IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

CONNIE HAGAN AND ROY DALE HAGAN,	)	
	)	
Plaintiffs,	)	
	)	**C.A. No.: N20C-10-208 PEL**
v.	)	
	)	
Boston Scientific Corporation (D/B/A Mansfield Scientific, Inc.) And Microvasive, Inc.,	)	
	)	
	)	
Defendants.	)	

Submitted: January 4, 2021
Decided: May 12, 2021

ON DEFENDANT'S MOTION TO DISMISS
DENIED in part / GRANTED in part

OPINION AND ORDER

Robert J. Leoni, Esquire, Shelby & Leoni, 221 Main Street Wilmington, DE 19804, Attorneys for Plaintiff.

Colleen Shields, Esquire and Alexandra D. Rogin, Esquire Eckert, Seamans, Cherin & Mellott LLC, 221 Main Street, Stanton, DE 19804, Attorneys for Defendant

Jones, J.

Plaintiffs Connie Hagan and Roy Dale Hagan (collectively, the "Hagans" or the "Plaintiffs") have brought the instant products liability claim. The Plaintiffs claim that Connie Hagan had surgery to implant a pelvic mesh device manufactured by Defendant Boston Scientific Corp. ("Boston Scientific" or "Defendants") inside her in 2012, and that defects in the device have since caused her to suffer physical injuries. Plaintiff has brough claims for Negligence, Breach of Warranty, Failure to Warn, and Loss of Consortium. Boston Scientific has filed a Motion to Dismiss (the "Motion") the Complaint for failure to meet Delaware's pleading standards and failure to state a claim for which relief can be granted. The matter has been fully briefed, and this Opinion will address the Defendant's Motion. For the following reasons, the Defendant's Motion to Dismiss is **GRANTED** in part and **DENIED** in part.

BACKGROUND

The background of this case is taken from the factual allegations set forth in Plaintiffs' Complaint in this action and the exhibits thereto. These allegations are presumed to be true at the Motion to Dismiss stage of this litigation.

Defendant Boston Scientific Corporation is a Delaware Corporation engaged in the business of designing, manufacturing, and selling medical devices.[1] One of the devices produced by Boston Scientific is called the Uphold. The Uphold is a

[1] Compl. At ¶ 3.

device targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakened or damaged vaginal walls.[2]

Plaintiffs Connie and Roy Dale Hagan are residents of Leoma, Tennessee.[3] On or about September 12, 2012, Connie Hagan was implanted with an Uphold that was designed, manufactured, packaged, labeled and sold by Boston Scientific.[4] Connie received the Uphold implantation with the intention of treating her for stress urinary incontinence and pelvic organ prolapse.[5] The Complaint asserts that after receiving the implantation, Connie Rae Hagan began to suffer "serious bodily injuries, including, but not limited to, lower back pain, lower pelvic pain and pressure, incomplete bladder emptying, dyspareunia, pelvic and bladder pain, urinary retention, abdominal pain, UTIs, yeast infections, extreme pain, infection of her internal bodily tissue, urinary problems, nerve damage, and other injuries. . ."[6] Connie underwent revision surgery to remove mesh from the Uphold device that had eroded through her vaginal wall on October 24, 2019.[7] Plaintiffs filed the instant Complaint on October 23, 2020.

Boston Scientific filed the instant Motion to Dismiss on December 4, 2020. The Motion asserts that the Hagans' Complaint should be dismissed because: (1) the Hagans' claims are time-barred due to the expiration of the relevant statute of

[2] Compl. At ¶ 4.
[3] Compl. At ¶ 1.
[4] Compl. At ¶ 43.
[5] Compl. At ¶ 44.
[6] Compl. At ¶ 46.
[7] Pl. Reply Br. At 1.

limitations, (2) the Complaint has failed to plead the Plaintiffs' claims with particularity as required by Rules 8(a) and 9(b), and (3) the Complaint has failed to state a claim upon which relief may be granted. This is the Court's decision on the Defendant's Motion.

STANDARD OF REVIEW

Defendant has moved to dismiss this action pursuant to Superior Court Rules of Civil Procedure 12(b)(6), 8(a), and 9(b).[8]

Under Superior Court Rule 12(b)(6), the Court may dismiss an action for failure to state a claim upon which relief can be granted. In order to state a claim upon which relief can be granted, a plaintiff need only make a "short and plain statement of the claim showing that the pleader is entitled to relief."[9] However, "conclusory allegations that lack a factual basis will not survive a motion to dismiss" under this standard.[10] On a Motion to Dismiss under to Rule 12(b)(6), the Court will accept all well-pled allegations of the Complaint as true and will draw all reasonable inferences that logically flow from those allegations in favor of the plaintiff as the non-moving party.[11] A Court can dismiss for failure to state a claim under Rule

[8] Both the Plaintiffs and Defendant agree that Delaware procedural law and Tennessee substantive law (including the Tennessee Products Liability Act) apply to the Plaintiffs' claims. See Pl.'s Response to Def.'s Mot. To Dismiss, at 8.
[9] Supr. Ct. R. 12(b)(6).
[10] *Shah v. Am. Sols., Inc*., N11C-07-196, 2012 WL 1413593, at *2 (Del. Super, Mar. 8, 2012).
[11] *Tanesha Maretta Williams v. Newark Country Club*, 2016 WL 6781221 at 1 (Del.Super., November 2, 2016); *William L. Spence Jr., v. Allison J. Funk, et al.,* 396 A.2d 967, 968 (Del. 1978); *Richard Clinton, et al. v. Enterprise Rent-a-Car Co., et al.,* 977 A.2d 892, 895 (Del. 2009).

12(b)(6) if "it appears with reasonable certainty that the plaintiff could not prove any set of facts that would entitle her to relief."[12]

Rule 9(b) requires plaintiffs to plead claims for negligence with particularity. To meet this standard, a plaintiff must include the "time, place, contents of the alleged [] negligence, as well as the individual accused of committing" the negligent act.[13] The plaintiff must also plead "sufficient facts out of which a duty is implied and a general averment of failure to discharge that duty."[14]

STATUTE OF LIMITATIONS

A. PERSONAL INJURY CLAIMS

Boston Scientific first asserts that this action should be dismissed because the Plaintiffs' personal injury claims are time-barred due to expiration of the statute of limitations. According to Defendant, Plaintiffs' claims accrued on the date when Connie Hagan underwent surgery to implant the Uphold device on September 12, 2012. This would mean that the Hagans' personal injury claims would be barred under either Delaware's two-year limitations period for products liability actions or Tennessee's one-year limitations period for such actions. It is not necessary for this Court to determine whether Tennessee or Delaware law controls the statute of limitations in this action, because the Plaintiffs' claims will survive a motion to dismiss under either standard.

[12] *Rammuno v. Cawley*, 705 A 2d 1029, 1034 (Del 1998).
[13] *TrueBlue, Inc. v. Leeds Equity Partners IV, LP*, 2015 WL 5968726, at *6 (Del Super. Sept. 25, 2015).
[14] *State Farm Fire & Cas. Ins. Co. v. Gen. Elec. Co*., 2009 WL 5177156, at *5 (Del. Super. Ct. Dec. 1, 2009).

Both Tennessee and Delaware apply the so-called "discovery rule" in order to determine when a plaintiff's cause of action accrues.[15] The discovery rule "prevents the anomaly of requiring that a plaintiff [must] file suit prior to knowledge of his injury or. . . that she sue to vindicate a non-existent wrong, at a time when [the] injury is unknown and unknowable."[16] The Tennessee legislature has codified the discovery rule for products liability actions: "[a] cause of action for injury to the person shall accrue on the date of the personal injury, not the date of the negligence or the sale of a product."[17] Similarly, in Delaware, "an injury is sustained under [10 *Del. C.* § 8119] when the harmful effect first manifests itself and becomes physically ascertainable."[18]

Boston Scientific argues that the Hagans' personal injury claims arose "no later than [the date of Connie Hagan's Uphold implant surgery on] September 12, 2012."[19] In Defendant's view, the date of Connie Hagan's surgery is the appropriate accrual date for inquiry notice of her possible Uphold injury because in October of 2008 (roughly four years prior to Connie's surgery) the Food & Drug Administration had issued a Public Health Notification describing over 1,000 complaints relating to pelvic mesh products such as the Uphold.[20]

[15] See *Teeters v. Currey*, 518 S.W.2d 512, 517 (Tenn. 1974).
[16] Id. at 515.
[17] Tenn. Ann. Code Sect. 28-3-104(b)(1).
[18] *Burrell v. AstraZeneca*, 2010 WL 370584 (Del. 2020).
[19] Def.'s Reply Br., at 6.
[20] *Id*.

The United States District Court for the Western District of Pennsylvania had the opportunity to address a similar argument previously and rejected it in a case which parallels the instant litigation. In *Wallace v. Boston Scientific Corp*., 2018 WL 6981220 (U.S. D.C. W.D. Pa), a plaintiff brought a personal injury lawsuit against Boston Scientific based on alleged defects in a surgically implanted pelvic mesh device. Boston Scientific moved to dismiss the case on the theory that the statute of limitations began to run on the date of the plaintiff's pelvic mesh surgery and had thus expired. The Court denied the motion to dismiss on this basis, holding that "By [Boston Scientific's] logic, [the plaintiff] arguably would have had reason to know of her alleged injury before she was even injured and well before she even contemplated having surgery. . . the defendant's statute of limitations argument invites us to find that its product was so notoriously, inherently, and obviously unsafe that the statute of limitations would begin to run from the moment it was implanted in the plaintiff."[21] Instead, the Court held that the date when the statute of limitations began to run was "not amenable to resolution on a motion to dismiss" and instead was a "question [which could be] better resolved at the summary judgment stage."[22]

This Court will elect to adopt the well-reasoned holding of *Wallace* with respect to the instant Motion to Dismiss. Boston Scientific's argument that the

[21] *Id*.
[22] *Id*.

statute of limitations began to run on the date of Connie Hagan's surgery on the theory that the Hagans' had inquiry notice of the Uphold's defects is rejected. The issue of when Connie Hagan's personal injury claims accrued it not amenable to a decision on the record established in this case thus far and cannot be decided at this stage of the proceedings. Plaintiffs' claim for loss of consortium in Count IV of the Complaint is derivative of the outcome of the Plaintiffs' underlying personal injury claim, and therefore is not amenable to a decision at this stage.

B. BREACH OF WARRANTY CLAIMS

Boston Scientific has also moved to dismiss Plaintiffs' claim for breach of warranty on the basis that the statute of limitations had expired by the time Plaintiffs filed their Complaint. Delaware applies a four-year statute of limitations to breach of warranty claims.[23] Breach of warranty claims accrue upon "tender of delivery. . . regardless of the aggrieved party's lack of knowledge of the breach." Here, the Plaintiffs' breach of warranty claims accrued on the date Connie Hagan's pelvic mesh implantation surgery on September 12, 2012. The statute of limitations for the breach of warranty claims expired four years later on September 12, 2016. This was over four years before the Plaintiffs filed the Complaint in the instant action on October 23, 2020. The statute of limitations for a breach of warranty claim thus expired before the Plaintiffs initiated this lawsuit. Accordingly, Boston Scientific's Motion is **GRANTED** with respect to

[23] 10 *Del. C.* § 2-725

Plaintiffs' claim for breach of warranty, and Plaintiff's Count III for Breach of Warranty is **DISMISSED**.

In summary, the Defendant's Motion to Dismiss is **DENIED** with respect to Plaintiffs' counts I, II, and IV for personal injury and loss of consortium. Counts I, II, and IV are subsumed and will be analyzed under the framework of the TPLA for the remainder of this litigation. Defendant's Motion to Dismiss is **GRANTED** with respect to Plaintiff's Count III for breach of warranty.

TENNESSEE PRODUCT LIABILITY ACT

Defendant has also moved to dismiss Plaintiffs' product liability claims for negligence, breach of warranty, and failure to warn based on the Tennessee Product Liability Act ("TPLA".) According to Defendant, "The TPLA governs all product liability actions, including all actions for personal injury resulting from the manufacture, construction, design. . . warning, instruction, marketing, packaging, or labeling or any product."[24] Defendant argues that this means that Plaintiffs' claims for negligence and failure to warn are subsumed by the TPLA and that Plaintiffs therefore cannot make independent claims for negligence, breach of warranty, and failure to warn based on the allegations in the Complaint. In their response, Plaintiffs do not dispute Defendant's argument that the TPLA subsumes these claims. Accordingly, the substance of these claims will be analyzed under the framework of the TPLA's standards for pleading products liability claims.

[24] Def.'s Mot. To Dismiss at 9, citing Tenn. Code Ann. § 29-28-102(6) (internal quotations omitted.)

To state a claim under the TPLA, a plaintiff must adequately plead "(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product."[25] It is insufficient to claim that there was "something wrong" with the product to adequately state a claim under this standard. Instead, the Plaintiff must trace his or her injury to a specific defect of the product.[26] While the Plaintiffs' Complaint does not appear to be specifically tailored to this standard, it nevertheless pleads sufficient facts to meet it.[27] Read as a whole, the Complaint gives fair notice of the claims asserted against Defendant and pleads sufficient facts to state a claim under the TPLA.[28]

First, the Complaint adequately pleads that the product as issue was defective and/or unreasonably dangerous. There are two tests under the TPLA to determine whether a product is defective or unreasonably dangerous. The first test is called the "consumer expectation test," which requires a showing that "the product's performance was below reasonable minimum safety expectations of the ordinary consumer having ordinary, common knowledge as to its characteristics."[29] Under

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[25] *Sigler v. Am. Honda Motor Co*., 532 F.3d 469, 483 (6th Cir. 2008); Moore v. C.R. Bard, 217 F. Supp. 3d 990, 996 (E.D. Tenn. 2016).
[26] *Tilden v. Gen. Elec. Co*., 2012 WL 1023617 at *3 (E.D. Tenn. Mar. 26, 2012) (emphasis added); *Fleming v. Janssen Pharm., Inc*., 186 F. Supp. 3d 826, 835 (W.D. Tenn. 2016).
[27] See *Higgs v. Gen. Motors Corp*., 655 F. Supp. 22, 23 (E.D. Tenn. 1985)("[I]t makes no difference whether the complaint is couched in terms of negligence, strict liability or breach of warranty, it has generally been held in the State of Tennessee that in order for a plaintiff to recover under any theory of product liability, the plaintiff must establish that the product was defective and unreasonably dangerous at the time the product left the control of the manufacturer.")
[28] *See Otk Associates, LLC*, 85 A.3d 696 (Del.Ch. Ct. 2014); see also, *In re New Valley Corporation Derivative Litigation*., 2001 WL 563244 (Del. Ch. Ct. Jan. 11, 2001).
[29] *Jackson v. Gen. Motors Corp*., 60 S.W.3d 800, 806 (Tenn. 13 2001).

the "prudent-manufacturer test," the Court "imputes knowledge of the dangerous condition to the manufacturer, and then asks whether, given that knowledge, a prudent manufacturer would market the product." The factual allegations of the Complaint meet both standards.[30] These factual allegations also lead to an inference that the alleged defects of the Uphold existed at the time that the product left the manufacturer's control, and proximately caused the injuries alleged in the Complaint.[31]

The Complaint does, however, not adequately plead that the Uphold which was surgically implanted within Connie Hagan had a manufacturing defect which caused her subsequent injuries. The Complaint summarily asserts that "Due to defects in [] manufacturing [the Uphold] Device was unreasonably dangerous at the time they left Defendant's control" and that Defendant was "negligent in… manufacturing" the Uphold, but does not claim that the Uphold which was implanted within Connie Hagan deviated from the manufacturer's specifications in any material way from other units of the product, or plead any specific facts which would lead to such an inference.[32] The Complaint contains no alternative pleading that the Uphold left Boston Scientific's possession in a state which was not intended by the manufacturer. The Complaint has therefore failed to adequately plead a claim for a

[30] See Pl.'s Reply to Mot. To Dismiss at 8-9 (describing design and manufacturing defects alleged in the Complaint in extensive detail.)
[31] Additionally, these allegations are sufficiently detailed to satisfy the special pleading standards of Superior Court Rule of Civil Procedure 9(b).
[32] Compl. ¶¶ 57, 63

manufacturing defect. Defendant's Motion is **GRANTED** to the extent that it asserts a claim for a manufacturing defect under the TPLA.

Defendant next contends that Plaintiffs have not adequately plead a failure to warn claim. To plead a failure to warn claim, a plaintiff must allege facts that state that a product was "in a defective condition or otherwise unreasonably dangerous by reason of the manufacturer's failure to provide an adequate warning informing users of the dangers of that product."[33] A plaintiff asserting a TPLA claim based on a failure to warn theory must show "(1) the warnings at issue were defective; (2) the defective warning made the product unreasonably dangerous; and (3) the inadequate labeling proximately caused the claimed injury."[34] In Defendant's view, "Plaintiffs do not identify any particular warning that Boston Scientific allegedly failed to provide to Ms. Hagan's unidentified prescribing physician. Nor do they assert any facts to show these unspecified warnings were inadequate or defective."[35] Plaintiffs' claim that the Complaint satisfied this standard because it alleges "that Boston Scientific consistently underreported and withheld information about the propensity of Defendant's Pelvic Mesh Products to fail and cause injury and complications, and misrepresented the efficacy and safety of the Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large."[36] These allegations in Plaintiffs' Complaint,

[33] *Goins v. Clorox Co*., 926 F.2d 559, 561 (6th Cir. 1991) (citations omitted).
[34] *Moore*, 217 F. Supp. 3d at 995
[35] Def.'s Mot. To Dismiss at 14.
[36] Pl.'s Reply to Mot. To Dismiss at 16 (citing Compl. At ¶ 9).

especially those allegations relating to the underreporting of injuries do the use of the product, are sufficient to adequately plead a claim for failure to warn under the Tennessee Act.

Defendant's Motion to Dismiss also argues that Plaintiffs failed to adequately plead a claim for breach of warranty. As discussed *supra*, the statute of limitations for a breach of warranty claim expired before the Hagans filed their Complaint. Since the statue of limitations on the breach of warranty claim has expired, the Court will not address whether Plaintiff has adequately stated a claim for breach of warranty in this Opinion.

In summary, Plaintiff has adequately plead a claim for violation of the TPLA. While the allegations in the Complaint may not have been specifically tailored to the TPLA, the Complaint nevertheless states facts sufficient to allege a breach of the statute. Defendant's Motion to Dismiss is **DENIED** with respect to this claim on this basis. However, Plaintiff has plead no facts indicating that the Uphold was defectively manufactured, and Defendant's Motion to Dismiss is **GRANTED** with respect to any manufacturing defect claim under the framework of the TPLA. Since the claim for breach of warranty is time-barred due to expiration of the statute of limitations, the Court will not address the parties' arguments on this issue.

LEARNED INTERMEDIARY DOCTRINE

Defendant next moves to dismiss the Hagans' Complaint based on the Learned Intermediary Doctrine. The Learned Intermediary Doctrine is a legal

principle which holds that a manufacturer's duty to warn runs to the physician who prescribes a medication or treatment regimen, rather than an individual patient or the general public. The Doctrine acts as an affirmative defense which protects manufacturers from liability when the physician who prescribed a treatment regimen was independently aware of the risks involved in the device's use. For the Doctrine to apply, however, "there must be either a warning – meaningful and complete so as to be understood by the recipient – or an individualized medical judgment that this treatment or medication is necessary and desirable for this patient." The issue of whether adequate warnings were issued is factual and is usually resolved by the trier of fact.[37]

In their Complaint, the Plaintiffs allege the following:

> The Defendant has *consistently underreported* and *withheld information* about the propensity of Defendant's Pelvic Mesh Products to fail and cause injury and complications, and have *misrepresented* the efficacy and safety of the Product, through various means and media, actively and *intentionally misleading* the FDA, *the medical community*, patients, and the public at large.[38]

While these allegations could have been fleshed out in greater detail and would have been stronger had they included a claim that the surgeon who implanted the Uphold device would not have done so if her or she had received an adequate warning, they are nevertheless sufficient to plead a claim for failure to provide an

[37] See Restatement (Third) of Torts: Prods. Liab. § 2 cmt. i, illus. 11, at 31 (1998) ("Whether the warning actually given was reasonable in the circumstances is to be decided by the trier of fact.")
[38] Compl. ¶ 9 (emphasis in original)

adequate warning to Connie Hagans' treating physicians at this stage of this litigation. It is possible that Boston Scientific will be able to demonstrate that the physicians in question received an adequate warning following full discovery. At that point, Boston Scientific may re-assert an affirmative defense based on the Learned Intermediary Doctrine with the benefit of a fully-developed factual record. At the Motion to Dismiss stage, this basis for dismissal is **DENIED**.

CONCLUSION

For the reasons stated above, Defendant's Motion to Dismiss is **GRANTED** with respect to Plaintiff's Count II for breach of warranty as this claim is time-barred. Counts I, III, and IV of the Complaint are subsumed by the TPLA, and the Defendant's Motion to Dismiss is **DENIED** with respect to these claims.

IT IS SO ORDERED.

/s/ Francis J. Jones, Jr.
Francis J. Jones, Judge

cc: File&ServeXpress