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

CHARLESTON DIVISION

BERTIE FRANKUM,

Plaintiff,

v. **Civil Action No. 2:12-cv-00904**

BOSTON SCIENTIFIC CORP.,

Defendant.

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

Pending before the court is defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment against Plaintiff Bertie Frankum [Docket 42]. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to Ms. Frankum's claims for strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent failure to warn, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, breach of express warranty, and fraudulent concealment. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Frankum's claims for negligent design and breach of implied warranty of merchantability.

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 70,000 cases currently pending, approximately 15,000 of which are in the 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. Frankum's case was selected as a Wave 1 case by the defendant.

Plaintiff Bertie Frankum was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx") on February 9, 2009. (BSC's Mot. for Summ. J. & Mem. of Law in Supp. ("Mem. in Supp.") [Docket 42], at 2). She received the surgery at a hospital in Shelby, North Carolina. (*Id.*). Ms. Frankum claims that as a result of implantation of the Obtryx, she has experienced multiple complications, including vaginal pain, dyspareunia, and bleeding with intercourse. (Pl.'s Resp. in Opp'n to BSC's Mot. for Summ. J. & Mem. of Law in Supp. ("Resp. Mem. in Supp.") [Docket 67], at 5). She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages. (Compl. [Docket 1]). In the instant motion, BSC moves for summary judgment on the grounds that plaintiff's "legal theories are without evidentiary or legal support." (Mem. in Supp. [Docket 42], at 1).

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. Frankum 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. Frankum received the implantation surgery in North Carolina. Thus, the choice-of-law principles of North Carolina guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of North Carolina law. For tort claims, North Carolina generally applies the *lex loci delicti* approach,

which provides that "the state where the injury occurred is considered the situs of the claim." *Harco Nat'l Ins. Co. v. Grant Thornton LLP*, 698 S.E.2d 719, 722–23 (N.C. Ct. App. 2010). Here, the alleged injury occurred in North Carolina, where Ms. Frankum was implanted with the allegedly defective device. Thus, I apply North Carolina's substantive law to the tort claims in this case. For warranty claims, North Carolina applies the "most significant relationship" approach, which "requires the forum to determine which state has the most significant relationship to the case." *Boudreau v. Baughman*, 368 S.E.2d 849, 853–54 (N.C. 1988). North Carolina courts have found that "the place of sale, distribution, delivery, and use of the product, as well as the place of injury . . . to be the state with the most significant relationship to the warranty claims." *Id.* at 855–56. Thus, I also apply North Carolina's substantive law to the warranty claims in this case.

III. Analysis

BSC argues that it is entitled to summary judgment in this case because Ms. Frankum's claims lack either evidentiary or legal support. Ms. Frankum agrees that this court should dismiss her claims for strict products liability. (Resp. Mem. in Supp. [Docket 67], at 1 n.1). Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's claims for strict products liability is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

A. Negligent Failure to Warn

Under North Carolina law, "[n]o manufacturer . . . shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant" can satisfy three requirements. N.C. Gen. Stat. § 99B-5(a). First, the claimant must establish "that the manufacturer . . . acted unreasonably in failing to provide such warning or instruction." *Id.* Second, the claimant must establish "that the failure to provide adequate warning or instruction

was a proximate cause of the harm for which damages are sought." *Id.* Finally, the claimant must establish either of the following:

> (1) At the time the product left the control of the manufacturer . . . , the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer . . . knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant[; or] (2) After the product left the control of the manufacturer . . . , the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

Id.

BSC first argues that, under subsection (c) of the same statute, the learned intermediary doctrine shields it from liability. (Mem. in Supp. [Docket 42], at 7 (citing N.C. Gen. Stat. § 99B-5(c))). Subsection (c) provides: "[N]o manufacturer . . . shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant . . . ." N.C. Gen. Stat. § 99B-5(c).

While I am not persuaded that the plain language of subsection (c) provides the basis for application of the learned intermediary doctrine to the instant case, "[t]here are indications that North Carolina courts would adhere to the learned intermediary doctrine" in matters of product liability. *Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000) (citing *Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530, 535–36 (E.D.N.C. 1987)). In fact, in *Baraukas*, the United States District Court for the Middle District of North Carolina determined that the learned intermediary doctrine applied where the manufacturer warned the plaintiff's physician about bone screws. *Id.* Accordingly, consistent

with the courts that have addressed this issue before me, I assess Ms. Frankum's negligent failure to warn claim under the learned intermediary doctrine.

Ms. Frankum cannot avoid the preclusive effect of the learned intermediary doctrine because reliance is required to establish causation. *Cf. Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 734 (S.D. W. Va. 2014) (applying California law) ("Even where a plaintiff proves that warnings were inadequate, the learned intermediary doctrine still applies. A plaintiff must prove that inadequate warnings altered the prescribing physician's decision to prescribe."). While Ms. Frankum points to Dr. Blackley's testimony wherein he stated that he *generally* reviews instructions before using a product the first time, (*see* Dr. Blackley Dep. [Docket 67-2], at 81:5–82:12), Dr. Blackley also admitted that he did "not read the DFU for the Obtryx transobulator sling." (Dr. Blackley Dep. [Docket 74-2], at 29:7–29:11). Thus, like in *Lewis v. Ethicon Inc.*, No. 2:12-cv-4301, 2014 WL 186869, at *4 (S.D. W. Va. Jan. 15, 2014), *rev'd in part on other grounds*, No. 2:12-cv-4301, 2014 WL 457551 (S.D. W. Va. Feb. 3, 2014), and *Jones v. C. R. Bard, Inc.*, No. 2:11-cv-00114, 2013 WL 5591948, at *6 (S.D. W. Va. June 4, 2013), the facts here demonstrate, indisputably, that Dr. Blackley failed to *rely* on the Obtryx DFU. (*See* Dr. Blackley Dep. [Docket 74-2], at 29:7–29:11). In turn, a reasonable juror could not infer that BSC's allegedly defective warnings proximately caused Ms. Frankum's injuries. *Cf. Lewis v. Johnson & Johnson*, No. 14-1244, 2015 WL 860371, at *2 (4th Cir. Mar. 2, 2015) (applying Texas law) ("When a physician relies on her own experience and examination of a patient in deciding to prescribe a device, and not on the device's warning, the warning is not the cause of the patient's injury.").[1]

Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's negligent failure to warn claim is **GRANTED**.

[1] For this reason, I need not address the adequacy of the warning provided.

B. Negligent Design

Under North Carolina law, a plaintiff alleging inadequate design first must prove "that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, [and] that this conduct was a proximate cause of the harm for which damages are sought . . . ." N.C. Gen. Stat. § 99B-6(a). To determine whether BSC acted unreasonably in designing the Obtryx, North Carolina requires that "the factors to be considered . . . include, but are not limited to, the following":

> (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product[;] (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm[;] (3) The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer[;] (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer[;] (5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation[;] (6) The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture[;] (7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

Id. § 99B-6(b). Additionally, a plaintiff must prove one of the following:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product[; or] (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

Id. § 99B-6(a).

Here, genuine disputes of material fact exist with regard to: (1) whether BSC acted unreasonably in designing the Obtryx, *see id.* § 99B-6(a); and (2) whether BSC unreasonably

failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design, *see id.* § 99B-6(a)(1), or whether the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use it.[2] *See id.* § 99B-6(a)(2).

Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's negligent design claim is **DENIED**.

C. Negligent Manufacturing

To the extent Ms. Frankum asserts a claim for negligent manufacture of the Obtryx, her claim fails because "[t]he record is absolutely devoid of any evidence regarding [BSC's] . . . manufacturing process, much less any negligent action or omission that occurred during those processes." *Carlton v. Goodyear Tire & Rubber Co.*, 413 F. Supp. 2d 583, 588 (M.D.N.C. 2005). Indeed, contrary to Ms. Frankum's argument, "the claim of selection of improper materials is a design defect claim, not a manufacturing defect claim." *Edwards v. ATRO SpA*, 891 F. Supp. 1074, 1078 (E.D.N.C. 1995).

Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's negligent manufacture claim is **GRANTED**.

D. Breach of Express Warranty

Under section 25-2-313 of the North Carolina General Statutes, express warranties are created by the seller in the following ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise[;] (b) Any description of the goods which is made part of the basis of the bargain

[2] BSC argues that the fact that BSC received FDA clearance for its products forecloses the possibility that a reasonable juror could determine that BSC acted unreasonably in designing the Obtryx. As I have previously held, however, 510(k) clearance from the FDA is not relevant to state tort law. *See, e.g.*, *Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 744 (S.D. W. Va. 2014) ("Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law."); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 753–56 (S.D. W. Va. 2014) (same).

> creates an express warranty that the goods shall conform to the description[;] (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Accordingly, any actionable express warranty under North Carolina law must be regarding a statement that is the "basis of the bargain."

BSC argues that because Ms. Frankum herself did not receive any materials from BSC, she could not have relied on any statement regarding the Obtryx. (Mem. in Supp. [Docket 42], at 16–17). While it is accurate that Ms. Frankum did not have communications with BSC, (Frankum Dep. [Docket 42-5], at 98:23–98:25), North Carolina law provides that Ms. Frankum need not prove contractual privity for her express warranty claim to survive. *See Alberti v. Manufactured Homes, Inc.*, 407 S.E.2d 819, 825 (N.C. 1991) ("[O]ur case law has recognized that a direct contractual relationship in the sale of the product itself is not a prerequisite to recovery for breach of express warranty against the manufacturer."). Importantly, even if Ms. Frankum merely relied on Dr. Blackley's medical judgment in deciding to have the Obtryx implanted, a reasonable juror could find that, by doing so, Ms. Frankum relied on the express warranties of BSC as they were provided to Dr. Blackley, which formed the basis for Dr. Blackley's medical judgment. *Cf. Michael v. Wyeth, LLC*, No. CIV.A. 2:04-0435, 2011 WL 2150112, at *9 (S.D. W. Va. May 25, 2011) (denying summary judgment on breach of express warranty because even though "plaintiff testified that she did not rely on any statements made by defendants . . . she did rely upon her doctors' recommendations," and as a result, "a presumption arises that [manufacturer's] affirmations were at least part of the 'basis of the bargain' that led plaintiff to ingest [the] drugs"); *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 972 (E.D. Wis. 2009) (denying summary judgment on express warranty claim where plaintiff did not read drug manufacturer's labeling but relied upon doctor's recommendations, and holding that "a

reasonable jury could find that [defendant's] representations to Dr. Todd, which were then communicated to the [plaintiffs], constitute an affirmation forming a 'basis of the bargain' for [plaintiff's] use of Paxil."); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625 (E.D. Pa. 2008) (same).

Nonetheless, the record does not provide any evidence suggesting that any express warranties were provided to Dr. Blackley. In fact, Dr. Blackley even admitted that he did "not read the DFU for the Obtryx transobulator sling." (Dr. Blackley Dep. [Docket 74-2], at 29:7–29:11). Accordingly, Ms. Frankum fails to assert that any express warranty was the "basis of the bargain." Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's breach of express warranty claim is **GRANTED**.

E. Breach of Implied Warranty of Merchantability

Under North Carolina law, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." N.C. Gen. Stat. § 25-2-314(1). For a good to be "merchantable," it must

> (a) pass without objection in the trade under the contract description; and (b) . . . [be] of fair average quality within the description; and (c) [be] fit for the ordinary purposes for which such goods are used; and (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and (e) [be] adequately contained, packaged, and labeled as the agreement may require; and (f) conform to the promises or affirmations of fact made on the container or label if any.

Id. § 25-2-314(2). The elements to establish a claim for breach of implied warranty of merchantability are: "(1) the goods bought and sold were subject to an implied warranty of merchantability, (2) the goods were defective at the time of the sale, (3) the defective nature of the goods caused plaintiff's injury, and (4) damages were suffered as a result." *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 454 (N.C. 1992).

Because a reasonable juror could determine that BSC negligently designed the Obtryx, *see supra* Section III.B, a reasonable juror could likewise find that BSC breached the implied warranty of merchantability. Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's breach of implied warranty of merchantability claim is **DENIED**.

F. Breach of Implied Warranty of Fitness for a Particular Purpose

Under North Carolina law, "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods," there is an implied warranty that the goods shall be fit for such purpose. N.C. Gen. Stat. § 25-2-315. Critically, "[a] 'particular purpose' differs from an ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business . . . ." *Id.* cmt. 2. On the other hand, "the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses customarily made of the goods in question." *Id.* Here, it is undisputed that the Obtryx was sold for its ordinary purpose—to treat SUI and POP—and not a particular purpose native to Ms. Frankum's circumstances. *See Foyle ex rel. McMillan v. Lederle Labs.*, 674 F. Supp. 530, 535 (E.D.N.C. 1987) ("In the present case the DPT vaccine had the ordinary purpose of preventing the contraction of disease. There was no particular purpose, native to the plaintiff's position, that would implicate the implied warranty for a particular purpose.").

Therefore, BSC's Motion for Summary Judgment on Ms. Frankum's breach of implied warranty of fitness for a particular purpose claim is **GRANTED**.

G. Fraudulent Concealment

Ms. Frankum's Short Form Complaint raises fraudulent concealment only as a safeguard to toll the statute of limitations. (Pl.'s Short Form Compl. [Docket 11], at 5 ("Count VIII – Discovery Rule, Tolling and Fraudulent Concealment")). Likewise, the Master Complaint does not discuss fraudulent concealment independent of the statute of limitations. Accordingly, to the extent a fraudulent concealment claim has been raised at the summary judgment stage, BSC's Motion for Summary Judgment on Ms. Frankum's fraudulent concealment claim is **GRANTED.**

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion for Summary Judgment [Docket 42] be **GRANTED IN PART** with respect to Ms. Frankum's claims for strict liability for manufacturing defect, strict liability for design defect, strict liability for failure to warn, negligent failure to warn, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, breach of express warranty, and fraudulent concealment, and **DENIED IN PART** with respect to Ms. Frankum's claims for negligent design and breach of implied warranty of merchantability.

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

ENTER: April 29, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE