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

CHARLESTON DIVISION

JOYCE OLIVER,

Plaintiff,

v. **Civil Action No. 2:13-cv-01736**

BOSTON SCIENTIFIC CORP.,

Defendant.

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

Pending before the court is Defendant Boston Scientific Corp.'s ("BSC") Motion for Summary Judgment and Memorandum in Support Against Plaintiff Joyce Oliver ("Motion") [Docket 33]. As set forth below, BSC's Motion is **GRANTED IN PART** with respect to BSC's defense of the statute of limitations regarding any claims based on the Obtryx Transobturator Mid-Urethral Sling System, and 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, breach of implied warranty of fitness for a particular purpose, and fraudulent concealment. 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

72,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corp. 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, 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. Oliver's case was selected as a Wave 1 case by the plaintiffs.

Plaintiff Joyce Oliver was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (the "Obtryx") on September 8, 2008, and the Advantage Fit System (the "Advantage Fit") on July 18, 2011.[1] (Pl. Fact Sheet [Docket 33-4], at 5). She received the surgery at a hospital in St. Petersburg, Florida, and Clearwater, Florida, respectively. (*Id.*). Her surgeries were performed by Dr. Meena Jain and Dr. Craig Barkley, respectively. (*Id.*). The plaintiff claims that as a result of implantation of the Obtryx and Advantage Fit, she has experienced multiple complications. She brings the following claims against BSC: strict liability for manufacturing defect, design defect, and failure to warn; negligence; breaches of express and implied warranties; fraudulent concealment; and punitive damages. (Short Form Compl. [Docket 1] ¶ 13).

[1] The plaintiff underwent another Advantage Fit implantation surgery on May 20, 2013. (Pl. Fact Sheet [Docket 33-4], at 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 such as this. The choice of law for these pretrial motions depends on whether they involve 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). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *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. Oliver did in this case, I consult the choice-of-law rules of the state in which the implantation surgery took place. *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. Oliver received her implantation surgery in Florida. (Short Form Compl. [Docket 1] ¶ 11). Thus, the choice-of-law principles of Florida guide this court's choice-of-law analysis.

These principles compel application of Florida law. "In an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant

relationship . . . .” *Bishop v. Fla. Specialty Paint Co.*, 389 So. 2d 999, 1001 (Fla. 1980) (quoting Restatement (Second) of Conflict of Laws (“Restatement”) § 146); *see also id.* (quoting Restatement § 145) (listing factors to consider when determining which state has the most significant relationship to a dispute).

Here, the plaintiff is a Florida resident. (Short Form Compl. [Docket 1] ¶ 4). In addition, she was implanted with the device and allegedly suffered injury in Florida. (*Id.* ¶¶ 11, 13). Accordingly, Florida has the most significant relationship of any state to the occurrence alleged in this lawsuit and to the parties. Thus, I apply Florida’s substantive law to this case.

III. Analysis

The plaintiff has conceded the following claims: strict liability for manufacturing defect, negligent manufacturing, breach of express warranty, breach of implied warranties, and fraudulent concealment. (Pl.’s Resp. in Opp’n to Def.’s Mot. for Summ. J. (“Resp.”) [Docket 67], at 17–18). Therefore, BSC’s Motion on these claims is **GRANTED**. I analyze the remaining claims below.

A. Statute of Limitations

In a products-liability action, the statute of limitations is four years. Fla. Stat. 95.11(3)(e). The statute of limitations “runs from the time the cause of action accrues,” *id.* § 95.031, but is subject to the discovery rule: “[T]he period run[s] from the date that the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence.” *Id.* § 95.031(2)(b). The limitations period is triggered when a plaintiff has knowledge of a possible causal connection between her injury and the product in question. *Walls v. Armour Pharm. Co.*, 832 F. Supp. 1467, 1478 (M.D. Fla. 1993) (citing *Babush v. Am. Home Prods. Corp.*, 589 So. 2d 1379, 1381 (Fla. Dist. Ct. App. 1991)), *aff’d sub nom. Christopher v. Cutter Labs.*, 53 F.3d 1184 (11th Cir. 1995); *see Carter v. Brown & Williamson Tobacco Corp.*, 778 So. 2d 932, 938 (Fla. 2000) (citing with approval *Tanner v. Hartog*, 618 So. 2d 177 (Fla. 1993)).

The plaintiff was implanted with the Obtryx on September 8, 2008. (Pl. Fact Sheet [Docket 33-4], at 5). In her deposition, she admitted that within a few weeks of her Obtryx implantation surgery, she told Dr. Jain, her implanting physician, that "I think it's the sling that's causing these problems." (Oliver Dep. [Docket 67-3], at 204:9–22). Therefore, I **FIND** that the limitations period was triggered at that time, a few weeks after September 8, 2008, and ran until a few weeks after September 8, 2012. *See Walls*, 832 F. Supp. at 1478. The plaintiff filed suit on January 31, 2013, several months outside of the limitations period. (*See* Short Form Compl. [Docket 1]). Thus, to the extent the plaintiff's claims arise out of the implantation of the Obtryx, BSC's Motion regarding the statute of limitations is **GRANTED**.

B. Strict Liability

In *West v. Caterpillar Tractor Co.*, the Supreme Court of Florida adopted section 402A of the Restatement (Second) of Torts as the standard for strict liability. 336 So. 2d 80, 87 (Fla. 1976). Accordingly, in Florida,

> [i]n order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages.

Id. at 86–87. Additionally, "a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning." *Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1170 (Fla. Dist. Ct. App. 1998).

1. Design Defect

Under the "government rules defense,"

> there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm: (a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or

> injury; (b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and (c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product.

Fla. Stat. § 768.1256(1).

BSC argues that the government rules defense applies in this case because the Federal Food, Drug, and Cosmetic Act ("FDCA") is designed to prevent the type of harm that allegedly occurred, and BSC complied with FDA regulations under the FDCA in clearing the Advantage Fit for sale to the public. (Def.'s Mot. for Summ. J. & Mem. of Law in Supp. ("Mem. in Supp.") [Docket 33], at 8–10).

In *Lewis v. Johnson & Johnson*, I held that

> [t]he 510(k) process is not a safety statute or administrative regulation. The Supreme Court has determined that "the 510(k) process is focused on equivalence, not safety." [*Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996)] (internal quotation omitted); *see also* [*Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008)] ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence.") (internal quotation omitted).

991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (footnote omitted); *see also Cisson v. C. R. Bard, Inc. (In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.)*, No. 2:11-cv-00195, 2013 WL 3821280, at *7 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own."). I also found in *Lewis* that section 82.008(a) of the Texas Civil Practice and Remedies Code did not apply because the product's "510(k) clearance [did] not relate to its safety or efficacy." *Lewis*, 991 F. Supp. 2d at 761; *see also* Tex. Civ. Prac. & Rem. Code § 80.008(a) ("[T]here 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.") (emphasis added).

Section 768.1256 of the Florida Statutes is nearly identical to the Texas statute at issue in *Lewis*. Both statutes provide a rebuttable presumption only when the product complies with government *safety* standards. Like I held in *Lewis*, because the 510(k) process is not "designed to prevent the type of harm that allegedly occurred," *see* Fla. Stat. § 768.1256(1)(b), I **FIND** that the government rules defense is inapplicable.

BSC has presented no other argument on design defect. Thus, BSC has failed to meet its burden of showing the absence of a genuine dispute as to 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). Furthermore, the plaintiff has offered concrete evidence from which a reasonable juror could return a verdict in her favor. Therefore, BSC's Motion on the plaintiff's claim of strict liability for design defect is **DENIED**.

2. Failure to Warn

To prevail on a claim of failure to warn, a plaintiff must show that the warnings accompanying the product are inadequate, and that the inadequacy of the warnings proximately caused the plaintiff's injury. *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009).

Florida follows the learned intermediary doctrine, under which the drug or medical device manufacturer's duty to warn is directed to the physician rather than the patient. *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *see Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007) (holding learned intermediary doctrine applies to prescription medical devices as well as prescription drugs); *Savage v. Danek Med., Inc.*, 31 F. Supp. 2d 980, 984 (M.D.

Fla.), *aff'd mem.*, 202 F.3d 288 (11th Cir. 1999) (same).[2] Under the learned intermediary doctrine, any warning read by the physician "means only that the learned intermediary would have incorporated the additional risk into his decisional calculus." *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992) (internal quotation marks omitted) (distinguishing preventable-risk warnings and unavoidable-risk warnings); *accord Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1021 (10th Cir. 2001); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992). A plaintiff must still show that her treating physician would not have implanted the product had the physician been given an adequate warning. *See Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 76 (Fla. Dist. Ct. App. 2009) ("[The plaintiff] failed to establish that the allegedly deficient warning was the proximate cause of his injury; therefore, we reverse."); *Boles v. Merck & Co. (In re Fosamax Prods. Liab. Litig.)*, 647 F. Supp. 2d 265, 279–82 (S.D.N.Y. 2009); *Baker v. Danek Med.*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998); *see also Maley v. Merck & Co. (In re Fosamax Prods. Liab. Litig.)*, 688 F. Supp. 2d 259, 265 (S.D.N.Y. 2010) (listing Florida as among the states where the plaintiff "has the burden of production on this aspect of causation").

Here, there is no evidence that Dr. Barkley, the implanting physician of the Advantage Fit, would have taken a different course of action even if he had been given an adequate warning. Dr. Barkley stated that if any information about the risks of a product changed, he would have

[2] The plaintiff argues that the learned intermediary doctrine is an affirmative defense. (Resp. [Docket 67], at 13–14). Thus, according to the plaintiff, BSC bears the burden of proof on this issue. (*Id.* at 10). Although a few Florida courts have indeed referred to the learned intermediary as an affirmative defense, upon review, I distinguish those cases and reject such a characterization. *See Walls v. Armour Pharmaceutical Co.*, 832 F. Supp. 1467, 1482 (M.D. Fla. 1993) (holding that the defendant bore the burden of proof with regard to the learned intermediary doctrine when moving for judgment as a matter of law under Federal Rule of Civil Procedure 50), *aff'd in part, rev'd in part on other grounds sub nom. Christopher v. Cutter Labs.*, 53 F.3d 1184 (11th Cir. 1995); *MacMorris v. Wyeth, Inc.*, No. 2:04CV596FTM-29DNF, 2005 WL 1528626, at *2 (M.D. Fla. June 27, 2005) (declining to resolve the issue of whether the learned intermediary doctrine applies at the motion to dismiss stage); *Horillo v. Cook, Inc.*, No. 10-15327, 2012 WL 6553611, at *3 (11th Cir. Nov. 7, 2012) (referring to the learned intermediary doctrine as an affirmative defense in the context of a defendant's ability to "avoid liability by demonstrating the treating physician was otherwise aware of the particular risk associated with the medical device").

incorporated those changes in how he advised his patients. (Barkley Dep. [Docket 67-2], at 16:14–17:23). However, without any indication that he would not have implanted the product had he been given such a warning, the plaintiff cannot establish proximate causation. *See Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d at 76 ("[The plaintiff] failed to establish that the allegedly deficient warning was the proximate cause of his injury; therefore, we reverse."). Therefore, BSC's Motion on the plaintiff's claim of strict liability for failure to warn is **GRANTED**.

C. Negligence

In a negligence suit, the plaintiff must establish (1) duty; (2) breach of duty; (3) causation; and (4) damages. *Kayfetz v. A.M. Best Roofing, Inc.*, 832 So. 2d 784, 786 (Fla. Dist. Ct. App. 2002); *see Clay Elec. Co-op, Inc. v. Johnson*, 873 So. 2d 1182, 1185 (Fla. 2003) (citing W. Page Keeton et al., *Prosser and Keaton on the Law of Torts* 164–65 (W. Page Keeton ed., 5th ed. 1984)).

1. Negligent Design

As explained earlier, the government rules defense does not apply to the plaintiff's design defect claim, whether based on strict liability or negligence, and BSC has failed to meet its summary judgment burden. *See supra* Part III.B.1. Therefore, BSC's Motion on the plaintiff's claim of negligent design is **DENIED**.

2. Negligent Failure to Warn

As explained earlier, there is no evidence that Dr. Barkley would have taken a different course of action even if he had been given an adequate warning, and thus, the plaintiff cannot establish proximate causation. *See supra* Part III.B.2. Therefore, BSC's Motion on the plaintiff's claim of negligent failure to warn is **GRANTED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 33] be **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, breach of implied warranty of fitness for a particular purpose, and fraudulent concealment, 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: October 5, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE