IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Izabella Shealy,	)	
	)	
Plaintiff,	)	
	)	**C.A. No.: N21C-01-068 PEL**
v.	)	
	)	
Boston Scientific Corporation,	)	
	)	
Defendants.	)	

Submitted: April 8, 2021
Decided: June 1, 2021

OPINION AND ORDER
ON DEFENDANT'S MOTION TO DISMISS

DENIED IN PART/GRANTED IN PART

Robert J. Leoni, Esquire, Shelby & Leoni, 221 Main Street Wilmington, DE 19804, *Attorneys for Plaintiff. Shanin Specter, Esquire, Lee B. Balefsky, Esquire Tracie L. Palmer, Esquire, Kline & Specter, P.C.*, 1525 Locust Street Philadelphia, PA 19102, *of Counsel - Attorney 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.

INTRODUCTION

Plaintiff, Izabelle Shealy, 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. Plaintiff alleges that this mesh device was defectively designed and manufactured by Boston Scientific. The Defendant has moved to dismiss the Complaint on the following grounds: (1) the Complaint fails to satisfy the pleading requirements of the Superior Court; (2) the failure to warn claims are barred by the learned intermediary doctrine; (3) any design or manufacturing defect claim should be dismissed for failure to specify a defect; (4) the breach of warranty claim fails because Plaintiff has failed to allege how or when the alleged representations of the warranty were made; (5) there is no allegation that the Defendant's device was the proximate cause of Plaintiff's injuries; and (6) Plaintiff's request for punitive damages should be stricken because she has not alleged sufficient facts to support a punitive damages claim under either Delaware or New York law. The parties appear to agree the substantive law of New York controls this action. For purposes of this motion the Court will accept that New York

law applies.[1] For the reasons set forth below, Boston Scientific'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 Plaintiff's Complaint, which this court must accept as true in deciding the motion to dismiss.

Plaintiff is a resident of New York. On January 7, 2019, Plaintiff underwent implantation of a pelvic mesh device manufactured by Defendant called the Obtryx. The surgery was performed in Santa Monica, California. As a result of the implant Plaintiff has suffered pain, erosion, urinary problems, dyspareunia, organ perforation, and vaginal scarring related to complications from Defendant's product. This included an additional surgery to remove eroded mesh performed at UCLA Medical Center on July 12, 2019. Plaintiff's Complaint was filed on January 11, 2021. The Complaint asserted claims against Defendant based on Negligence (Count I), Breach of Warranty (Count II), and Failure to Warn (Count III).

Defendant filed a Motion to Dismiss the action on February 23, 2021. The parties have fully briefed the Motion to Dismiss and this Opinion represents the Court's decision on that Motion.

[1] Plaintiff is a resident of New York. The two medical procedures related to the mesh implant occurred in California. This Court's review of California law suggests that the result reached in this opinion is the same if the Court applied California law to this analysis.

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 reasonably conceivable set of circumstances or facts susceptible of proof that may be inferred from the allegations. 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."[2] 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 and will not be dismissed unless it is clearly without merit, either as a matter of law or fact.[3] A Court can dismiss for failure to state a claim on which relief can 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."[4]

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.[5] Under Rule 9(b) it is usually necessary to allege only

[2] *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).
[3] *Wilen v. Pollution Control Industries,* Inc., Del. Ch. C.A. No 7254-NC (Consolidate). Harnett, V.C. (Oct 15, 2984).
[4] *Rammuno v. Cawley*, 705 A 2d 1029, 1034 (Del 1998).
[5] *Chesapeake & Potomac Tel. Co. of Maryland v. Chesapeake Utilities Corp.*, 436 A2d 314, 338 (Del 1981).

sufficient facts out of which a duty is implied and a general averment of failure to discharge that duty.[6]

FAILURE TO WARN CLAIMS

Defendant alleges that the learned intermediary doctrine bars all failure to warn claims contained in Count III of Plaintiff's Complaint.[7] Under the learned intermediary doctrine a "medical professional acts as an 'learned intermediary' between the manufacturer [of a medical device] and the patient" and the manufacturer is relieved of any responsibility to directly warn the patient.[8] Thus, a manufacturer's duty to warn in this context only extends to the physician. However, the learned intermediary doctrine does not compel dismissal of claims that warning labels were insufficient, since these claims are premised on Defendant's failure to provide proper warnings to Plaintiff's prescribing medical professionals, and not on Defendant's failure to warn Plaintiff directly. [9]

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

[6] *State Farm Fire & Cas., Co v. Gen. Elec. Co.*, 2009 WL 5177156 (Del. Super., 2009).
[7] *Bukowski v. CooperVision Inc.*, 592 NY.2d 807, 809 (N.Y. App. Div. 1993).
[8] *Banker v. Hoehn.*, 718 N.Y. S.2d 438, 440 (N.Y. App. Div. 2000).,
[99] See *Martin v. Hacker.*, 83 N. Y 2d 1, 9 (N.Y. 1993).

> 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 ¶ 12).
>
> - **Causation**: After, and as a result of the implantation of the Medical Devices, 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. (¶ 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 ¶ 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 ¶ 50.)

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. The Complaint clearly indicates that the Defendant mislead the medical community and the Plaintiff's injuries would not have occurred but for the Defendant's wrongful conduct. By reasonable inference from the facts alleged, this would include the treating physician electing another product had they not been misled. While the Complaint could have been more clearly drafted by containing a specific allegation that the doctor who implanted the Obtryx would not have done so had they received

a proper warning, 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. At the motion to dismiss stage there is a reasonable set of facts that exist that could place liability against the defendant for failure to warn.

Accordingly, Defendant's Motion to Dismiss is **DENIED** with respect to the failure to warn claim described in Count III of the Complaint.

BREACH OF WARRANTY CLAIM

Defendant next seeks to dismiss Plaintiff's Count II for breach of warranty. Defendant argues that the Complaint "does not describe any representation that Boston Scientific made to [Plaintiff] or her prescribing physician" or where or how such a representation was made.[10] An express warranty is an "affirmation of fact or promise made by the seller to the buyer which relates to goods and becomes part of the basis of the bargain."[11] To state a claim for breach of an express warranty under New York law, a plaintiff must prove "that an express warranty existed, was breached, and that plaintiff had relied on that warranty."[12] The Plaintiff must allege where, when or how the alleged promise or statement was provided to her or her physicians.[13]

[10] Def.'s Mot. To Dismiss at 7.
[11] N.Y. U.C.C. S 2-313(1)(a); *See Friedman v. Medtronic, Inc.* 345 N.Y.S.2d 637, 643 (N.Y. App. Div. 1973).
[12] *Reed v. Pfizer*, Inc., 839 F.Supp.2d 571, 578 (E.D.N.Y. 2012).
[13] *Fisher v. APP PHARMACEUTICALS, LLC, et al.,* 783 F.Supp.2d 424, 431 (S.D.N.Y. 2011).

Plaintiff argues that she has pled the breach of warranty claim adequately, pointing to Paragraph 17 of the Complaint. In that section of the Complaint, she alleges: "Defendant provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increased the sales and also leading to the dissemination of inadequate and misleading information to patients, including plaintiff." The Plaintiff also points to paragraphs 5-8, 24, 25 and 46-50 of the Complaint. These paragraphs contain, among other allegations, the following:

- "…these products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, the emerging scientific evidence suggests that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendant's Pelvic Mesh Products containing this material." (¶ 5).
- Defendant's Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ 3 prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products. (¶ 6).
- The Defendant has marketed and sold the Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized

are documents, brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the products. (¶ 7).

- Defendant failed to undertake their duties to properly know the qualities of their product and in representations to Plaintiff and/or to Plaintiff's healthcare providers, to and concealed and intentionally omitted [] material information (¶ 24).[14]
- These injuries would not have occurred but for the defective nature of the products implanted and/or Defendant's wrongful conduct. (¶ 49).

These allegations, taken together, are sufficient to allege an express breach of warranty claim. Defendant's Motion to Dismiss is **DENIED** with respect to the breach of warranty claims detailed in Count II of the Complaint.

REMAINING NELIGENCE CLAIMS

Defendant alleges that the remaining negligence claims found in Count I of the Complaint which are not based on a failure to warn theory are not adequately pled. With respect to the design and manufacturing defect claims found in Count I, Defendant maintains that Plaintiff's allegations fail to establish the existence of a defect or to tie any particular defect to her injuries. According to Defendant, the Plaintiff does little more than assert the bare elements of a negligence claim.

Plaintiff has alleged the following in her complaint:

- Moreover, these products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, the emerging scientific evidence suggests that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendant's Pelvic Mesh Products containing this material. This immune response promotes degradation of the pelvic tissue and can

[14] The Complaint contains eleven specific pieces of allegedly omitted material information in this paragraph.

contribute to the formation of severe adverse reactions to the mesh. (¶ 5).

- Defendant's Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products. (¶ 6)
- The Defendant has marketed and sold the Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the products. (¶ 7)
- Contrary to the Defendant's representations and marketing to the medical community and to the patients themselves, the Defendant's Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law. The defects stem from any or all of the following:

    a. the use of polypropylene material in the Mesh itself and the immune reaction that results, causing adverse reactions and injuries;

    b. the design of the Pelvic Mesh Device to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

    c. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury

> d. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region.
>
> d. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury.
>
> e. the welding of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike.
>
> f. the design of trocars, as Device to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries. (¶ 8)

These allegations, taken together, are sufficient to state claims for failure to warn and sufficiently plead that defects in the Obryx device were the proximate cause of the Plaintiff's injuries.

MANUFACTURING DEFECT

To state a claim for a manufacturing defect under New York law, a plaintiff must allege that (1) the product was defective due to error in the manufacturing process and (2) the defect was the proximate cause of Plaintiff's injury.[15] Defendant alleges that any claims premised on a manufacturing defect fail because Plaintiff: (1) concedes that the devices at issue were in the condition intended by Boston Scientific when they Boston Scientific's possession (Compl. ¶18); (2) fails to identify a particular design defect in the devices; and (3) fails to plead that any alleged defect plausibly caused her injuries. Defendant is correct that the Plaintiff has alleged that the devices at issue were in the condition intended by Boston

[15] *Williamson v. Stryker Corp.*, 2013 WL 3833081, at 4 (S.D.N.Y. July 23, 2013).

Scientific when they left Boston Scientific's possession. There is no alternative pleading in the complaint that relates to a manufacturing defect that is premised on an allegation that the Obtryx device was in the condition other then what Boston Scientific intended when it left the company's possession. On this basis, Defendant's motion to dismiss claims based on a manufacturing defect is **GRANTED**.[16]

DESIGN DEFECT

To state a cause of action for a design defect, Plaintiff must allege that the product was unreasonably dangerous for its intended use and must allege with sufficient specificity how the design of the product was defective.[17] According to Boston Scientific, Plaintiff has not done this. In paragraph 5 and 6 of the Complaint (set forth above) plaintiff alleges that Defendant designed the Obtryx to contain polypropylene, a material they knew was incompatible with tissues found in the human body. The Complaint further alleges that Plaintiff's tissue rejected the Obtryx, causing her injury. These allegations are sufficient to allege a design defect in the Obtryx. Defendant's Motion to Dismiss with respect to Plaintiff's claim for design defect is **DENIED**.

[16] See *Zetz v. Boston Scientific*, 398 F Supp 3rd 700 (E.D. Cal 2019).
[17] *Tears v. Bos. Sic Corp.*, 344 F Supp 3rd 500, 510 (S.D.N.Y 2018).

PUNITIVE DAMAGES CLAIM

Plaintiff's Complaint contains a demand for punitive damages. Defendant seeks to dismiss Plaintiff's claim for punitive damages. Defendant argues that Plaintiff's allegations that Boston Scientific acted in a "willful disregard for Plaintiff's safety cannot sustain a request for punitive damages". Defendant also seeks to strike Plaintiff's request for punitive damages on the grounds that the other claims in the Complaint should be dismissed. Plaintiff's Complaint specifically alleges the following:

- Despite emerging scientific evidence that polypropylene is incompatible with human tissue, Defendant continues to market the Obtryx to the medical community. (Compl. At ¶ 5-6.)
- Contrary to the Defendant's representations and marketing…the Defendant's products suffer from high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating reoperations, and have caused severe reversible injuries. (*Id.* at ¶ 8.)
- The Defendant has chronically 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. (*Id.* at ¶. 9-10.)
- Defendants "failed to accurately and completely inform the FDA, health providers and the patients. (*Id.* at ¶ 11.)
- Defendant continues to mislead the public into believing their products are safe and effective. *Id.*

At the motion to dismiss stage these allegations are sufficient for a punitive damage claim to survive, as other causes of action have survived the instant motion

to dismiss. Defendant's Motion to Dismiss is **DENIED** with respect to Plaintiff's claim for punitive damages.

CONCLUSION

In summary, the Defendant's Motion to Dismiss is **GRANTED** with respect for the claims for a manufacturing defect as described above. Defendant's Motion to Dismiss is **DENIED** with respect to all other claims found in the Complaint.

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

cc: File&ServeXpress