product liability cases. Tincher v. Omega Flex, Inc., 104 A.3d 328, 415 (Pa. 2014). At issue in this case is Comment k to § 402A of the Restatement, which deals specifically with "unavoidably unsafe products." See Restatement (Second) of Torts § 402A cmt. k. Comment k states: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs." Id. According to Comment k, "[t]he seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use." Id.

In 1996, the Pennsylvania Supreme Court relied on Comment k in holding that strict liability cannot be the basis for a cause of action against a drug manufacturer for failure to warn. Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996).[4] Years later, the

---

[3] Because I find that Pennsylvania law does not recognize such a claim under either a "design defect" or "failure to warn" theory, I will dismiss the plaintiff's strict liability claim to the extent that it is based upon either of these theories of liability.

Pennsylvania Supreme Court reiterated that "for policy reasons, this Court has declined to extend strict liability into the prescription drug arena." Lance v. Wyeth, 85 A.3d 434, 453 (Pa. 2014). Following the Hahn decision, the Pennsylvania Superior Court applied Comment k to medical devices, "find[ing] no reason why the same rationale applicable to prescription drugs may not be applied to medical devices." Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006). The Pennsylvania Supreme Court has yet to address this issue.

It appears that Pennsylvania courts have considered product liability cases against medical device manufacturers. See Beard v. Johnson & Johnson, Inc., 41 A.3d 823, 836–37 (Pa. 2012) (acknowledging without criticism that the plaintiff brought a "product liability action" against a medical device manufacturer under "multiple theories of liability, including an asserted defective design" of the device). In Beard, the plaintiff brought a product liability action with respect to a medical device. 41 A.3d at 824. While the Pennsylvania Supreme Court did not specifically address Comment k to § 402A, it noted the case dealt with "a medical-device product liability action in which a strict-liability, design-defect theory was asserted." Id. Ultimately, the Pennsylvania Supreme Court affirmed the granting of judgment for the defendant based on the lower court's application of the risk-utility test used in product liability cases. Id. at 121–22.[5]

---

[4] Pennsylvania recognizes three separate types of claims for strict liability: (1) design defect; (2) manufacturing defect; and (3) failure to warn. Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995).

[5] Under Pennsylvania law, "[t]he question of whether a product is unreasonably dangerous is a question of law." Riley v. Warren Mfg., Inc., 688 A.2d 221, 224 (Pa. Super. Ct. 1997). In deciding this question, courts apply a risk-utility test. Id. at 224–25. This risk-utility test considers several factors, such as the product's utility to the public versus its risk of causing injury. Id. at 225. After applying this test to a product liability claim, if a court finds as a matter of law that the product is not unreasonably dangerous then it may dismiss the claim on that basis.

2. Federal Courts' Interpretations of Pennsylvania Law

Some federal courts have concluded that Comment k's preclusion of strict liability claims against prescription drug manufacturers applies equally to product liability claims against medical device manufacturers. E.g., Wilson v. Synthes USA Prods., LLC, 116 F. Supp. 3d 463, 466 (E.D. Pa. 2015) (collecting cases). Other federal courts see Pennsylvania law differently. These courts have found that, although Pennsylvania law prohibits strict liability claims based on a "design" defect or a "failure to warn," it does not prohibit strict liability claims against medical device and drug manufacturers for "manufacturing" defects. E.g., Bergstresser v. Bristol-Myers Squibb Co., No. 12–1464, 2013 WL 1760525, at *2 (M.D. Pa. Apr. 24, 2013) (concluding that "although Pennsylvania law does not recognize a strict-liability claim based on a design defect or a failure to warn as a viable cause of action against a manufacturer of prescription drugs or devices, Pennsylvania law does not preclude a strict-liability claim based on a manufacturing defect"); Tatum v. Takeda Pharms. N. Am., Inc., Civ. Action No. 12–1114, 2012 WL 5182895, at *2 (E.D. Pa. Oct. 19, 2012) (agreeing with the rationale espoused by some courts that "strict liability claims for manufacturing defects are not prohibited" against drug manufacturers); Dougherty v. C.R. Bard, Inc., Civ. Action No. 11–6048, 2012 WL 2940727, at *4 (E.D. Pa. July 18, 2012) (William H. Yohn, J.) (concluding the same in part because "the Pennsylvania Supreme Court has not . . . addressed the 'properly prepared' condition . . . or otherwise discussed whether comment

k's exemption from strict liability extends to manufacturing-defect claims");[6] Kline v. Zimmer Holdings, Inc., Civ. Action No. 13–513, 2013 WL 3279797, at *5 (W.D. Pa. June 27, 2013) (allowing manufacturing-defect claim to proceed after finding that "the Pennsylvania Supreme Court has not extended its application of comment k to manufacturing defect claims"); Killen v. Stryker Spine, Civ. Action No. 11–1508, 2012 WL 4498865, at *4 (W.D. Pa. Sept. 28, 2012) (adopting "the rationale . . . that while Hahn instructs that strict liability applies to failure to warn claims, comment k's exemption from strict liability does not extend to manufacturing defects" in denying motion to dismiss product liability claim against manufacturer of a medical device). These rulings seem consistent with the Pennsylvania Supreme Court's recent statement: "No product is expressly exempt [from strict liability] and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." Tincher, 104 A.3d at 386. The term "any product" as used in Tincher would likely include a medical device.

3. Analysis

There is every good reason to believe the Pennsylvania Supreme Court would extend its product liability jurisprudence to manufacturing defects in medical devices. Recent rulings from the Pennsylvania Supreme Court reflect its desire to apply § 402A broadly. As recently as 2012, the Pennsylvania Supreme Court addressed "a medical-device product liability action in which a strict-liability, design-defect theory was

[6] The "properly prepared" exception referred to here comes from Comment k, which states that sellers of unavoidably dangerous products are "not to be held to strict liability" so long as those products are "properly prepared." Restatement (Second) of Torts § 402A cmt. k.

asserted." Beard, 41 A.3d at 824. The claim was brought against a medical device manufacturer. Id. at 825. Although the Pennsylvania Supreme Court affirmed the lower court's grant of judgment for the defendant, it did so because it found the court had properly applied the risk-utility analysis used in product liability cases. Id. at 836–37. There was no statement, or even implication, that such a claim is not allowed under Pennsylvania law. Cf. Creazzo, 903 A.2d at 31 (finding "no reason why the same rationale applicable to prescription drugs may not be applied to medical devices" in dismissing strict liability claim against medical device manufacturer).

Indeed, it is telling that in the decade since the Pennsylvania Superior Court decided Creazzo, the Pennsylvania Supreme Court has only cited Creazzo one time in a footnote.[7] It has never relied on, adopted, or even addressed Creazzo's rationale that medical device manufacturers cannot be subject to strict liability claims. This certainly calls into question other courts' assumptions that the Pennsylvania Supreme Court would adopt Creazzo and apply Comment k to medical device manufacturers in the same way it has applied Comment k to prescription drug manufacturers. In fact, quite the opposite can be inferred from the Pennsylvania Supreme Court's decisional law. For example, it recently reviewed the viability of Pennsylvania's entire product liability law in Tincher v. Omega Flex, Inc., 104 A.3d 328, 415 (Pa. 2014). In doing so, the Pennsylvania Supreme Court went out of its way to emphasize strongly, for the first time ever, that "any" product may form the basis for strict liability:

---

[7] The citation had nothing to do with whether or not a strict liability claim against a medical device manufacturer was allowable. Rather, it referred to the principle of spoliation of evidence, which was another (unrelated) aspect of the Creazzo case. Pyeritz v. Commonwealth, 32 A.3d 687, 692 n.5 (Pa. 2011).

> No product is expressly exempt [from strict liability] and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect. See Restatement (2d) of Torts § 402A cmt. b (cause of action in strict liability "cover[s] the sale of **any product** which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property")

104 A.3d at 386 (emphasis in original).[8] The Beard and Tincher cases provide a sufficient basis for me to predict that, if faced with this issue, the Pennsylvania Supreme Court would permit strict liability claims against medical device manufacturers.

In addition to recent case law, there are other reasons to believe the Pennsylvania Supreme Court would allow manufacturing defect claims against medical device manufacturers. The language of Comment k itself contains an express prerequisite for a product to be deemed "unavoidably unsafe" and thus exempt from strict liability. This prerequisite is that the product must be "properly prepared." Restatement (Second) of Torts § 402A cmt. k. Indeed, Comment k affirmatively states that this "properly prepared" language is a prerequisite: "The seller of such products, *again with the qualification that they are properly prepared* . . . is not to be held to strict liability." Id. (emphasis added). In Dougherty, Judge Yohn recognized this language in concluding that Pennsylvania law does not prohibit a medical-device strict liability claim based on a manufacturing defect. 2012 WL 2940727, at *3. In the same vein, he recognized that few of the cases that find Pennsylvania law to preclude such a claim have addressed the

[8] The Court did note its holding in Hahn, which affirmed the inapplicability of strict liability to prescription drug manufacturers. However, this was the only exception, cited by the Court, to the general rule that manufacturers of "any product" may be strictly liable. If it had intended to apply Hahn to medical device manufacturers, the Pennsylvania Supreme Court would have. But they did not. See Tincher, 104 A.3d at 386 (recognizing Hahn's holding that "manufacturer[s] [are] immune from strict liability defective design claim[s] premised upon sale of *prescription drugs* without adequate warning") (emphasis added).

"properly prepared" language or distinguished the three types of strict liability claims. Id. at *4. The Eastern District of Pennsylvania decision in Dougherty makes sense.[9] The plain language of Comment k rightly recognizes that, in order for a product to be deemed "unavoidably" unsafe, it must have been prepared properly. If this were not the case, manufacturers could exercise no care at all in the preparation of their products, but then be able to enjoy the argument that their product was "unavoidably" dangerous. Such an approach defies logic and fairness since, if little—or no—care is exercised in the preparation (*i.e.* manufacturing) of a product, then the product's danger is certainly not "unavoidable." The Pennsylvania Supreme Court is unlikely to take such an approach.

Relevant scholarly works support the position adopted in Dougherty. In the absence of specific direction from the Pennsylvania Supreme Court, "scholarly works" are appropriate resources "tending convincingly to show how the [Pennsylvania Supreme Court] would decide the issue at hand." Barrier, 563 F.3d at 46. In Tincher, the Pennsylvania Supreme Court relied on a scholarly article by William Prosser, a renowned torts scholar. Id. (citing William L. Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, 1103–04 (1960)). Its reliance on Prosser for this proposition—that "all" products fall under strict liability—indicates that the Court would likely find strict liability claims based on manufacturing defects against medical device manufacturers viable. There is further support, in case law and academia,

---

[9] Kimberly-Clark relies on Wilson v. Synthes USA Products, LLC, 116 F. Supp. 3d 463 (E.D. Pa. 2015) and argues that, since this case is more recent than Dougherty and other case law following Dougherty's approach, I should follow the dictates of Wilson. However, regardless of its date, Wilson is still just one among many federal district court cases interpreting Pennsylvania law. These cases are clearly split on how they rule on this issue. Wilson's precedential value is equally—not more—persuasive than the other federal district cases. Also, it does nothing to call into question Pennsylvania case law that I have relied on—namely, Beard and Tincher.

suggesting that Comment k views manufacturing defect claims differently than other types of strict liability claims. See Dougherty, 2012 WL 2940727, at *5 ("Courts and commentators thus generally agree that comment k's immunity from strict liability does not extend to manufacturing defects.").

I find that Pennsylvania law does not preclude a strict liability claim based on a "manufacturing" defect and I predict the Pennsylvania Supreme Court would permit a strict liability claim for a manufacturing defect in a medical device.

B. Breach of Warranty Claim (Count III)

Plaintiff does not oppose Kimberly-Clark's motion to dismiss the breach of warranty claim in Count III. (Doc. No. 6 at 1). Accordingly, I will grant Kimberly-Clark's motion to dismiss Count III with prejudice.

V. CONCLUSION

Because plaintiff's strict liability claims based on design defect and failure to warn are not cognizable under Pennsylvania law, I will strike with prejudice all language in plaintiff's complaint that relates to a "design" defect or "failure to warn." I will deny Kimberly-Clark's motion to dismiss plaintiff's strict liability claim to the extent that plaintiff pleads that claim based on a manufacturing defect. Finally, because plaintiff does not oppose the dismissal of its breach of warranty claim, I will dismiss Count III with prejudice.

An appropriate Order follows.