UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

EDWARD PATCHCOSKI, *et al.*,	**:**	
Plaintiffs	**:**	**CIVIL ACTION NO. 3:19-1556**
v.	**:**	**(JUDGE MANNION)**
W.L. GORE & ASSOCIATES, INC., *et al*.,	**:**	
	:	
Defendants	**:**	

MEMORANDUM

Before the court is defendants' motion to dismiss the plaintiffs' complaint pursuant Fed.R.Civ.P. 12(b)(6). (Doc. 6). For the reasons stated below, defendants' motion to dismiss will be **DENIED** as to being time barred by the applicable statute of limitations, and as to the failure to state claims of strict liability, negligence, and loss of consortium.

I. PROCEDURAL HISTORY

The Plaintiffs, Edward Patchcoski ("Plaintiff") and his wife Susan Patchcoski, instituted this product liability case by the filing of a Praecipe for Writ of Summons in the Court of Common Pleas of Lackawanna County on January 25, 2019 (Doc. 7-1). Thereafter, Plaintiffs allege the parties entered

into a Tolling Agreement on February 21, 2019, with both parties agreeing that the Plaintiffs had tolled the statute of limitations on any claims against the Defendants W.L. Gore & Associates, Inc., Gore Medical, and W.L. Gore & Associates, Inc. Medical Products Division, ("Gore"), as of that date.[1] (Doc. 1-1 at 7). However, the Defendants contend that while Plaintiffs and Gore entered into a Tolling Agreement, the agreement extended only through June 3, 2019, in order to allow time for a pre-litigation assessment of Plaintiffs' claims. Pursuant to the terms of the agreement, the Plaintiffs withdrew their Praecipe for Writ of Summons without prejudice on February 27, 2019. (Doc. 7-2). Thereafter, the parties engaged in settlement negotiations.

When the parties were unable to resolve this matter, Plaintiffs filed a Complaint in the County Court on August 14, 2019. (Doc. 1-1). Plaintiffs raise three claims in their Complaint, namely, Count I, strict liability alleging that the GORE-TEX® Soft Tissue Patch ("Gore Mesh") was defective and that it caused the Plaintiff's infection after it was implanted in him and lead to his

[1] Gore notes that the only proper defendant is W.L. Gore & Associates, Inc. As such, the court directs the parties to confer as to the proper defendant(s), and if they agree, to file a stipulation as to the proper defendant(s) when Gore files the answer to the plaintiff's complaint.

multiple surgeries, Count II, negligence by failing to provide the Plaintiff with a safe product, and Count III, loss of consortium claim by the Plaintiff's wife.

On September 9, 2019, Defendants filed a Notice of Removal of this case to federal court based on diversity jurisdiction. (Doc. 1).

After being granted an extension of time, Gore filed a Motion to Dismiss the Plaintiffs' Complaint on October 14, 2019, arguing that the Complaint was filed well-beyond the applicable statute of limitations, and that there are no cognizable claims for strict liability and negligence stated. (Doc. 6). Gore's motion was then briefed by the parties and Exhibits were submitted. (Docs. 7, 12 & 17). Thus, the matter is now ripe for decision.

II. FACTUAL BACKGROUND[2]

On July 23, 1999, the Plaintiff underwent a ventral incisional hernia repair surgery performed by Dr. David Mariner during which the Gore Mesh was implanted. In March 2001, the Plaintiff underwent herniorrhaphy and abdominoplasty for the repair of a complex symptomatic ventral hernia. The GORE Mesh was left intact during this surgery.

[2] The court accepts all of the Plaintiffs' well-pleaded facts as true as it must for a motion to dismiss. *See* Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937 (2009).

On April 6, 2001, the Plaintiff underwent an aspiration of intra-abdominal and pelvic collections of fluid. The GORE Mesh was left intact during this procedure.

On May 14, 2001, the Plaintiff was diagnosed with an abscess on the top of the midline incision and he later tested positive for MRSA.

On September 7, 2001, the Plaintiff was diagnosed with abdominal pain and infected Gore Mesh.

On November 1, 2001, the Plaintiff had surgery for the removal of the GORE Mesh and subsequent testing showed the Mesh was infected.

After the removal of the GORE Mesh, the Plaintiff felt better but continued to have muscle weakness, fatigue, and delay healing in his stomach muscles and abdomen.

In the summer of 2019, the Plaintiff suffered a scratch on the scar tissue on his stomach from his surgeries. The Plaintiff's scratch quickly became infected. Due to the infection, the Plaintiff required treatment at a wound care center and he had numerous procedures to treat his wound.

During the treatment for his wound in the summer of 2019, the Plaintiff alleges that he first discovered that the infected GORE Mesh remained in his stomach, causing him sharp pains and requiring treatments, including

invasive procedures, medication and pain reduction creams, as well as changes in his lifestyle.

The Plaintiff alleges that he was unaware that his multiple medical problems were related to the GORE Mesh until March 21, 2017, when he was advised by his treating physician and discovered that defects in the GORE Mesh could have led to his medical problems.

This court has subject matter jurisdiction over this case based on diversity of the parties and the amount in controversy exceeds $75,000. *See* 28 U.S.C. §1332. Venue is proper because a substantial part of the events giving rise to Plaintiffs 'claims occurred in this district. *See* 28 U.S.C. §1391(b)(2), §1404(a).

III. LEGAL STANDARD

The defendants' motion to dismiss is brought pursuant to the provisions of Fed.R.Civ.P. 12(b)(6). This rule provides for the dismissal of a complaint, in whole or in part, if the Plaintiff fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated, Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005), and dismissal is appropriate only if, accepting all of the facts alleged in the complaint as true, the Plaintiff has failed to plead "enough facts to state a

claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007) (abrogating "no set of facts" language found in Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). The facts alleged must be sufficient to "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. This requirement "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of" necessary elements of the Plaintiffs' cause of action. *Id.* Furthermore, in order to satisfy federal pleading requirements, the Plaintiffs must "provide the grounds of his entitlement to relief," which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Phillips v. County of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008) (brackets and quotations marks omitted) (quoting Twombly, 550 U.S. 544 at 555).

In considering a motion to dismiss, the court generally relies on the complaint, attached exhibits, and matters of public record. *See* Sands v. McCormick, 502 F.3d 263 (3d Cir. 2007). The court may also consider "undisputedly authentic document[s] that a defendant attaches as an exhibit to a motion to dismiss if the Plaintiffs' claims are based on the [attached] documents." Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993). Moreover, "documents whose contents are alleged in the complaint and whose authenticity no party questions, but which

are not physically attached to the pleading, may be considered." Pryor v. Nat'l Collegiate Athletic Ass'n, 288 F.3d 548, 560 (3d Cir. 2002). However, the court may not rely on other parts of the record in determining a motion to dismiss. *See* Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250,1261 (3d Cir. 1994).

Generally, the court should grant leave to amend a complaint before dismissing it as merely deficient. *See, e.g.,* Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 252 (3d Cir. 2007); Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002); Shane v. Fauver, 213 F.3d 113, 116-17 (3d Cir. 2000). "Dismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility." Alston v. Parker, 363 F.3d 229, 236 (3d Cir. 2004).

IV. DISCUSSION

A. STATUTE OF LIMITATIONS

Initially, Gore raises the defense of the statute of limitations to all claims asserted by the Plaintiffs. A brief summary of the applicable times and events is warranted. While the initial implantation of the surgical Gore Mesh occurred on July 23, 1999, long before Plaintiff initiated his action, the Plaintiff contends that he did not discover the fact that he had been injured

and that the injury was caused by Gore until March 21, 2017. For the purposes of the motion to dismiss, this allegation will be accepted as true.

Gore states that "Plaintiff[] allege[s] that [he] was diagnosed with infected Gore Mesh on September 7, 2001 and underwent the explant of same on November 1, 2001", and that "the statute of limitations expired on November 1, 2003 at the latest; nearly 16 years before Plaintiffs filed its complaint against Gore." (Doc. 7).

Gore also argues that the discovery rule does not save the Plaintiffs' claims. Gore contends that "Plaintiff's Complaint fails to explain what facts became apparent in March of 2017, nor why they were incapable through due diligence of discovering the purported connection for well over a decade." (Id.).

Plaintiffs first argue that Gore's affirmative defense of the statute of limitations is premature and should not be considered in a Rule 12(b)(6) motion. Although a defense based on the statute of limitations generally cannot be raised with a Rule 12(b)(6) motion, it can be raised in such a motion if the face of the Complaint reveals that the applicable statute of limitations would bar the claims. *See* Webb v. Susquehanna Tp. School Dist., 93 F. Supp. 3d 343 (M.D. Pa. 2015) (citing Robinson v. Johnson, 313 F. 3d 128 (3d Cir. 2002)). *See also* Hanna v. U.S. Veterans' Administration

Hospital, 514 F.2d 1092, 1094 (3d Cir. 1975) (the Third Circuit has stated that a statute of limitations defense may only be raised in a motion to dismiss if "the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations.").

Under Pennsylvania law, which applies in this case, the limitations period applicable to the Plaintiffs' tort claims is two years. *See* 42 Pa.C.S.A. §5524(2). Generally, the statute of limitations for a tort action under Pennsylvania law begins to accrue when an injury is sustained. Debiec v. Cabot Corp., 352 F. 3d 117 (3d Cir. 2003). This includes the Plaintiff's claims for strict liability and negligence. Dailey v. Encore Medical Corp., 2014 WL 6982828, at *4 (M.D. Pa. Dec. 10, 2014). A cause of action accrues for statute of limitations purposes when the Plaintiff knows or has reason to know of the injury that constitutes the basis of the cause of action. Sameric Corp. of Delaware, Inc. v. City of Phila., 142 F.3d 582, 599 (3d Cir. 1998); *see also* Nelson v. County of Allegheny, 60 F.3d 1010 (3d Cir. 1995). However, "[t]he discovery rule is designed to 'ameliorate the sometimes-harsh effects of the statute of limitations." Soutner v. Covidien, LP, 2019 WL 3801438, *4 (M.D. Pa. Aug. 13, 2019). The discovery rule tolls the accrual of the statute of limitations when the Plaintiff is unable, "despite the exercise of due diligence, to know of the injury or its cause." *Id*. (quoting Pocono Int'l

Raceway, Inc. v. Pocono Produce, Inc., 468 A.2d 468, 471 (Pa. 1983)). "To demonstrate reasonable diligence, a plaintiff must 'establish[ ] that he pursued the cause of his injury with those qualities of attention, knowledge, intelligence, and judgment which society requires of its members for the protections of their own interests and the interests of others." *Id*. (quoting Cochran v. GAF Corp., 666 A.2d 245, 250 (Pa. 1995)). A plaintiff is considered "on notice" of his claims when he is sufficiently aware that his injury was caused by a third party. Coleman v. Wyeth Pharms., Inc., 6 A.3d 502, 511 (Pa. Super. Ct. 2010).

"A court may only determine as a matter of law that the discovery rule does not apply when 'reasonable minds would not differ in finding that a party knew or should have known' of the injury and its cause." Wallace v. Boston Scientific Corp., 2018 WL 6981220, *5 (M.D. Pa. Nov. 29, 2018), adopted by 2019 WL137605 (M.D. Pa. Jan. 8, 2019), (quoting Hanna, 514 F.2d at 1094). "Moreover, Pennsylvania courts have held that the question of whether a plaintiff was diligent in determining that she was injured and the cause of the injury is 'best determined by the collective judgment, wisdom, and experience of jurors.'" *Id*. (citations omitted).

In cases involving medical devices, the salient question regarding cause under Pennsylvania law is "whether a Plaintiff knows or has reason to

know that the device caused her injury, not whether a Plaintiff has actual or constructive knowledge as to precisely how or why her injury occurred." McLaughlin v. Bayer Essure, Inc., 2019 WL 1382710, at *5 (E.D. Pa. Mar. 27, 2019) (citations omitted). "The Supreme Court of Pennsylvania has clarified that reasonable diligence is not 'an absolute standard, but is what is expected from a party who has been given reason to inform himself of the facts upon which his right to recovery is premised." Soutner, 2019 WL 3801438, *5 (quoting Fine v. Checcio, 870 A.2d 850, 858 (Pa. 2005)).

"'[T]here are [very] few facts which diligence cannot discover, but there must be some reason to awaken inquiry and direct diligence in the channel in which it would be successful. This is what is meant by reasonable diligence." *Id.* (alterations in original) (quoting Crouse v. Cyclops Indus., 765 A.2d 606, 611 (Pa. 2000)). "Put another way, [t]he question in any given case is not, what did the Plaintiff know of the injury done him? [B]ut, what might he have known, by the use of the means of information within his reach, with the vigilance the law requires of him." *Id.* (quoting Scranton Gas & Water Co. v. Lackawanna Iron & Coal Co., 31 A. 484, 485 (Pa. 1895)).

The Plaintiff alleges that he did not discover his injury and its cause until March 21, 2017. In the first instance, the Plaintiff's "injury" is alleged to be sharp pains, muscle weakness, fatigue, etc., essentially a claim for pain

and suffering and losses of life's pleasures during the time period at issue from 2001 through 2017. Importantly, the GORE Mesh was allegedly removed in 2001, leading a person of reasonable diligence to believe his injuries were unrelated to the continuing presence of the GORE Mesh in his body through March 2017. Regarding the "injury" itself, it is uncertain for purposes of Rule 12(b)(6) whether the Plaintiff knew or reasonably knew that this injury was from the ventral incisional hernia repair surgery performed in 1999, the infection and removal in 2001, or from some other injury.

Even more importantly, the "cause" of the injury was allegedly not discovered until March 21, 2017, when plaintiff was told that the Gore Mesh could have been the cause of his ongoing symptoms. The Plaintiff also alleges that he believed that the Mesh was removed from him in November of 2001, but that it was not until the summer of 2019 when he discovered that the infected GORE Mesh remained in his stomach. This is allegedly the first-time the Plaintiff was made aware by any medical professional that the GORE Mesh was still in his body and a likely cause of his symptoms. Thus, Plaintiff has sufficiently alleged that he could not have reasonably known earlier that his medical problems were caused by the GORE Mesh.

Therefore, at this stage of the case, the Plaintiff has sufficiently shown that the cause of the source of his injury was too difficult to identify with

reasonable diligence over the years from 2001 through 2017. This issue can be more appropriately considered at the summary judgment stage after discovery is complete.[3]

Moreover, even though the Plaintiffs did not file their Complaint until August 2019, two months after the Tolling Agreement expired in June 2019, they have alleged that they did not discover until the summer of 2019 that not all of the GORE Mesh was removed from the Plaintiff. The court will permit discovery regarding this issue.

Viewing the allegations in the Complaint in the light most favorable to the Plaintiffs, Gore's motion to dismiss the Complaint in its entirety based upon a statute of limitations defense will be **DENIED**.

B. STRICT PRODUCTS LIABILITY

In Count I, the Plaintiff relies upon the theory of strict liability and basically alleges that the GORE Mesh medical device was a defective product under Pennsylvania law and caused his injuries. Gore argues that

[3]*See* Adams v. Zimmer US, Inc., 943 F.3d 159 (3d Cir. 2019) (Third Circuit reversed district court's grant of summary judgment finding that plaintiff's claim was time barred since factual disputes remained regarding the application of the Pennsylvania discovery rule.). Based on Zimmer, the court finds that discovery is required with respect to when the Plaintiff discovered his injuries allegedly caused by the GORE mesh.

the Plaintiff's complaint fails to state a cognizable claim for strict liability, and that Pennsylvania law does not recognize strict liability claims against medical device manufacturers like Gore.

Under Pennsylvania's strict liability law, it applies Section 402A of the Restatement (Second) of Torts and presumes that products can be the subject of strict product liability suits. Tincher v. Omega Flex, Inc., 628 Pa. 296, 104 A.3d 328, 382, 389 (2014) (citing Restatement (Second) of Torts §402A cmt. b). To state a claim for strict products liability under Pennsylvania law, a Plaintiff must sufficiently plead: (1) that the product was defective; (2) that the defect was a proximate cause of the Plaintiff's injuries; and (3) that the defect causing the injury existed at the time the product left the seller's hands. Nilson ex rel. Nilson v. Hershey Entertainment and Resorts Co., 649 F. Supp. 2d 378, 387 (M.D. Pa. 2009). There are three types of defective conditions that may give rise to strict liability under Pennsylvania law: manufacturing defect; design defect; and failure to warn defect. Weiner v. American Honda Motor Co., Inc., 718 A.2d 305, 307 (Pa. Super. Ct. 1998).

Here, the Plaintiff's strict lability claim against Gore appears to be based on a design defect as well as a manufacturing defect. (*See* Doc. 1-1 at 8-9).

At the outset, the court finds that the Plaintiff's allegations in his Complaint plausibly state a strict liability claim against Gore in Count I and meet the pleading requirements of Fed.R.Civ.P. 8(a).

Gore argues that the Complaint lacks sufficient facts as to how Gore Mesh is allegedly defective. It also argues that the Complaint fails to allege a design flaw, specific defect, or how the device deviated from specification for a manufacturing defect. Moreover, Gore contends the Complaint fails to allege why the device is dangerous, or how it failed to perform in the manner reasonably expected. Gore contends that the Plaintiff's Complaint, which merely states, "the defect in the mesh product caused the Plaintiff[] to undergo multiple additional surgeries and to suffer multiple additional losses", is insufficient. (S*ee* Doc. 1-1 at ¶38). Moreover, Gore maintains that the Plaintiff has failed to assert any facts establishing a causal connection between any alleged defect in its Mesh and his injuries.

Here, accepting all the facts alleged in the Complaint as true, the Plaintiff has pled enough facts to state a strict liability cause of action in Count I. The Plaintiff's Complaint alleges that the GORE Mesh was defective, unreasonably safe, and not suitable for implantation into the Plaintiff and other similarly situated patients. The Complaint further alleges that the product caused harm to the Plaintiff as a user or a consumer. The Complaint

also alleges that the GORE Mesh, which left GORE as intended, was implanted into the Plaintiff, and that he acquired an infection requiring its removal and, these allegations raise a reasonable expectation that discovery will reveal evidence to show that the medical device implantation was the proximate cause of his injuries resulting in damages. Thus, the Plaintiff has alleged sufficient facts to state a cognizable cause of action under the theory of strict liability.

As such, Gore's motion to dismiss Count I on the basis that it fails to meet the pleading requirements under F.R.C.P. 8 will be **DENIED**.

Next, Gore argues that the Plaintiff's strict liability claim should be dismissed because it is prohibited by Pennsylvania law. Gore relies upon Comment k to §402A. "Comment k to §402A, …, creates an exception to strict tort liability for 'unavoidably unsafe products,' which are products 'incapable of being made safe for their intended and ordinary use.'" Wallace, 2018 WL 6981220, *6 (citing §402A cmt. K). "A seller of such a product, '... with the qualification that [it] is properly prepared and marketed, and proper warning is given ...' will not be held strictly liable for consequences involving its use." *Id*. "[T]he Supreme Court of Pennsylvania has explicitly held that, where comment k applies, a plaintiff is barred from asserting a claim of design defect in strict liability." *Id*. (citing Incollingo v. Ewing, 282 A.2d 206,

219 (Pa. 1971) (finding that a drug manufacturer is not held strictly liable "merely because of dangerous propensities of the product")).

The Plaintiff contends that federal district courts would allow his design defect and manufacturing defect strict liability claims to proceed under Pennsylvania law, but Gore argues that Pennsylvania law does not recognize such strict liability claims against prescription medical device manufacturers, including surgical mesh implants.

According to Gore:

> On March 26, 1992, [the Gore Mesh] was first cleared by the FDA through the 510(k)-clearance process and has a clinical history of safe and effective use in hernia repairs, including supportive literature and studies. Moreover, Gore Mesh has never been the subject of a recall, subjected to FDA or regulatory corrective action, or implicated in any consolidated hernia mesh lawsuits. The Gore Mesh design, manufacturing, specifications, performance characteristics, and labeling are all appropriate for its intended uses. (Doc. 7 at 2).

Interestingly, the Pennsylvania Supreme Court has yet to directly address whether Pennsylvania's law regarding strict liability claims related to medical devices is cognizable. *See* Wallace, 2018 WL 6981220, *7; Gross v. Coloplast Corp., 434 F.Supp.3d 245, 250 (E.D. Pa. 2020) (court held that while "prescription drugs are … indisputably exempt from strict liability under Pennsylvania law", "Defendant asks the Court to conclude that the Pennsylvania Supreme Court would extend Hahn to prescription medical

devices as the pelvic mesh at issue here.") (internal citations omitted). "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 [the] case." Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 45-46 (3d Cir. 2009). "In predicting how the highest court of the state would resolve the issue, [this court] must 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.* (quoting McKenna v. Ortho Pharm. Corp., 622 F.2d 657, 663 (3d Cir. 1980)). Further, "[t]he federal courts in this circuit that have dealt with manufacturing defect strict liability claims are divided, with some holding that comment k provides a complete bar to all strict liability claims against medical device manufacturers, and some holding that manufacturing defect claims are permitted." Wallace, 2018 WL 6981220, *7.

"In diversity cases, 'where the applicable rule of decision is the state law, it is the duty of the federal court to ascertain and apply that law, even though it has not been expounded by the highest court of the state.'" Gross, 434 F.Supp.3d at 249 (quoting Jewelcor, Inc. v. Karfunkel, 517 F.3d 672, 676, n. 4 (3d Cir. 2008)). "Although not dispositive, decisions of the state

intermediate appellate court should be accorded significant weight in the absence of an indication that the highest court would rule otherwise." Jewelcor, Inc., 517 F.3d at 676, n. 4. Even though such decisions are not binding, they are not "to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would rule otherwise" *Id*. (quoting Northern Ins. Co. of New York v. Aardvark Associates, Inc. 942 F.2d 189,193 (3d Cir. 1991)).

From the review of the available sources, including the decisions and admonitions of the Pennsylvania Supreme Court in Tincher and in Lance v. Wyeth, 4 A.3d 160 (Pa. Super. Ct. 2010), aff'd in part, rev'd in part on other grounds, 85 A.3d 434 (Pa. 2014), as well as more recent federal district court decisions interpreting the Supreme Court as requiring a case-by-case analysis of comment k and its application to an allegedly defective medical device product, the court will allow plaintiff's strict liability design defect and manufacturing defect causes of action regarding the GORE Mesh to proceed. *See* Gross, 434 F.Supp.3d at 251-52; Schrecengost v. Coloplast Corp., 425 F.Supp.3d 448 (W.D. Pa. 2019).

Gore's Motion to Dismiss Plaintiff's strict liability claim rests on two arguments: 1. Gore contends that this court should extend the Hahn v. Richter, 673 A.2d 888 (Pa. 1996) (court held that "where the adequacy of

warnings ... is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, *i.e.* the manufacturer's negligence, is the only basis of liability"), decision to prescription medical devices precluding the Plaintiff's strict liability claims; and 2. Despite the Pennsylvania Supreme Court's silence on the exact issue in this case, Gore urges this court to follow the Superior Court in Creazzo v. Medtronic, Inc., 903 A.2d 24 (Pa. Super. 2006) (holding that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices"), and rule that prescription medical devices, such as its mesh, are within the ambit of comment k and not subject to strict liability claims.

With respect to its first argument, Gore cites several district court opinions within the Third Circuit predicting that the Pennsylvania Supreme Court would support its contention. Gore points out that in June 2019, a federal court in the Eastern District of Pennsylvania dismissed a strict liability claim similar to Plaintiff's and rejected the same arguments Plaintiff makes here. Rosenberg v. C.R. Bard, Inc., 387 F. Supp. 3d 572, 582 (E.D. Pa. 2019). The Rosenberg court dismissed all of the Plaintiffs' strict liability claims with prejudice by reasoning that Hahn only allows for claims brought against a medical device manufacturer for negligence. *Id.*; *see also* Hahn v. Richter, 673 A.2d at 890–91. The Court noted that Plaintiffs also rely on

Tincher; however, the court stated that there is "nothing in Tincher [that] reopens the door to strict liability claims for prescription drugs or prescription medical devices, a door Hahn had firmly closed." Rosenberg, 387 F. Supp. 3d at 580–81 (reasoning that Tincher expressly recognized Hahn's exception to the general rule that all products are subject to strict liability).

A more detailed analysis of the Hahn decision, and its ability to be extrapolated to other medical products, is required.

Initially, there is no question Pennsylvania has adopted and applied comment k of Section 402A to "exempt prescription drugs from the imposition of strict liability on manufacturers selling these drugs." Schrecengost, 425 F.Supp.3d at 464 (citing Hahn v. Richter, 543 Pa. 558, 673 A.2d 888, 889-90 (Pa. 1996)).[4] In analyzing comment k's application to prescription drugs,

[4] The court in Schrecengost, 425 F.Supp.3d at 463 held that "it appears that the Pennsylvania Supreme Court would permit a cause of action against medical device manufacturers—specifically manufacturers of surgical mesh implants—under design defect and failure to warn theories of strict liability." In Gross, 434 F.Supp.3d at 250-51, the court allowed plaintiff's design defect, manufacturing defect and failure to warn theories of strict liability to proceed at the motion to dismiss stage. This court agrees with these two courts and will allow Plaintiff's design defect and manufacturing defect strict liability claims to proceed against Gore. *But see* Wallace, 2018 WL 6981220, *6 (court found that the plaintiff's design defect and failure to warn strict liability claims should be dismissed because they were prohibited by Pennsylvania law, based on Creazzo, but allowed plaintiff's manufacturing defect strict liability claim to proceed). Other courts have dismissed all of the strict liability claims in the context of medical devices. *See* Rosenberg v. C.R. Bard, Inc.,

the Hahn decision noted comment k exempts liability for "unavoidably unsafe products." The Court went on to conclude, in a general way, that prescription drugs neatly fit in that comment k category.

In summary, the Hahn Court applied a rather broad application of the language of comment k to the particular medical and legal protocols and procedures in creating, manufacturing, selling and monitoring drugs, as well as the specific risks and benefits of prescription drugs, and opined they were precisely the type of regulated product envisioned by comment k. Hence, it was a categorical approach that carried the day.

Importantly, the Hahn decision was limited to its facts and did not expand comment k to products beyond prescription drugs. In fact, the Pennsylvania Supreme Court has more specifically cautioned against thoughtlessly extending Hahn and comment k. Gross, 434 F.Supp.3d at 250 ("Following Creazzo, a few Pennsylvania Supreme Court decisions [Tincher and Lance] cautioned, both in general terms and with specific reference to Hahn- and comment k, against lightly altering the common law of products liability." For Hahn "applied a rather one-dimentional analysis in its adoption

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387 F. Supp. 3d 572, 576–81 (E.D. Pa. 2019). *See also* Kohn v. Ethicon, Inc., 2020 WL 733126, at *4 (E.D. Pa. Feb. 13, 2020) (the court cited to cases predicting that Pennsylvania law would not allow plaintiffs to bring strict liability claims in medical device cases).

of a blanket approach to comment k…[T]he truncated analysis in the Hahn line offers a poor foundation for extrapolation." Lance v. Wyeth 85 A.3d 434, 454, n. 2 (Pa. 2014). "The terse opinion in Hahn does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections." *Id*.

Gore contends that this court should follow the Pennsylvania Superior Court's lead in Creazzo, and include prescription medical devices within comment k.

Specifically, in Creazzo v. Medtronic, Inc., 903 A.2d 24 (Pa. Super. 2006), the Pennsylvania Superior Court held that the plaintiffs could not pursue a strict liability claim against the manufacturer of an implantable neurological electrical stimulation device. *Id.* at 26, 31. In so holding, the Pennsylvania Superior Court explained that it "[found] no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Id.* at 31. Therefore, the Superior Court concluded that comment k applied to prescription medical devices, and thus strict liability was not a viable basis for liability in that case. *Id*. at 32.

"In Creazzo v. Medtronic, Inc., 903 A.2d 24, [31] (Pa. Super. Ct. 2006), the Superior Court noted, after determining that no significant distinction

could be drawn between the medical device before the court and the drug in Hahn, that there was 'no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." Schrecengost, 425 F.Supp.3d at 464. Defendants in Schrecengost, *id*., like our defendants, essentially "assert that Creazzo closed the door for all strict liability claims against medical device manufacturers in Pennsylvania."

However, since the 2006 Creazzo decision, criticism of the Superior Court's analysis and extension of comment k to medical devices has been consistent and broad-based. *See* Schrecengost, 425 F.Supp.3d at 465. Most importantly for our purposes, the Pennsylvania Supreme Court has remained silent on the particular expansion of comment k to medical devices. *See id*.

But the Supreme Court has not remained silent on the evaluation process regarding common law strict liability claims. More recently the Pennsylvania Supreme Court has issued two opinions cautioning against "altering the common law of products liability," in both "general terms and with specific reference to Hahn and comment k." Gross v. Coloplast Corp., –— F.Supp.3d ——–, 2020 WL 264691, at *3 (E.D. Pa. Jan. 17, 2020). These cases, Tincher and Lance, taken together, undermine Creazzo's persuasive force and suggest that the Pennsylvania Supreme Court would not apply comment k to categorically exempt all prescription medical devices from

strict liability claims. In Schrecengost, 425 F.Supp.3d at 465-66, the court explained that "[t]he Pennsylvania Supreme Court itself has struggled with [the interpretation and application of comment k], stating that 'comment k is not itself a model of clarity.'" (quoting Lance, 85 A.3d at 451). The court also stated that it is "unclear whether comment k would be a categorical shield of immunity or one for a court to assess on a case by case basis by comparing the utility of a product to its unavoidably dangerous propensities." *Id*. at 466 (citation omitted). Further, "these are policy decisions that require careful consideration more suited for a legislature." *Id*. (citing Tincher, 104 A.3d at 396).

Tincher cautions courts against creating such categorical exemptions: "Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which individual products, or categories and types of products, should be exempt." Tincher, 628 Pa. 296, 104 A.3d at 396. Rather, Pennsylvania's highest court counsels that decision making should be made in the presence of a rich factual record to allow for "a comprehensive discussion of the competing policies ... which would support an informed, legislative-type judgment…." Lance v. Wyeth, 624 Pa. 231, 85 A.3d 434, 454 (2014) (citations omitted).

The Lance case more specifically cautions courts against expanding the reach of Hahn and comment k. The Lance Court reaffirmed the decision in Hahn—i.e., categorically applying comment k to prescription drug manufacturers—but not without criticism. *See Id.* at 438, 452 n. 21. Indeed, the Court admitted that Hahn "applied a rather one-dimensional analysis in its adoption of a *blanket* approach to comment k" and that its "truncated analysis ... offers a poor foundation for extrapolation." *Id.* at 452 n. 21 (emphasis added). The Court further noted that "the terse opinion in Hahn does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections." *Id.* (citations omitted).

The cautionary language of Tincher and Lance leads this court to predict that the Pennsylvania Supreme Court would not categorically extend Hahn and comment k to all prescription medical device manufacturers, such as Gore, and would not follow the lead of the Superior Court in Creazzo.

This court concurs with the district court decisions in the Third Circuit that have declined to dismiss strict liability claims against medical device companies, and have allowed such claims to proceed based upon a more thorough review of the Tincher and Lance decisions. "As Tincher made clear,

the principles of the Restatement must be adopted into Pennsylvania common law and there is no dispute that the Pennsylvania Supreme Court has not applied comment k to shield medical device manufacturers from strict liability." Schrecengost, 425 F.Supp.3d at 466 (citing Tincher, 104 A.3d at 399). As in Schrecengost, *id*. at 466, this court finds that "Defendants' reliance on Creazzo and Hahn is misplaced", and "the Court interprets [Tincher], as an implicit recognition by the Pennsylvania Supreme Court that these strict liability claims are cognizable against medical device manufacturers [of surgical mesh implants]." Thus, "[a]s the law stands, neither the Pennsylvania Supreme Court nor the Pennsylvania General Assembly have created immunity from strict liability for medical device manufacturers like Coloplast." *Id*.

Similarly, in Gross, 434 F.Supp.3d at 250-52, the court denied Defendants' motion to dismiss the Plaintiffs' strict liability claims based on all three theories concerning an allegedly defective pelvic mesh. In Gross, 434 F.Supp.3d at 251-52, the court explained:

> This post-Creazzo methodological guidance undermines Creazzo's reliability as evidence of what the Pennsylvania Supreme Court would decide. Creazzo, in a few sentences, apparently with limited briefing, categorically extended comment k and Hahn's reasoning to medical devices. But Tincher and Lance discourage Pennsylvania courts from making such categorical decisions at all, especially briefly, especially on limited records, and especially based on comment k and Hahn.

> Creazzo, therefore, is not persuasive authority of how the Pennsylvania Supreme Court would decide this question. This Court, therefore, cannot dismiss these claims based on Creazzo.
>
> The court in Gross, 434 F.Supp.3d at 252, then concluded:
>
> The Pennsylvania Supreme Court has cautioned Pennsylvania courts against making categorical carveouts from the presumption of strict liability without, at the least, a rich factual record on the policy issues that should inform a common-law analysis of whether to allow these claims. Because this Court faces the question of whether to allow these claims to proceed on a Rule 12 motion to dismiss, this Court has no such factual record. This Court concludes, considering all the circumstances, including the distinct possibility the Pennsylvania Supreme Court may allow these claims to proceed, a better result is to allow Plaintiffs' claims to proceed in this case, at this stage.

In Moultrie v. Coloplast Corp., 2020 WL 1249354, *10 (W.D. Pa. Mar. 16, 2020), the court "declin[ed] to hold that comment k bars Plaintiffs' strict liability claims [based upon design defect and failure to warn]" and found that a comprehensive review of the district court cases revealed that "extending comment k to medical devices is a matter that should be addressed by the Pennsylvania General Assembly or the Pennsylvania Supreme Court." *See also* Ebert v. C.R. Bard, Inc., ---F.Supp.3d---, 2020 WL 2332060 (E.D. Pa. May 11, 2020) ("The cautionary language of Tincher and Lance leads the Court to predict that the Pennsylvania Supreme Court would not categorically extend Hahn and comment k to all prescription medical device manufacturers. Rather, the Court predicts that Pennsylvania's highest court

would instead analyze comment k's applicability to prescription medical devices on a case-by-case basis, determined largely by each case's developed factual record and the individual characteristics of the medical device at issue."). *See also* Wallace, 2018 WL 6981220, *7 (the court "join[ed] the[] [other] [cited] courts in concluding that the plaintiff's manufacturing defect strict liability claim [with respect to defendant's mesh product] is not explicitly prohibited under Pennsylvania law.") (citing Smith v. Howmedica Osteonics Corp., 251 F.Supp.3d 844, 848-49 (E.D. Pa. 2017) (stating that the court "held that a plaintiff is permitted to bring a manufacturing defect claim against a manufacturer of a medical device" and that "the court reasoned that comment k exempts a product from strict liability when it is 'properly prepared,' and that interpreting this language as preserving a manufacturing defect claim is consistent with the Pennsylvania Supreme Court's products liability jurisprudence."); Doughtery v. C.R. Bard Inc., 2012 WL 2940727, at *4 (E.D. Pa. July 18, 2012) (stating that the court "reason[ed] that the Pennsylvania Supreme Court has had ample opportunity to preclude manufacturing defect claims in strict liability, and has not yet done so."); Schrecengost, 425 F.Supp.3d at 465 ("In the absence of a shield of strict liability immunity granted by the Pennsylvania Supreme Court or

Pennsylvania General Assembly, the Court defers to the general rule in Pennsylvania that no product is immune from strict liability.").

This position is also supported by the well-reasoned federal district court decisions referenced above. *See* Gross, *supra* ("Creazzo, therefore, is not persuasive authority of how the Pennsylvania Supreme Court would decide this question."); Ebert, *supra* ("The Court gives little persuasive weight to Creazzo; it is supported by scant reasoning and in the fourteen years since Creazzo, the Pennsylvania Supreme Court has not relied on it."). *See also* Moultrie, *supra* ("Most of the cases that cite Creazzo with approval predate the Pennsylvania Supreme Court's holding in Tincher, which cautioned courts from making categorical exemptions of immunity strict liability…"); Schrecengost, *supra*.

In short, this court concurs with the court in Ebert, 2020 WL 2332060, *10, "to predict that the Pennsylvania Supreme Court would not categorically extend Hahn and comment k to all prescription medical device manufacturers." (citations omitted). As such, "the Court predicts that Pennsylvania's highest court would instead analyze comment k's applicability to prescription medical devices on a case-by-case basis, determined largely by each case's developed factual record and the individual characteristics of the medical device at issue." *Id.* Thus, this court

will not dismiss the Plaintiff's strict liability claims without the benefit of a fully developed factual record. *See* Ebert, *supra*.

Therefore, the court does not find either of Gore's arguments persuasive and will not grant its motion to dismiss the Plaintiff's strict liability claims at this stage of the case.

As such, Gore's motion to dismiss Count I of the Complaint with respect to the Plaintiff's manufacturing defect and design defect strict liability claims will be **DENIED**.

C. NEGLIGENCE

To prevail on a negligence claim, a Plaintiff must show that the defendants had "(1) a duty to conform to a certain standard of conduct, (2) that the defendants breached that duty, (3) that such breach caused the injury in question, and (4) actual loss or damage.'" Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 61 (3d Cir. 2009)(quoting Phillips v. Cricket Lighters, 576 Pa. 644, 841 A.2d 1000, 1008 (2003)). In Count II, Plaintiff alleges that Gore did not provide him with a reasonably safe product, that such a failure was negligent, and that this unreasonably safe product was the proximate cause of his injuries and damages.

Gore argues that the Plaintiff does not plead sufficient facts to identify any duty of care it allegedly owed or how it allegedly breached any duty. Gore contends that Plaintiff's vague references to adverse reports and complaints without specifying the contents, or the alleged impact of such reports on physicians and patients is insufficient and does nothing to further his negligence claim. Gore also contends the Plaintiff has failed to identify any single act or omission by it or its agents or employees that fell below the standard of care for manufacturers, and likewise failed to plead how any such act or omission caused or contributed to Plaintiff's alleged injuries. Lastly, Gore contends Plaintiff fails to allege facts to show that he was exposed to an unreasonable risk of harm, as abdominal pain, infection, and erosion are common, recognized risks associated with mesh implants.

In order to survive a Motion to Dismiss, the Plaintiff must set forth information from which each element of a claim may be inferred. (Kost v. Kozakiewicz, 1 F.3d 176 (3d Cir. 1993).

Here, the factual allegations in the Complaint, i.e., that Plaintiff was injured as a result of the infection and removal from the GORE Mesh, is plausible. The element that the duty Gore owed to the Plaintiff was breached is also plausibly stated since Gore designed, manufactured and supplied the GORE Mesh for the plaintiff's 1999 hernia repair surgery. The infection and

removal of the device in 2001, coupled with the fact the GORE Mesh was found in the Plaintiff's body years later, plausibly states that GORE was the proximate cause of his injuries. The adverse reports and complaints concerning the Mesh, allegedly known by Gore, suggest that Gore was engaged in an act or omission to act that infers that its duty owed to Plaintiff fell below the standard of care required for manufacturers. All of these allegations set forth enough facts with respect to the requisite elements of plaintiff's negligence claim under Pennsylvania law.

Thus, Gore's motion to dismiss Count II of the complaint will be **DENIED**.

D. LOSS OF CONSORTIUM

In Count III of the complaint, the Plaintiff's wife asserts a loss of consortium claim that is dependent on the viability of her husband's claims for strict liability and negligence. *See* McPhee v. Depuy Orthopedics, Inc., 989 F. Supp. 2d 451, 467 (W.D. Pa. 2012) (court held that a claim of loss of consortium is derivative of the strict liability and negligence claims). Since the court has found that Plaintiff's claims for strict liability and negligence are viable and shall proceed, his wife's derivative claim for loss of consortium

also survives Gore's motion to dismiss. *See* Schrecengost, 425 F.Supp.3d at 467.

Therefore, Gore's motion to dismiss Count III of the complaint will be **DENIED**.

V.

VI. CONCLUSION

For the reasons stated above, Gore's Motion to Dismiss, **(Doc. 6)**, will be **DENIED IN ITS ENTIRETY**. In particular, Gore's motion will be **DENIED** as to all of the Plaintiffs' claims raised in Counts I-III of their complaint, (Doc. 1-1), namely, the Plaintiff's manufacturing defect and design defect strict liability claims in Count I, the Plaintiff's negligence claim in Count II, and the loss of consortium claim of the Plaintiff's wife in Count III. An appropriate order shall follow.

s/ Malachy E. Mannion
MALACHY E. MANNION
United States District Judge

DATE: July 28, 2020
19-1556-01