IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Julia Barnett and Tim McCurty,	)	
	)	
Plaintiff,	)	
	)	**C.A. No.: N20C-12-076 PEL**
v.	)	
	)	
Boston Scientific Corporation	)	
(D/B/A Mansfield Scientific, Inc.)	)	
And Microvasive, Inc.,	)	
	)	
Defendants.	)	

Submitted: February 24, 2021
Decided: May 13, 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.

Plaintiff Julia Barnett has brought suit against the defendant, Boston Scientific Corporation ("Boston Scientific"), alleging numerous claims sounding in strict liability, negligence, and breach of various warranties. Plaintiff's claims arise out of personal injuries she claims to have suffered from a mesh device that was surgically implanted in her, which she alleges was defectively designed and manufactured by Boston Scientific. Plaintiff Tim McCurty has filed a derivative loss of consortium claim based on Julia's direct claims. Defendant has moved to dismiss the complaint on the following grounds: (1) the claims are time barred; (2) the claims are not pled with the required specificity; (3) plaintiff's claims are subsumed by the Mississippi Product Liability Act ("MPLA") and those claims lack the facts sufficient to support such a claim. For the reasons set forth herein, 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, which this Court must accept as true in deciding the motion to dismiss.

Plaintiffs are residents of Mississippi. On April 24, 2014, Plaintiff Julie Barnett, underwent implantation of a Boston Scientific pelvic mesh device known as the "Obtryx" at Forest General Hospital in Hattiesburg, Mississippi. On February 19, 2020, Ms. Barnett underwent revision surgery at East Jefferson General Hospital in Metairie, Louisiana, to remove mesh from the Obtryx device which had eroded

through her vaginal wall. Despite the revision surgery, Ms. Barnett suffered from and continues to suffer from pain, infection, urinary and bowel problems, organ perforation, mesh exposure, fisulae, dyspareunia and neuromuscular problems due to complications from Defendant's defective mesh product. Plaintiff's Complaint was filed on December 7th, 2020. Defendant filed a Motion to Dismiss the case on January 25th, 2021. This Opinion will address the Motion to Dismiss.

STANDARD OF REVIEW

Under Superior Court Rule 12(b)(6), the Court may dismiss a claim for failure to state a claim upon which relief can be granted only where the plaintiff cannot recover under any reasonable conceivable set of circumstances or facts susceptible of proof that may be inferred from the pleadings. The Court accepts the well-pled allegations of the Complaint as true and draws "all reasonable information that logically flow from those allegations in favor of the non-moving party."[1] Under Delaware law, in order to survive a motion to dismiss for failure to state a claim, a Complaint need only give general notice of the claim asserted. A claim will not be dismissed unless it is clearly without merit, either as a matter of law or fact.[2] A Court can grant a motion to dismiss for failure to state a claim on which relief can

[1] *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).
[2] *Wilen v. Pollution Control Industries,* Inc., Del. Ch. C.A. No 7254-NC (Consolidate). Harnett, V.C. (Oct 15, 2984).

be granted only if "it appears with reasonable certainty that the plaintiff could not prove any set of facts that would entitle her to relief."[3]

Under Del. Super. Ct. Civ. Rule 9(b) a plaintiff must plead negligence with particularity. The purpose of Rule 9(b) is to apprise the adversary of the acts or omissions by which it is alleged that a duty has been violated so that an opponent is able to prepare a defense to them.[4] Under Rule 9(b) "it is usually necessary to allege only sufficient facts out of which a duty is implied and a general averment of failure to discharge that duty."[5]

STATUTE OF LIMITATIONS

Defendant maintains that Plaintiffs' Complaint is untimely and barred by the statute of limitations. According to Boston Scientific, the statute of limitations began to run on April 24, 2014, the date Ms. Barnett was implanted with the Obtryx device. Because both Delaware and Mississippi apply the so-called "discovery rule" to determine when a personal injury claim accrues for statute of limitations purposes, Defendant's motion to dismiss will be **DENIED** with respect to the personal injury claims which Plaintiff has asserted.

Delaware applies a two-year statute of limitations to personal injury actions. 10 *Del. C.* §8119. For purposes of determining when a cause of action accrues in Delaware, "an injury is sustained under §8119 when the harmful effect first

[3] *Rammuno v. Cawley*, 705 A 2d 1029, 1034 (Del 1998).
[4] *Chesapeake & Potomac Tel. Co. of Maryland v. Chesapeake Utilities Corp.*, 436 A2d 314, 338 (Del 1981).
[5] *State Farm Fire & Cas., Co v. Gen. Elec. Co.*, 2009 WL 5177156 (Del. Super., 2009).

manifests itself and becomes physically ascertainable."[6] Mississippi applies a three-year statute of limitations. See Miss. Code. Ann Section 15-1-49. Like Delaware, Mississippi law provides that the statute of limitations begins to run at the time the plaintiff can reasonably be held to have knowledge of his or her injury or disease.[7] In both Delaware and Mississippi, the question of when an injury first manifests itself is an issue of fact to be decided by a jury when there is a genuine dispute.[8]

Defendant makes the novel argument that women implanted with their products are injured upon implant for the purposes of calculating when the statute of limitation begins to run. Under this theory the statute began to run on the date of Plaintiff's surgery on April 24, 2014. The United States District Court for the Western District of Pennsylvania addressed this argument in *Wallace v. Boston Scientific Corp.*, a case that parallels the instant litigation. The *Wallace* Court held::

> This is a curious argument. By this logic, Wallace [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. In short, 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. If we were to adopt the defendant's rationale. Wallace's statute of limitations would have expired promptly on July 28, 2017 – exactly two years after she had her surgery – because she was "aware" of the risks and complications of the mesh product since 2004, and thus she should have known that she would be injured by the product as soon as it was implanted in her. We should decline the defendant's unusual invitation on a motion

[6] *Burrell v. AstraZeneca*, 2010 WL 370584 (Del. 2020).
[7] *Owens-Illinois, Inc v. Edwards*, 573 So.2d 704 (Miss. 1990).
[8] *Ridgeway Lane & Assoc., Inc. v. Watson*, 189 So.2d 626 (Miss. 2016); *Morton v Sky Nails*, 884 A.2d 480 (Del. 2005)

> to dismiss to declare their products so obviously unsafe that the statute of limitations immediately begins to run as soon as someone relies upon that product.
>
> Rather, Wallace alleges that she had several complications after her surgery in July 2015, but did not know that those complications were a result of the mesh product. She contends that she did not know the defendant's mesh product was the cause of her injuries until December 6, 2016 when she had surgery to remove the eroded mesh from her body. (Doc. 7-2, at 9). On this score, we cannot conclude as a matter of law that Wallace knew or should have known that her injuries were caused by the defendant's mesh product before December 6, 2016. Initially, it is unclear from the complaint exactly how long after the surgery she began having these complications. Indeed, because this argument is brought by way of motion to dismiss, we are unaware of the efforts undertaken by the plaintiff to pursue an explanation for the complications from which she suffered after her surgery. For this reason, we believe that this is an issue that this is not amenable to resolution on a motion to dismiss, where we are confined to consideration of the pleadings. Instead, this question would be better resolved at the summary judgment stage, where the court can review the record to determine if "reasonable minds could differ" on the question of Wallace's diligence, and accordingly, whether she was on notice of the cause of her injury before December 6, 2016. Therefore, we recommend that the defendant's motion to dismiss be denied on this ground.[9]

The analysis in *Wallace* is equally applicable to the instant action.[10] It is unclear from the complaint when Barnett was first aware that that she had physical symptoms consistent with implant issues. This is a question of fact that requires a fully developed record and is not amenable (nor should it be) on a motion to

[9] *Wallace v. Boston Scientific Corp.*, 2018 WL 6981220 (U.S. D.C W. D. Pa. 2018)

[10] This Court specifically rejects the argument that this is not a latent defect case. An erosion of mesh occurs inside a vagina and is gradual process whose full extent can only be known through surgical intervention.

dismiss.[11] At this stage, the Defendant's Motion to Dismiss is **DENIED** with respect to Plaintiff's personal injury claims based on expiration of the statute of limitations.

Defendant also moves for dismissal on the warranty claims in Count II of the Complaint on grounds that the statute of limitations for breach of warranty claims has expired. The Delaware statute of limitations on breach of warranty claims is 4 years. The Mississippi Statute of Limitations for such claims is 6 years.[12] Under either standard, the claims for breach of warranty are time-barred. Under both the Delaware and Mississippi statutes, the limitations period for warranty claims begins to accrue upon the delivery of the product regardless of the aggrieved party's lack of knowledge of the breach.[13] A breach of warranty claim accrues when tender of delivery is made, except that the cause of action accrues when the breach is or should have been discovered where a warranty explicitly extends to future performance of goods and discovery of the breach must await the time of performance.[14] Under Delaware law, the statute of limitations for Plaintiff's breach of warranty claims expired four years after her surgery, on April 24, 2018. Under Mississippi law, the

[11] Defendant's reliance on *Hutchinson v Boston Scientific Corp.*, 2020 WL 5752393 (U.S.D.C. Del 2020) is misplaced. This Court reads Hutchinson to stand for the proposition that once a plaintiff has physical symptoms that are consistent with mesh implant issues the plaintiff is on notice that these problems could be related to the mesh implant. *Burrell v AstraZeneca LP*. 2010 WL 3706584 (Del. Super. 2010). In the instant case there remains a fact question, to be more fully developed, as to when the plaintiff first started experiencing symptoms associated with the implant. To the extent that this Court has read Hutchinson too narrowly it declines to follow it and any rule that the statute of limitations begins to run from the time of the first implant regardless of when the plaintiff first had adverse physical symptoms. The statute of limitations does not begin to accrue until there are signs of a physical injury that are consistent with implant issues.

[12] Miss. Code Ann. S 75-2-725.

[13] 6 *Del. C.* § 2-725; *Lima Delta Company v. Gulfstream Aerospace Corporation,* 2019 WL 624589 (Del. Super. 2019). Miss. Code Ann. § 75-2-725; *Janssen Pharmaceutical Inc. v. Bailey*, 878 So.2nd 31, (Miss. 2004).

[14] *Id.*

statute of limitations expired six years after the date of her surgery, on April 24, 2020. Plaintiff did not file the Complaint in this action until December of 2020. There is no express or implied extension to future performance at issue in this case. Based on the clear language of both the Delaware and Mississippi statutes, Plaintiff's claims for breach of warranty are barred by the statute of limitations and are dismissed.[15] The Defendant's Motion to Dismiss is **GRANTED** with respect to the Plaintiff's breach of warranty claims.

MISSISSIPPI PRODUCT LIABILITY ACT

Defendant has advanced several arguments all of which revolve around the point that Plaintiff's complaint is insufficient as pled and deficient as a matter of law.

First, Defendant has drawn the Court's attention to the Mississippi Product Liability Act ("MPLA"), Miss. Code Ann. §11-1-63. According to Boston Scientific, the MPLA applies in any action for damages caused by a product, including but not limited to any action based on a theory of strict liability, negligence, or breach of implied warranty. Common law claims based on damages caused by a product are subsumed by the MPLA and therefore any such claims should be dismissed, in Defendant's view. In response, Plaintiffs contends that Mississippi law is unclear on whether the MPLA provides an exclusive remedy for such claims.

[15] *Id.*

This Court's review of Mississippi law leads it conclude that the MLPA provides the exclusive remedy for products-liability claims, including the instant claims over the pelvic mesh device implanted within Plaintiff.[16] To the extent that the Plaintiffs are making common law claims beyond the claims subsumed within the MPLA, those claims are dismissed.

Under the MPLA, the Plaintiff must establish that when the product left the control of the Defendant:

> (i) 1. The product was defective because it deviated in a material way from the manufacturer's or designer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
> 2. The product was defective because it failed to contain adequate warnings or instructions, or
> 3. The product was designed in a defective manner, or
> 4. The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product; and
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.
> Miss. Code Ann. § 11-1-63(a); *Lim v. Ethicon, Inc*., No. 3:20-CV-780-KHJ-LGI, 2021 WL 612399, at *6 (S.D. Miss. Feb. 12, 2021).

Plaintiffs assert claims of (1) manufacturing defect; (2) failure to warn; and (3) design defect. According to Defendant, the Plaintiffs have not adequately pled

[16] *Elliott v. El Paso Corp.,* 181 So. 3d 263 (Miss. 2015); *Lim v. Ethicon, Inc.*, 2021 WL 612399 (U.S.D.C.S.D. Miss 2021).

the elements of these claims under the MLPA. Plaintiffs have properly plead a design defect claim pursuant to the MPLA, but not a manufacturing defect claim.

To assert a design defect claim under the MPLA the Plaintiffs must show that at the time the product left the manufacturer's control: (1) the manufacturer knew or should have known about the danger that caused the damage for which recovery is sought; and (2) the product failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability prevented the harm. Miss Code Ann. § 11-1-63(f). In paragraphs of 5-10 of the Complaint lays out facts Plaintiffs' rely upon to properly plead a design defect claim. The facts contained in these paragraphs, along with all reasonable inferences therefrom, properly plead a design defect claim.

To bring a manufacturing defect claim under the MPLA, Plaintiffs must show that when the product left the control of the manufacturer, the product "was defective because it deviated in a material way from the manufacturer' specifications or from otherwise identical units manufactured to the same manufacturing specifications." Miss. Code Ann S 11-1-63(a). To state a claim, Plaintiffs must allege how the products in question deviated from the manufacturers' specifications for other units.[17] Defendant is correct that the Plaintiff has alleged that the devices at issue were in the condition intended by Boston Scientific when they left Boston Scientific's possession. There is no alternative pleading in the Complaint that relates

[17] *Adams v. Energizer Holdings, Inc.* 2013 WL 1791373 (S.D. Miss. Apr., 2013).

to a manufacturing defect that alleges that the product left Boston Scientific's hands in the condition other than that specified by Boston Scientific. On this basis Defendant's motion to dismiss claims based on a manufacturing defect is **GRANTED**.

In summary, Plaintiff has properly plead a design defect claim and Defendant's Motion to Dismiss is **DENIED** with respect to this claim. Plaintiff has not stated a claim for a manufacturing defect, and the Motion to Dismiss is **GRANTED** with respect to the manufacturing defect claim. Arguments with respect to the failure to warn claim are addressed below.

LEARNED INTERMEDIARY DOCTRINE

Boston Scientific further challenges Plaintiffs' complaint arguing that the failure to warn claims are barred by the learned intermediary doctrine and the claims should be dismissed on this basis. Mississippi follows the learned intermediary doctrine for products liability claims for certain medical products. Under this doctrine, a manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary (i.e., the doctor, surgeon, or other educated professional who is trusted to provide care to the patient.)[18] The issue of

[18] *Thomas v. Hoffman-LaRoche, Inc.* 949 F2d 806, 811 (5th Cir. 1992; *Lim v. Ethicon, Inc.,* 2021 WL 612399 (U.S.D.C. S.D. Miss 2021; *Janssen v. Pharmaceutical, Inc. v. Bailey,* 878 So.2d 31, 58 (Miss. 2004).

the adequacy of the warnings is factual and usually resolved by the trier of fact.[19] In the instant case plaintiff has alleged the following in her complaint:

- Defendant has known and continue to know that some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate Device; that there were and are differences between the Defendant's Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and exited between the Pelvic Mesh Products and their predecessors and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed information and failed to accurately and completely disseminate or share this and or critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh products and the procedure for implantation was and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh products into the Plaintiff. (*Id.* at para. 12).
- **Causation**: After, and as a result of the implantation of the Medical Devises, Plaintiff Izabella Shealy suffered serious bodily injuries, including, but not limited to erosion and other injuries similar to the ones described in the FDA's Public Health Advisory of October 20, 2008. (para. 48).
- **Causation**: These injuries would not have occurred but for the defective nature of the products implanted and/or Defendant's wrongful conduct. (*Id.* at para. 49.)
- As a result of having the Medical Devise implanted into her, Izabella Shealy has experienced significant mental and physical pain and suffering, and she has sustained permanent injury. (*Id.*. at para. 50.)

[19] *Wyeth Laboratories v. Fortenberry*, 530 So.2d 688 (Miss 1988).

At this stage of the proceedings, the above allegations lead this Court to conclude that the Plaintiff has sufficiently pled a failure to warn claim as the claim clearly indicates that the Defendant mislead the medical community and that had the injuries would not have occurred but for the Defendant's wrongful conduct which by a reasonable inference from the facts alleged would include the treating physician electing another product had they not been misled. The Complaint could have been more clearly drafted by containing a specific allegation that the implanting doctor would not have implanted the device had a proper warning. However, the Complaint is sufficient, (although barely), at this stage of the proceedings to withstand a motion to dismiss on the learned intermediary doctrine and the proximate cause requirements that follow from that doctrine. There is a reasonable set of facts that exist that could place liability against the defendant for failure to warn. Accordingly, the Defendant's Motion to Dismiss is **DENIED** with respect to the failure to warn claim.

LOSS OF CONSORTIUM

Defendant argues that Plaintiff McCurty's claim for loss of consortium should be dismissed on the grounds that it is a derivative claim based on Plaintiff Barnett's injuries. For the reasons described above, Barnett's personal injury and tort claims will survive Defendant's Motion to Dismiss. Accordingly, McCurty's derivative loss

of consortium claim will survive as well. Defendant's Motion to Dismiss is **DENIED** with respect to the loss of consortium.

CONCLUSION

In summary, Defendant's Motion to Dismiss is **GRANTED** with respect to the Complaint's claims for breach of warranty due to expiration of the statute of limitations. Plaintiff's personal injury claims are subsumed by the MPLA. Plaintiff has properly stated a claim for a design defect and failure to warn at this stage under the MPLA, and Defendant's Motion to Dismiss is **DENIED** with respect to these claims as well as the derivative loss of consortium claim. Plaintiff has failed to state a manufacturing defect claim and defendant's Motion to Dismiss is **GRANTED** on this claim.

IT IS SO ORDERED.

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

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