

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

CHARLESTON DIVISION

JACQUELYN TYREE, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-08633

BOSTON SCIENTIFIC CORPORATION,

Defendant.

AMENDED MEMORANDUM OPINION AND ORDER
(Motion for Summary Judgment re: Campbell)

It is **ORDERED** that the Memorandum Opinion and Order entered on October 17, 2014 [Docket 445] is **AMENDED**. The only change to this decision is the omission of original footnote two. This deletion does not alter my ruling denying summary judgment on the strict liability for failure to warn claim.

Pending before the court is Defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment Against Plaintiff Carol Sue Campbell [Docket 255]. Responses and replies have been filed, and the motion is ripe for review. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to the plaintiff's strict liability for manufacturing defect, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, and fraudulent concealment claims. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to the plaintiff's strict liability for failure to warn, strict liability for design defect, negligent design, negligent warning, breach of express warranty, and

breach of implied warranty of merchantability claims.¹

I. Background

This consolidated 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 and stress urinary incontinence. In the seven MDLs, there are over 60,000 cases currently pending, over 13,000 of which are in the Boston Scientific Corporation MDL, MDL 2326. In this particular case, the four consolidated plaintiffs were surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (“the Obtryx”), a mesh product manufactured by BSC. (*See* Pretrial Order #78 [Docket 9], at 1–2). All of the plaintiffs received their surgeries in West Virginia. They claim that as a result of implantation of the Obtryx, they have experienced “erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.” (*Id.* at 4 (quoting the master complaint)).

In the instant motion, BSC moves for summary judgment on each of the claims brought by one of the plaintiffs, Ms. Carol Campbell [Docket 255]. Ms. Campbell’s Complaint alleges the following causes of action: negligence; strict liability for design defect; strict liability for manufacturing defect; strict liability for failure to warn; breach of express warranty; breach of implied warranty; and equitable tolling due to fraudulent concealment. (Compl. 2:13-cv-18786 [Docket 1], at 4).

¹ Based on the consolidated nature of this case, the court has accepted the plaintiffs’ request to “incorporate by reference any and all arguments of other plaintiffs within this consolidated trial group to the extent that they may have application to [Ms. Campbell’s] claims.” (Pl.’s Resp. in Opp. to BSC’s Mot. for Summ. J. Against Pl. Carol Sue Campbell (“Pl.’s Resp. re: Campbell”) [Docket 291], at 1).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue 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., Ltd. 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 Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm’ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, 490 U.S. 228 (1989).

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).

This case was originally filed in the Southern District of West Virginia. Therefore, I apply West Virginia choice-of-law rules. In West Virginia, the applicable substantive law is the law of the place of injury. *McKinney v. Fairchild Intern., Inc.*, 487 S.E.2d 913, 922 (W. Va. 1997) (“Traditionally, West Virginia courts apply the *lex loci delicti* choice-of-law rule; that is, the substantive rights between the parties are determined by the law of the place of injury.”). West Virginia courts have deviated from this rule only in occasions of “particularly thorny conflicts problems,” including “complex, or unusual, contractual situations . . . and torts which very existence are dependent upon the brea[d]th and legality of contracts.” *Ball v. Joy Mfg. Co.*,

755 F. Supp. 1344, 1351 (S.D. W. Va. 1990) (quoting *Oaks v. Oxygen Therapy Servs.*, 363 S.E.2d 130, 131 (W. Va. 1987)). These MDLs do not raise such conflicts-of-law issues, and so I see no reason to depart from West Virginia’s traditional principles.

Here, Ms. Campbell’s implant surgery took place at St. Francis Hospital in Charleston, West Virginia. (Compl. 2:13-cv-18786 [Docket 1], at 3). Consequently, any alleged injuries occurred in West Virginia. Therefore, I **FIND** that the substantive laws of West Virginia apply to the issues in this case.

III. Analysis

BSC argues that it is entitled to summary judgment in this case because the plaintiff’s claims lack evidentiary or legal support. Below, I apply the standard for summary judgment to each claim in turn.

A. Strict Liability

For purposes of strict products liability, “a defective product may fall into three broad, and not mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the adequacy of, warnings, instructions, and labels.” *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682 (W. Va. 1979). In this case, BSC has moved for summary judgment on each category of strict products liability.

1. Manufacturing Defect

A manufacturing defect is present “when a product comes off the assembly line in a substandard condition.” *Morningstar*, 253 S.E.2d at 681 (quoting *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 454 (Cal. 1978)). To prevail on a manufacturing defect claim, the plaintiff must establish that (1) the product was defective; (2) due to a manufacturing defect; (3) present at the time the product left the manufacturer’s control; (4) which proximately caused the plaintiff’s

injury. *Id.* at 680. The plaintiff did not respond to BSC's Motion for Summary Judgment on the issue of manufacturing defect.

But even if I consider the responses raised by other plaintiffs in this consolidated trial, no material facts exist suggesting that the Obtryx had manufacturing defects. Plaintiff Jacquelyn Tyree, for instance, argues that “[t]he weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them.” (Pl. Tyree's Mem. of Law in Opp. to BSC's Mot. for Summ. J. [Docket 290], at 9). She also notes that polypropylene is impure, and Prolene™ mesh is not inert. (*Id.*). She describes multiple defects regarding polypropylene mesh's tendency to shrink, degrade, and oxidize. (*Id.* at 10). In sum, Plaintiff Tyree relies on the expert opinion of Dr. Ostergard that polypropylene is not appropriate for permanent implantation in the body to establish a manufacturing defect. (*Id.* at 9–11). These arguments, however, relate to the product's design and behavior after implantation. The plaintiffs point to no evidence that the Obtryx sling departed from its intended design at the time it left BSC's control. Accordingly, BSC's Motion for Summary Judgment on the manufacturing defect claim is **GRANTED**, and this claim is **DISMISSED**.

2. Failure to Warn

A defect arising from failure to warn “covers situations when a product may be safe as designed and manufactured,” but then “becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner.” *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 609 (W. Va. 1983). To substantiate a failure to warn claim under strict liability, the plaintiff must show that the failure to adequately warn “made the product not reasonably safe” and “that the defect was the probable cause of her injuries.” *Id.* at 610.

BSC asserts that the plaintiff has provided no evidence to support these requirements of a failure to warn claim. I disagree. The plaintiff has presented sufficient evidence on the inadequacy of BSC's warnings and on the existence of proximate cause to show that there is a genuine dispute of material fact. Therefore, BSC's Motion for Summary Judgment on the claim of failure to warn is **DENIED**.

3. Design Defect

A design defect is present when a “product is not reasonably safe for its intended use due to a specific design flaw.” Philip Combs, Andrew Cooke, *Modern Products Liability Law in West Virginia*, 113 W. Va. L. Rev. 417, 425 (2011) (citing *Morningstar*, 253 S.E.2d at 666). To prevail on a design defect claim, the plaintiff must establish that (1) the product was not reasonably safe; (2) for its intended use; (3) due to a defective design feature; (4) which proximately caused the plaintiff's injury. *See Morningstar*, 253 S.E.2d at 682–83.

BSC addresses the plaintiff's design defect claim in one sentence: “For these same reasons, Plaintiff's design defect claim also fails.” (Def.'s Mem. of Law in Supp. of Mot. for Summ. J. Against Pl. Carol Campbell (“Def.'s Mem. re: Campbell”) [Docket 256], at 17). The plaintiff argues that this conclusory assertion is not sufficient to support a motion for summary judgment. (Pl.'s Resp. re: Campbell [Docket 291], at 2). Regardless, the plaintiff has presented sufficient evidence on design defect, as discussed in my ruling on the defective manufacturing claim, to show that there is a genuine dispute of material fact. Therefore, BSC's Motion for Summary Judgment on the plaintiff's design defect claim is **DENIED**.

B. Negligence

BSC moves for summary judgment on all of the plaintiff's claims premised on negligence, arguing that the plaintiff has not put forth any evidence of wrongful conduct on the

part of BSC. (Def.'s Mem. re: Campbell [Docket 256], at 11–12). In a negligence suit, the plaintiff must establish (1) duty; (2) breach of duty; (3) causation; and (4) damages. *See Hersh v. E-T Enters., Ltd.*, 752 S.E.2d 336, 341 (W. Va. 2013). “To prevail in a negligence suit, the plaintiff must prove by a preponderance of the evidence that the defendant owed a legal duty to the plaintiff and that by breaching that duty the defendant proximately caused the injuries of the plaintiff.” *Strahin v. Cleavenger*, 603 S.E.2d 197, 205 (W. Va. 2004). In the present case, the plaintiff’s negligence claims fall into the same three categories as her strict liability claims: (1) negligent manufacturing; (2) negligent design; and (3) negligent warning. (*See* Master Long Form Compl. & Jury Demand, MDL No. 2326, ¶¶ 55–59); *see also* Combs & Cooke, *supra*, 425 (“The elements of a negligence products claim [are] the following: (1) the manufacturer owed the consumer a duty to design/manufacture/warn regarding the product, (2) the product was defective thereby breaching that duty, (3) the breach of the duty proximately caused the plaintiff’s injuries, and (4) the plaintiff was injured.”).

1. Negligent Manufacturing

Much like her strict liability claim, the plaintiff does not provide sufficient evidence to create a “genuine issue as to any material fact” on the issue of negligent manufacturing. Fed. R. Civ. P. 56(a). The plaintiff contends that “Defendant BSC did not act with reasonable care in the design of the Obtryx product,” but she fails to offer evidence of a flaw in the manufacturing process. (Pl.’s Resp. re: Campbell [Docket 291], at 17). Accordingly, BSC’s Motion for Summary Judgment on the negligent manufacturing claim is **GRANTED**, and this claim is **DISMISSED**.

2. Negligent Design & Negligent Warning

Although BSC's Memorandum in Support generally encompasses the plaintiff's "negligence claims," it fails to make a specific argument regarding negligent design defect and failure to warn. The argument section addressing negligence refers solely to negligent manufacturing, merely mentioning multiple claims in the heading. (*See* Def.'s Mem re: Campbell [Docket 256] at 6–9 ("I. Plaintiff's Strict Liability and Negligence Claims Fail for Lack of Evidence.")). The only argument that appears to apply to all negligence claims is BSC's contention that there is a "conceptual overlap between negligence and strict products liability claims in West Virginia," and therefore, if the strict liability claims fail, the negligence claims should fail as well. (Def.'s Mem. re: Campbell [Docket 256], at 7). I disagree. In *Ilosky v. Michelin Tire Corp.*, the Supreme Court of Appeals of West Virginia explicitly states that "Product liability actions may be premised on three independent theories—strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover." Syl. pt. 6, 307 S.E.2d 603. The plaintiff has presented sufficient evidence of negligent design defect and negligent failure to warn, independent of her strict liability claims, to show that there is a genuine dispute of material fact. Accordingly, BSC's Motion for Summary Judgment is **DENIED** with respect to the plaintiff's claims premised on negligent design defect and negligent failure to warn.

C. Breach of Express Warranty

West Virginia Code § 46-2-313 provides that "[a]ny 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." W. Va. Code § 46-2-313 (2012). To succeed on a breach of express warranty claim, "a plaintiff must

show the existence of an express warranty, breach of the express warranty, and damages proximately caused by the breach.” *Michael v. Wyeth, LLC*, No. 2:04-0435, 2011 WL 2150112, at *7 (S.D. W. Va. May 25, 2011) (internal quotations omitted).

BSC contends that the plaintiff cannot prove the existence of an express warranty because Ms. Campbell testified that she did not receive any written materials from BSC or her physician prior to her implant surgery. Considering the Obtryx’s Directions for Use (“DFU”), however, a reasonable juror could conclude that BSC created an express warranty that applied to Ms. Campbell. Indeed, in light of the DFU, only the jury can answer the question of whether an express warranty existed. *See Sylvia Coal Co. v. Mercury Coal & Coke Co.*, 156 S.E.2d 1, 6 (W. Va. 1967) (“It has always been true . . . that where there is a conflict in the evidence with regard to whether an express or implied warranty exists the question is one for the jury to determine . . .”). BSC stresses that Ms. Campbell never relied on the DFU, and as a result, any breach of an express warranty did not proximately cause her injuries. West Virginia law provides, however, that “no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement.” § 46-2-313 (editors’ notes); *see also Michael*, 2011 WL 2150112, at *9 (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”). Because there is a material issue of fact in dispute as to whether an express warranty existed and as to whether it formed the basis of the bargain that led Ms. Campbell to opt for surgery, I **DENY** summary judgment on the breach of express warranty claim.

D. Breach of Implied Warranties

West Virginia law provides for two types of implied warranties: (1) the implied warranty of merchantability; and (2) the implied warranty of fitness for a particular purpose. *See* W. Va. Code §§ 46-2-314, 46-2-315.

1. Implied Warranty of Merchantability

BSC moves for summary judgment on the plaintiff's claim for breach of implied warranty of merchantability, arguing that the plaintiff "cannot demonstrate by a preponderance of the evidence that the Obtryx was not fit for its ordinary purpose." (Def.'s Mem. re: Campbell [Docket 256], at 14). Under West Virginia 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." § 46-2-314(1). The Code also lists six minimum requirements goods must conform to in order to be considered merchantable, including:

(a) pass without objection in the trade under the contract description; and (b) in the case of fungible goods, are of fair and average quality within the description; and (c) are 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) are 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. § 46-2-314(2). The comments explain that a fundamental concept of this warranty is that the goods be fit for their ordinary purpose and that merchantable goods are those that are "honestly resalable in the normal course of business because they are what they purport to be." *Id.* at cmt. 8 (internal quotation marks omitted).

BSC contends that the plaintiff produced no evidence that the Obtryx was not fit for its ordinary purpose—treating SUI—because Ms. Campbell's medical records indicate that the Obtryx did in fact effectively treat her SUI. (Def.'s Mem. re: Campbell [Docket 256], at 5). The plaintiff incorporates her prior arguments on strict liability for design defect to establish that the

Obtryx was not “reasonably safe.” (Pl.’s Resp. re: Campbell [Docket 291], at 15.) By challenging the safety of the Obtryx as a permanent implant, the plaintiff has presented sufficient evidence on her implied warranty of merchantability claim to show that there is a genuine dispute of material fact. Therefore, BSC’s Motion for Summary Judgment on the plaintiff’s implied warranty of merchantability claim is **DENIED**.

2. Implied Warranty of Fitness for a Particular Purpose

The West Virginia Code defines the implied warranty of fitness for a particular purpose as follows:

Where 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 unless excluded or modified under the next section [46-2-316] an implied warranty that the goods shall be fit for such purpose.

§ 46-2-315. The Code also distinguishes between the implied warranty of merchantability and the implied warranty of fitness by explaining that

[a] “particular purpose” differs from the 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 whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question.

Id. at cmt. 2. Therefore, it is essential that the plaintiff allege a particular purpose that is *different* from the ordinary purpose of the Obtryx. *See Beattie v. Skyline Corp*, 96 F. Supp. 2d 528, 535 (S.D. W. Va. 2012) (dismissing claim because plaintiffs did not point to any particular purpose for which the mobile home was to be used, other than the ordinary purpose of being a dwelling). BSC designed the Obtryx to treat SUI, which is the reason Ms. Campbell had it implanted in her body. (Def.’s Mem. re: Campbell [Docket 256], at 2–3).

The plaintiff has offered no evidence indicating an additional and/or different purpose for her

use of the Obtryx. Furthermore, the plaintiff has not opposed BSC's Motion for Summary Judgment on her breach of implied warranty of fitness for a particular purpose claim. Accordingly, BSC's Motion for Summary Judgment on the implied warranty of fitness for a particular purpose claim is **GRANTED**, and this claim is **DISMISSED**.

E. Fraudulent Concealment

In West Virginia, fraudulent concealment “involves the concealment of facts by one with knowledge or the means of knowledge, and a duty to disclose, coupled with an intention to mislead or defraud.” *Trafalgar House Const., Inc. v. ZMM, Inc.*, 567 S.E.2d 294, 300 (W. Va. 2002). The facts concealed must be “material,” and the concealment must cause damage to the plaintiff. *Id.* Heightened pleading requirements apply to fraud allegations—“a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). This means the party must identify “the time, place, and contents of the false representations, as well as the identity of the person making the representation and what he obtained thereby.” *McCauley v. Home Loan Inv. Bank, F.S.B.*, 710 F.3d 551, 559 (4th Cir. 2013). Put simply, when making allegations of fraud, Federal Rule of Civil Procedure 9(b) ensures that defendants have “fair notice of claims against them and the factual grounds upon which they are based.” *Id.*

The plaintiff did not abide by Rule 9(b) in asserting fraudulent concealment. In the Master Long Form Complaint, the only discussion of fraudulent concealment is in the context of tolling the statute of limitations under Count VIII. (*See* Master Long Form Compl. & Jury Demand, MDL No. 2326, at ¶92 (“Defendants are estopped from asserting a statute of limitations defense due to Defendants’ fraudulent concealment . . . ”)). BSC has not challenged the statute of limitations, and so Count VIII has no significance in the present case. Furthermore, the plaintiff did not indicate that she might pursue a fraudulent concealment claim until prompted

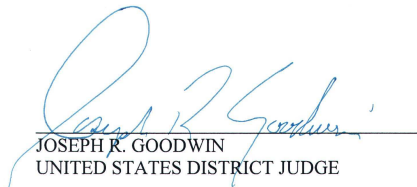
to respond to BSC's Motion for Summary Judgment. (*See* Pl.'s Resp. re: Campbell [Docket 291], at 19–20). The plaintiff did not provide fair notice to BSC that BSC would have to defend against a fraudulent concealment claim. For failure to allege fraud with particularity under Rule 9(b), I **GRANT** BSC's Motion for Summary Judgment regarding the claim of fraudulent concealment. Therefore, to the extent that the plaintiff intended to bring a separate claim of fraudulent concealment, that claim is **DISMISSED**.²

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion for Summary Judgment [Docket 255] is **GRANTED IN PART** with respect to the plaintiff's strict liability for manufacturing defect, negligent manufacturing, breach of implied warranty of fitness for a particular purpose, and fraudulent concealment claims, and **DENIED IN PART** with respect to plaintiff's strict liability for failure to warn, strict liability for design defect, negligent design, negligent warning, breach of express warranty, and breach of implied warranty of merchantability claims. Consequently, the claims that remain in this matter are (1) strict liability for failure to warn; (2) strict liability for design defect; (3) negligent design and negligent warning; (4) breach of express warranty; and (5) 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.

ENTERED: October 20, 2014


JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

² This holding is limited to the independent claim of fraudulent concealment. In the event that future issues arise concerning fraudulent concealment as it relates to the statute of limitations, the court will review such arguments anew.