IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

CATHERINE STARK,

Plaintiff,

v. **Civil Action No. 2:13-cv-21637**

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Motion for Summary Judgment)

Pending before the court is Defendant Boston Scientific Corporation's Motion for Summary Judgment and Memorandum in Support Against Plaintiff Catherine Stark ("Motion") [Docket 51]. As set forth below, BSC's Motion is **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, strict liability for failure to warn, negligent manufacturing, negligent failure to warn, breach of express warranty, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose. BSC's Motion is **DENIED IN PART** with respect to the plaintiff's claims of strict liability for design defect and negligent design.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corp.

("BSC") MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* http://www.wvsd.uscourts.gov/MDL/boston/orders.html). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Stark's case was selected as a Wave 1 case by BSC.

On October 19, 2010, Ms. Stark was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (the "Obtryx"), a product manufactured by BSC to treat SUI. (*See* Mot. [Docket 51], at 1–2). Dr. Terri Scott implanted the product at St. Luke's The Woodlands Hospital in The Woodlands, Texas. (Short Form Compl. [Docket 1], at 4). Ms. Stark claims that as a result of implantation of the Obtryx, she has experienced multiple complications. She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breach of express and implied warranties; and punitive damages. (*Id.* at 4–5).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the

evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, I generally refer to the choice-of-law rules of the jurisdiction where the plaintiff first filed her

claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Stark did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Stark received the Obtryx implantation surgery in Texas. Thus, the choice-of-law principles of Texas guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of Texas law to the plaintiff's claims. In tort actions, Texas adheres to the Restatement (Second) of Conflict of Laws. (Am. Law Inst. 1971). *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under section 145 of the Restatement (Second) of Conflict of Laws, the court must apply the law of the state with the most "significant relationship to the occurrence and the parties." Here, Ms. Stark resides in Texas, and the product was implanted in Texas. Thus, I apply Texas's substantive law to this case.

III. Analysis

BSC argues that it is entitled to summary judgment because Ms. Starks's legal theories are without evidentiary or legal support. (Mot. [Docket 51], at 1). Ms. Stark concedes her claims for (1) breach of express warranty, (2) breach of implied warranty, (3) strict liability for manufacturing defect, and (4) negligent manufacturing. (*See* Pl.'s Resp. in Opp'n to Def.'s Mot. for Summ. J. ("Resp.") [Docket 67], at 1). Accordingly, BSC's Motion as to those claims is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

A. Statute of Limitations

BSC first argues that each of the plaintiff's personal injury claims are barred by Texas's statute of limitations. (Mot. [Docket 51], at 6–7). Under Texas law, the statute of limitations for personal injury actions is two years. Tex. Civ. Prac. & Rem. Code Ann. § 16.003(a). Accordingly, a plaintiff must file her claims within two years of the date the alleged wrongful act caused her injury. *Childs v. Haussecker*, 974 S.W.2d 31, 36 (Tex. 1998). This period, however, may be tolled by application of the discovery rule. The discovery rule tolls accrual "until a plaintiff knows or, through the exercise of reasonable care and diligence, should have known of the wrongful act and resulting injury." *Id.* (internal quotations and citation omitted); *see also Woodruff v. A.H. Robbins Co.*, 742 F.2d 228, 230 (5th Cir. 1984) ("[T]he Texas discovery rule . . . provides that certain 'inherently undiscoverable causes of action' do not accrue until the plaintiff learns or reasonably should have learned of the negligent cause . . . .").

Ms. Stark filed this action on August 8, 2013. (Short Form Compl. [Docket 1]). According to BSC, the statute of limitations dictated that the action be filed by May 26, 2013, two years after Ms. Stark expressed concern that her incontinence and pain were related to the implantation of the

Obtryx. (Mot. [Docket 51], at 7 (citing Pl. Medical Rs., Ex. E [Docket 51-1], at 1)). The record, however, is not indisputable, as BSC presents. In fact, the patient's medical records state:

> She noted one episode of incontinence yesterday. She is concerned about her bladder sling. She also notes that her sexual partner was hospitalized with a bladder infection for 4 days recently. She states they always use a condom. She is having left low back pain which radiates to the left lower quadrant. She has been taking some pain medication she had at home. She is to see Dr[.] Scott next week. She states she had bladder issues in the past while on ambilify which she is taking now.

Contrary to BSC's view, I am not persuaded that the reference to the Obtryx shows that "Ms. Stark voiced concerns that the issues were related to the implantation of the Obtryx device." A generalized statement that "she is concerned about her bladder sling" says nothing, as a matter of law, about Ms. Stark's belief that the Obtryx was responsible for her incontinence or any other symptom. BSC has not pointed to any other evidence that Ms. Stark discovered her potential claims against the defendant more than two years before filing this lawsuit. On this reasoning, and bearing in mind my duty to draw all legitimate inferences in favor of the nonmovant, I **DENY** BSC's Motion with respect to the statute of limitations.

B. Strict Liability

Texas has adopted the doctrine of strict liability for defective products set forth in section 402A of the Restatement (Second) of Torts. *See McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 789 (Tex. 1967). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although

> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (c) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (Am. Law Inst. 1965). "The concept of defect is central to a products liability action brought on a strict tort liability theory, whether the defect be in conscious design, or in the manufacture of the product, or in the marketing of the product." *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979).

1. Statutory Defense

BSC argues that Chapter 82 of the Texas Civil Practice and Remedies Code provides two separate statutory presumptions of non-liability that apply to FDA-regulated prescription medical devices, both of which bar Ms. Stark's claims. (Mot. [Docket 51], at 9–13). The first, section 82.008(a) of the Texas Civil Practice and Remedies Code states that:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design *complied with mandatory safety standards or regulations* adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

Tex. Civ. Prac. & Rem. Code § 82.008(a) (emphasis added).

As I have previously held, the 510(k) process is not a safety statute or administrative regulation. *See generally Lewis, et al. v. Johnson & Johnson, et al.*, 991 F. Supp. 2d 748 (S.D. W. Va. 2014). The Supreme Court determined that "the 510(k) process is focused on equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493, 116 S. Ct. 2240 (1996) (internal quotation omitted); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323, 128 S. Ct. 999 (2008) ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not

equivalence.") (internal quotation omitted).[1] FDA regulations also state that 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97 (2012). The FDA thus prohibits manufacturers of devices cleared through the 510(k) process from making any representations that their devices have been approved by the FDA. *See id.* ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."). Because the FDA's 510(k) clearance process is not a mandatory safety standard or regulation, I **FIND** section 82.008(a) inapplicable here.

Next, BSC relies on Section 82.008(c) of the Texas Civil Practice and Remedies Code, which provides as follows:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that *after full consideration of the product's risks and benefits the product was approved or licensed* for sale by the government or agency.

Tex. Civ. Prac. & Rem. Code § 82.008(c) (2013) (emphasis added). The FDA conducts a full analysis of the product's risks and benefits when a product goes through the premarket approval process, not the 510(k) clearance process. As discussed above, the 510(k) process relates to a medical device's equivalence to a preexisting device; it does not require "full consideration of the

[1] Other courts interpreted *Lohr* as I do, holding that the 510(k) process does not go to whether a product is safe and effective or impose any requirements on its own. *See, e.g., Martin v. Am. Med. Sys., Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001); *Mack v. Stryker Corp.*, 893 F. Supp. 2d 976, 985 (D. Minn. 2012); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 747 n.6 (E.D. Pa. 2007); *Nicoll v. I-Flow, LLC*, No. 12-1593, 2013 WL 2477032, at *3 (E.D. La. June 7, 2013).

product's risks and benefits." Also, as stated above, 510(k) clearance does not constitute FDA "approval" of the device. Therefore, I **FIND** that section 82.008(c) does not apply to BSC in this case.

2. Design Defect

In Texas, a plaintiff bringing a design defect claim under strict liability must prove by a preponderance of the evidence that (1) the product was unreasonably dangerous due to a defect, (2) "there was a safer alternative design," and (3) "the defect was a producing cause" of the damages. Tex. Civ. Prac. & Rem. Code Ann. § 82.005; *see also Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). To determine whether a product is unreasonably dangerous, Texas courts apply a risk-utility test that considers the following factors:

> (1) the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use; (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive; (3) the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs; (4) the user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and (5) the expectations of the ordinary consumer.

Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 432 (Tex. 1997); *see also Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). Whether the product is unreasonably dangerous is generally an issue for the jury. *Timpte Indus.*, 286 S.W.3d at 312; *Am. Tobacco*, 951 S.W.2d at 432.

BSC argues that comment k to section 402A bars the plaintiff's design defect claim. Comment k exempts certain products from strict liability because they are "unavoidably unsafe."[2]

[2] Comment k provides as follows:
Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not

The interpretation and treatment of this exemption varies. Some courts have found that comment k categorically bars design defect claims for certain medical products. *See, e.g., Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (leading case adopting categorical approach). In these states, comment k is an absolute bar to design defect claims for particular classes of products. Other courts have adopted a case-by-case approach. *See, e.g., Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308 (Idaho 1987) (leading extant case adopting case-by-case approach). Thus, in these states, whether comment k bars a claim for design defect depends on the particular product at hand.

As an initial matter, I reject BSC's contention that Texas's absolute bar for FDA-approved prescription drugs, *see Carter v. Tap Pharm., Inc.*, No. SA-03-CA-0182, 2004 WL 2550593, at *2 (W.D. Tex. Nov. 2, 2004) ("Under Texas law, all FDA-approved prescription drugs are unavoidably unsafe as a matter of law."), applies here, given that the products are neither FDA-approved nor prescription drugs. *See Lofton v. McNeil Consumer & Speciality Pharm.*, 682 F. Supp. 2d 662, 679 (N.D. Tex. 2010) (refusing to "take a leap not taken by Texas courts" in applying comment k categorically outside the prescription drug context).

BSC has presented no other argument on design defect. Thus, BSC has failed to meet its burden under the summary judgment standard of showing the absence of a genuine dispute as to

---

defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965).

any material fact. *See* Fed. R. Civ. P. 56(a); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), *superseded on other grounds by Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Therefore, BSC's Motion on the plaintiff's claim of strict liability for design defect is **DENIED**.

3. Failure to Warn

Texas, like many jurisdictions, has adopted the learned intermediary doctrine. Under this doctrine, a plaintiff must establish two elements: "(1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (applying Texas law).

Under Texas law, causation—the second element—must be proven by showing "a proper warning would have changed the decision of the treating physician." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)). In other words, the plaintiff must show "that but for the inadequate warning, the treating physician would have not used or prescribed the product." *Id.* (quoting *Dyer*, 115 F. Supp. 2d at 741). If a physician, as the learned intermediary, does not testify that he or she would not have used or prescribed the product, the causal chain is broken, the plaintiff cannot show causation, and the failure to warn claim fails.

BSC argues that the implanting physician, Dr. Scott, was adequately warned of the risks associated with the Obtryx before implanting it in Ms. Stark, and that the plaintiff cannot establish causation. The record does not include any evidence that but for the inadequate warning, Dr. Scott would not have used the product. Contrary to the plaintiff's assertion, "Dr. Scott's commitment to discussing issues with her patients, her lack of knowledge about certain dangers prior to her deposition, and her admission that had she been informed about such issues, she would have [addressed] those issues with her patients," (Resp. [Docket 67], at 11), is insufficient to sustain the

plaintiff's burden of proffering evidence on causation. Because the failure to warn claim fails for lack of causation, I need not address the adequacy of the warnings. *See Celotex*, 477 U.S. at 322–23. Accordingly, BSC's motion for summary judgment on the strict liability failure to warn claim is **GRANTED**.

C. Negligence

The learned intermediary doctrine applies with equal force to the plaintiff's negligent failure to warn case. *See Centocor*, 372 S.W.3d at 173 (finding the learned intermediary doctrine applies to all claims premised on the manufacturer's alleged failure to warn). Consequently, the negligent failure to warn claim fails for the same reason the strict liability failure to warn claim failed: the plaintiff did not meet her burden of demonstrating that the alleged inadequate warning was the producing cause of the plaintiff's injuries. Accordingly, the court **GRANTS** the defendant's Motion with respect to the plaintiff's negligent failure to warn claim.

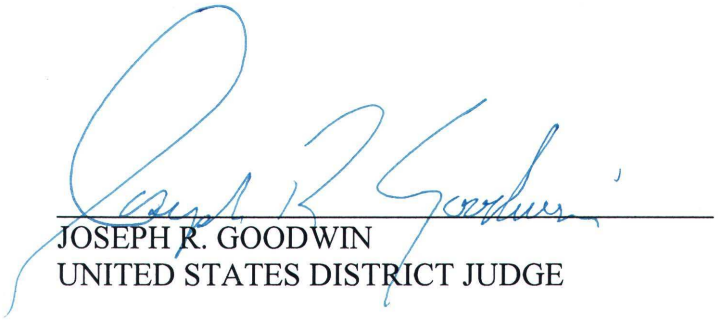
The defendant has also not presented arguments with respect to the negligent design defect claim beyond those I have already rejected. Accordingly, BSC's Motion as to the negligent design defect claim is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 51] is **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, strict liability for failure to warn, negligent manufacturing, negligent failure to warn, breach of express warranty, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose, and **DENIED IN PART** with respect to the plaintiff's claims of strict liability for design defect and negligent design.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 3, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE