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

CHARLESTON DIVISION

DONNA EDENFIELD,

Plaintiff,

v. **Civil Action No. 2:13-cv-13702**

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 Donna Edenfield ("Motion") [Docket 46]. As set forth below, BSC's Motion is **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, negligent manufacturing, 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, strict liability for failure to warn, negligent design, and negligent failure to warn.

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. Edenfield's case was selected as a Wave 1 case by the defendant.

Plaintiff Donna Edenfield was surgically implanted with the Lynx Suprapubic Mid-Urethral Sling System (the "Lynx") on October 20, 2009. (Short Form Compl. [Docket 1] ¶¶ 8, 10). She received the surgery at a hospital in Tallahassee, Florida. (*Id.* ¶ 11). Her surgery was performed by Dr. Joseph Camps. (*Id.* ¶ 12). The plaintiff claims that as a result of implantation of the Lynx, 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).

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. Edenfield 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. Edenfield 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, and breach of implied warranties. (Pl.'s Mem. in Opp'n to Def.'s Mot. for Summ. J. ("Resp.") [Docket 67], at 1). Therefore, BSC's Motion on these claims is **GRANTED**. I analyze the remaining claims below.

A. 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 Lynx for sale to the public. (Def.'s Mot. for Summ. J. & Mem. of Law in Supp. ("Mem. in Supp.") [Docket 46], at 6–8).

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).[1] 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").

Furthermore, the "causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." *Beale*, 492 F. Supp. at 1365

[1] 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").

(quoting *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995)). Similarly, a physician's failure to read the warning breaks the chain of causation because the warning would have played no role in the physician's decision to prescribe the product. *Fields v. Mylan Pharm., Inc.*, 751 F. Supp. 2d 1260, 1263 (N.D. Fla. 2009).

Here, the plaintiff has offered concrete evidence from which a reasonable juror could return a verdict in her favor and genuine disputes of material fact exist with regard to (1) whether BSC's warning was adequate, and (2) whether the alleged inadequate warning proximately caused the alleged harm to the plaintiff. Therefore, BSC's Motion on the plaintiff's claim of strict liability for failure to warn is **DENIED**.

B. 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.A.1. Therefore, BSC's Motion on the plaintiff's claim of negligent design is **DENIED**.

2. Negligent Failure to Warn

As explained earlier, genuine disputes of material fact exist with regard to (1) whether BSC's warning was adequate, and (2) whether the alleged inadequate warning proximately caused the alleged harm to the plaintiff. *See supra* Part III.A.2. Therefore, BSC's Motion on the plaintiff's claim of negligent failure to warn is **DENIED**.

C. Fraudulent Concealment

The plaintiff's Short Form Complaint raises fraudulent concealment only as a safeguard to toll the statute of limitations. (*See* Short Form Compl. [Docket 1] ¶ 13 ("Count VIII – Discovery Rule, Tolling and Fraudulent Concealment")). Likewise, the Master Complaint does not discuss fraudulent concealment independent of the statute of limitations. (*See* Master Long Form Compl. & Jury Demand, MDL No. 2326, ¶¶ 89–92). Therefore, to the extent that the plaintiff intended to bring a separate claim of fraudulent concealment, BSC's Motion regarding that claim is **GRANTED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 46] be **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, negligent manufacturing, 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, strict liability for failure to warn, negligent design, and negligent failure to warn.

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