IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:21-CV-68-FL

KATINA TEAGUE, Plaintiff, v. JOHNSON & JOHNSON, INC. and ETHICON, INC., Defendants.	)	ORDER

This matter is before the court on defendants' motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) (DE 14). The motion has been briefed fully, and in this posture the issues raised are ripe for ruling. For the following reasons, the motion is granted in part and denied in part.

STATEMENT OF THE CASE

Plaintiff commenced this products liability action on February 8, 2021, against defendants, alleging that defendants' medical device, the GYNECARE TVT ABBREVO Continence System ("TVTA product"), is defectively designed, that defendants failed to warn of the dangers associated with the TVTA product, and that they breached implied warranties regarding the TVTA product, all as arising under North Carolina law.[1] Plaintiff seeks compensatory damages, interest, and costs and fees.

[1] This case is related to multi-district litigation case In re Ethicon, Inc. Pelvic Repair System Products Liability Litigation, Master File No. 2:12-MD-2327, MDL No. 2327 (S.D. W. Va.). The parties represent in their Rule 26(f) joint report that

On April 9, 2021, defendants filed their respective answers to the complaint. Shortly after, they jointly filed the instant motion for judgment on the pleadings. Plaintiff responded in opposition, and defendants filed a reply in support.

STATEMENT OF THE FACTS

The facts alleged in the complaint may be summarized as follows.

Defendants are alleged to be in the business of developing, manufacturing, marketing, and selling medical devices, including the TVTA product, with defendant Ethicon, Inc. serving as the wholly owned subsidiary of defendant Johnson & Johnson. Defendants promote the use of the TVTA product to "women who suffer from . . . stress urinary incontinence" as a "minimally invasive procedure" that "permanently correct[s] . . . stress urinary incontinence." (Compl. ¶ 11). The TVTA product "contain[s] polypropylene mesh," which can result in "severe adverse reactions" in "a large subset of the population," including plaintiff. (Id. ¶¶ 12, 31-32). The TVTA product also has a "biomechanical issue[] with [its] design" in that it has a "propensity . . . to contract or shrink inside the body . . . , resulting in injury." (Id. ¶ 39).

Plaintiff, who suffers from stress urinary incontinence, had defendants' TVTA product implanted on or about October 15, 2015, to treat her condition. Thereafter, she began suffering from "infections; dyspareunia; open wounds; constant excruciating pain; and mesh erosion," (id. ¶ 61), which, based on alleged "medical and scientific literature studying the effects" of the TVTA product," are "causally related" to the TVTA product. (Id. ¶¶ 49-50). Accordingly, on August 25, 2020, she underwent a procedure to remove the TVTA product. Plaintiff alleges that, because of

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> [u]ntil last year, cases such as this one would have been transferred to the Ethicon MDL for coordinated proceedings. Now that the Ethicon MDL is closed, the parties seek to strike a balance in managing cases that both avoids duplication and is consistent with the standards and requirements of individual jurisdictions.

(Joint Report & Plan (DE 16) at 1).

the TVTA product implantation, she suffered "significant mental and physical pain," "permanent injury," and "economic loss" and will likely require additional medical treatment in addition to that she has already received due to the product. (Id. ¶ 63).

Additional alleged facts pertinent to the motion will be discussed in the analysis below.

COURT'S DISCUSSION

A. Standard of Review

"After the pleadings are closed[,] . . . a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). In reviewing a motion for judgment on the pleadings, the court "appl[ies] the same standard as a 12(b)(6) motion to dismiss." Mayfield v. Nat'l Ass'n for Stock Car Auto Racing, Inc., 674 F.3d 369, 375 (4th Cir. 2012); see, e.g., Occupy Columbia v. Haley, 738 F.3d 107, 115 (4th Cir. 2013); Butler v. United States, 702 F.3d 749, 752 (4th Cir. 2012).

"To survive a motion to dismiss" under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. In evaluating whether a claim is stated, "[the] court accepts all well-pled facts as true and construes these facts in the light most favorable to the plaintiff," but does not consider "legal conclusions, elements of a cause of action, . . . bare assertions devoid of further factual enhancement[,] . . . unwarranted inferences, unreasonable conclusions, or arguments." Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009).

B. Analysis

Defendants argue that plaintiff fails to allege sufficient facts to support her claims under North Carolina law. The court addresses each claim in turn.

1. Design Defect Claim

Per North Carolina statute, "[n]o manufacturer of a product shall be held liable in any product liability action for the inadequate design . . . of the product unless the claimant proves that at the time of its manufacture the manufacturer acted unreasonably in designing . . . 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). Additionally, such a plaintiff-claimant must prove either that "[a]t 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 . . . that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product" or that "[a]t the time the product left the control of the manufacturer, the design . . . 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)(1)-(2).

Accordingly, "[u]nder North Carolina law, . . . a plaintiff bringing a products liability action based on negligence must prove (1) the product was defective at the time it left the control of the defendant, (2) the defect was the result of defendant's negligence, and (3) the defect proximately caused plaintiff damage." Farrar & Farrar Farms v. Miller-St.Nazianz, Inc., 477 F. App'x 981, 984 (4th Cir. 2012) (quoting Red Hill Hosiery Mill, Inc. v. MagneTek, Inc., 138 N.C. App. 70, 75 (2000)); see Ruffin v. Shaw Indus., Inc., 149 F.3d 294, 301 (4th Cir. 1998). Further, North Carolina's courts recognize that "a product defect may be inferred from evidence of the product's malfunction, if there is evidence the product had been put to its ordinary use." Red Hill, 138 N.C.

App. at 76-77; see DeWitt v. Eveready Battery Co., 355 N.C. 672, 684 (2002). This is true even where "a plaintiff does not produce evidence of a specific defect." Cf. DeWitt, 355 N.C. at 684; see also DeWitt v. Eveready Battery Co., 144 N.C. App. 143, 150 (2001), aff'd, 355 N.C. 672.

Here, plaintiff alleges that the TVTA product, by design, "contain[s] polypropylene mesh," which can result in "severe adverse reactions" in "a large subset of the population," including plaintiff. (Compl. ¶¶ 12, 31-32, 39, 78).[2] The inclusion of such material in defendants' product plausibly could constitute a defect in its design. See Huskey v. Ethicon, Inc., 848 F.3d 151, 156-57 (4th Cir. 2017) (concluding at the summary judgment stage that plaintiff had "offered sufficient evidence for a reasonable jury to find that [defendant's] use of heavyweight polypropylene mesh in the TVT–O caused [plaintiff's] injuries," which constituted proof of "a specific defect of the TVT-O's design"); accord Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1320 (11th Cir. 2017). Plaintiff alleges that this inclusion was negligent and supports this with competent factual allegations rising above a speculative level. (See, e.g., Compl. ¶¶ 12, 31-32, 37-38, 53).

Plaintiff also alleges that the TVTA product has a "biomechanical issue[] with [its] design" in that it has a "propensity . . . to contract or shrink inside the body . . . , resulting in injury." (Id. ¶¶ 34, 39, 78). This is joined with allegations that the Food and Drug Administration has issued public health notifications regarding the risk of "contraction" and "shrinkage" in use of "mesh" for such procedures, which can result in "vaginal shortening, vaginal tightening, and vaginal pain," in congruence with the findings of other scientific and medical organizations. (Id. ¶¶ 18-27). Plaintiff alleges that the defects of the TVTA product described in her complaint,[3] including its

[2] The complaint refers to the "GYNECARE TVT ABBREVO Continence System" and "Mesh Products" interchangeably. (Compl. ¶ 10).

[3] Plaintiff identifies a number of additional perceived defects in the TVTA product's design, including the lack of a safe, effective procedure for removing the TVTA product. (See Compl. ¶ 39, 43, 78). However, because the two exemplary defects discussed above support a claim to relief under a defective-design theory of recovery that is plausible on its face, the court does not analyze the other alleged defects seriatim.

propensity to contract or shrink inside the body, caused her injuries such as vaginal pain. (See id. ¶ 21, 63, 80). Factual matter alleged in the complaint makes plausible that this defect's inclusion in the TVTA product was the product of defendants' negligence. (See, e.g., id. ¶ 28).

In sum, plaintiff has pleaded sufficient factual material, taken as true and construed in the light most favorable to her, to raise her right to relief for a negligent design defect above a speculative level.

Defendants advance several arguments contesting this conclusion which are unavailing.

First, defendants contend that plaintiff's allegations regarding "biomechanical issues with the design of the Mesh Products" fail to "identify how the design of the products" leads to alleged biomechanical issues. (Defs.' Mem. (DE 15) at 4 n.1). However, the complaint describes these biomechanical issues as issues with the design of the product that stem from the propensity of the TVTA product to contract, retract, and shrink inside the body, which happened even when the product was "implanted in [p]laintiff . . . in the condition directed by and expected by [d]efendants." (Compl. ¶¶ 39, 47). See generally Boudreau v. Baughman, 322 N.C. 331, 345 (1988) ("A design defect is an injury-producing hazard accompanying normal use of a product that was intentionally manufactured according to design."). This is sufficient "to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests," and this is all that is required at this stage. McCleary-Evans v. Md. Dep't of Transp., State Highway Admin., 780 F.3d 582, 585 (4th Cir. 2015) (quoting Twombly, 550 U.S. at 555).

Moreover, as is also relevant defendants' argument that "plaintiff must also specifically identify the defect that allegedly caused her injury," (Defs.' Mem. (DE 15) at 3-4), North Carolina law recognizes that "in a products liability action, based on tort or warranty, a product defect may be inferred from evidence of the product's malfunction, if there is evidence the product had been

put to its ordinary use." Red Hill, 138 N.C. App. at 76-77. Where plaintiff would not need to "produce evidence of a specific defect" to defeat a motion for summary judgment, if she presented evidence from which a defect could be inferred, DeWitt, 144 N.C. App. at 150, defendants do not explain why a higher evidentiary standard would apply at the pleading stage.

For similar reasons, defendants' citation to Lester v. Danek Med. Inc., No. 2:96CV1006, 1999 WL 1061973, at *3 (M.D.N.C. Apr. 16, 1999), is inapt. The court in Lester granted summary judgment to the defendants because plaintiff had not met her burden of "establishing the existence of a defective condition" in the bone screw product at issue. Id. at *3-4. Instead, "[p]laintiff's medical records clearly indicate[d] that her instrumentation was not defective." Id. at *4. Plaintiff, here, has pleaded factual matter from which a reasonable inference of a defect in the design of the TVTA product arises, which is satisfactory at this stage.

So, too, does the court find allegations in this case instructively distinguishable from the factual predicate of the cases cited by defendants in string form. (See Defs.' Mem. (DE 15) at 5 n.2). None apply North Carolina law or even this circuit's law, see, e.g., Moore v. C.R. Bard, Inc., 217 F. Supp. 3d 990, 995 (E.D. Tenn. 2016), and most considered complaints bereft of the factual allegations in the instant complaint. See, e.g., Nowell v. Medtronic Inc., 372 F. Supp. 3d 1166, 1246-47 (D.N.M. 2019) ("[T]he Amended Complaint does not allege any facts that plausibly establish a connection between Nowell's injuries and the Defendants' mesh."), aff'd on other grounds, No. 19-2073, 2021 WL 4979300 (10th Cir. Oct. 27, 2021); Baca v. Johnson & Johnson, No. CV-20-01036-PHX-DJH, 2020 WL 6450294, at *4 (D. Ariz. Nov. 2, 2020) ("The Complaint does not, however, state that Plaintiff suffered from an adverse immune response."); Hernandez v. Johnson & Johnson, No. 4:20-CV-05136-SMJ, 2021 WL 320612, at *3 (E.D. Wash. Jan. 8, 2021) (explaining that while the complaint alleged the relevant pelvic mesh product could not be safely

removed, plaintiff did not "allege that the design's alleged inability to be safely removed caused her injuries").

Accordingly, defendants' motion for judgment on the pleadings is denied in this part seeking dismissal of plaintiff's design defect claim.

2. Failure-to-Warn Claim

Section 99B-5(a) of the North Carolina General Statutes provides that "[n]o . . . seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning . . . unless the claimant proves that the . . . seller acted unreasonably in failing to provide such warning" and "that the failure to provide adequate warning . . . was a proximate cause of the harm for which damages are sought." N.C. Gen. Stat. § 99B-5(a). In addition, such a claimant must prove either that "[a]t 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 that "[a]fter the product left the control of the manufacturer . . . , the manufacturer . . . 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. § 99B-5(a)(1)-(2).

Accordingly, "[i]n North Carolina, a failure to warn claim requires the plaintiff to prove that the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product 'posed a substantial risk of harm' without an adequate warning either at the time of or after leaving the manufacturer's control." Carlson v. Bos. Sci. Corp., 856 F.3d 320, 324 (4th Cir. 2017).

Section 99B-5 adopts the legal principle known as the learned intermediary doctrine, see N.C. Gen. Stat. § 99B-5(c), which guides that the "obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients." Restatement (Third) of Torts: Product Liability § 6 cmt. b (Am. Law Inst. 1998) (emphasis added); see also Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362 (4th Cir. 1975) (applying North Carolina law and stating that "a manufacturer of an ethical drug must exercise reasonable care, commensurate with the risk, to warn physicians effectively of the drug's inherent dangers" (emphasis added)). However, per its text, section 99B-5(c) only applies to the "manufacturer or seller of a prescription drug," rather than medical devices. Although it is not clear whether "the limitation on pharmaceutical liability outlined in § 99B-5(c) likewise extends to medical devices . . . , several federal courts—including the MDL court previously handling this case—have presumed that it does." Smith v. Ethicon, Inc., No. 1:20CV212, 2020 WL 3256926, at *2 (M.D.N.C. June 16, 2020).

In such instances, where this court must apply unclear state law, it "appl[ies] the law . . . as it appears the highest court of that state would rule." Brendle v. Gen. Tire & Rubber Co., 505 F.2d 243, 245 (4th Cir. 1974); see also Priv. Mortg. Inv. Servs., Inc. v. Hotel & Club Assocs., Inc., 296 F.3d 308, 312 (4th Cir. 2002) ("[I]n a situation where the [state] [s]upreme [c]ourt has spoken neither directly nor indirectly on the particular issue before us, we are called upon to predict how that court would rule if presented with the issue."). What indicia may be gleaned from North Carolina courts' jurisprudence indicates that the learned intermediary doctrine would apply just as equally to the manufacturer of a medical device. See Holley v. Burroughs Wellcome Co., 74 N.C. App. 736, 742 (1985) ("[T]he standard of care or duty allegedly owed by defendants to [patient-

plaintiff] was to warn the personnel responsible for his anesthesia of the risk that the use of their products to induce anesthesia could cause malignant hyperthermia and to provide information to the responsible personnel concerning how to recognize and treat the condition."), aff'd, 318 N.C. 352 (1986). Further, plaintiff's complaint seemingly acknowledges that defendants' duty was "to warn and instruct [p]laintiff's implanting physician," rather than to warn plaintiff herself. (See Compl. ¶ 83). Accordingly, the court assumes for the sake of resolving this motion that North Carolina courts would apply the learned intermediary doctrine to the manufacturer of a medical device's duty to warn a patient prescribed the medical device by his or her physician.

Here, plaintiff alleges that defendants did not warn her implanting physician about, inter alia, the TVTA product's "propensities to contract, retract, and/or shrink inside the body," "the risk of chronic inflammation resulting from" the TVTA product, "the risk of recurrent, intractable pelvic pain . . . resulting from" the TVTA product, or that "complete removal of the [TVTA product] may not be possible and may not result in complete resolution of . . . complications." (Id. ¶ 40; see also id. ¶ 46). On the complaint, based on the FDA's guidance, other scientific bodies' opinions, the state of the art, and defendants' own knowledge, it was unreasonable not to warn about these risks and complications. (See id. ¶¶ 28, 37, 53). Plaintiff asserts that had her implanting physician known of the omitted or concealed risks, the physician would not have recommended the TVTA product. (Id. ¶ 89). Finally, the factual matter alleged raises the reasonable inference that the TVTA product, without an adequate warning or instruction, created an unreasonably dangerous condition that defendants knew posed a substantial risk of harm, such as inflammation, negative immune responses, and vaginal pain, to reasonably foreseeable patients like plaintiff. (Id. ¶¶ 31-32, 37, 40).

In sum, plaintiff states a plausible claim for relief for failure to warn regarding the TVTA product.

Defendants assert that plaintiff was required to "identify the warnings, statements, or materials which [p]laintiff's implanting surgeon actually received." (Defs.' Mem. (DE 15) at 6). However, the complaint contains sufficient allegations regarding the warnings that are material to plaintiff's claim, that is, warnings that the TVTA product had a propensity to contract, retract, and shrink inside the body and could cause chronic inflammation and recurrent, intractable pelvic pain, which allegedly were not given. What other warnings were provided are not required to make the determination of whether the factual allegations in the complaint give rise to a reasonable inference that defendants acted unreasonably in failing to provide the relevant warnings. Neither federal procedural law nor state substantive law require plaintiff to state the particularity of the circumstances constituting a failure to warn, as, for example, Federal Rule of Civil Procedure 9(b) does for allegations of fraud. Plaintiff is not required to offer up the warnings given to the physician so defendant and court may consider the veracity of her claim that her physician was not properly warned of these specific risks because, at this stage, plaintiff's properly pleaded factual matter is accepted as true.

Thus, defendants' motion for judgment on the pleadings is denied in this part seeking dismissal of plaintiff's failure-to-warn claim.

3. Implied Warranty Claim

Although North Carolina law recognizes implied warranties of both merchantability and fitness for a particular purpose, see DeWitt, 355 N.C. at 683, plaintiff's response to the instant motion clarifies that she asserts only a breach of the implied warranty of merchantability. (Pl.'s Resp. (DE 17) at 7).

Under North Carolina law, a plaintiff may base a products liability action on a breach of a warranty. N.C. Gen. Stat. § 99B-1.2.

> To establish a breach of implied warranty of merchantability . . . , a plaintiff must prove the following elements: (1) that the goods bought and sold were subject to an implied warranty of merchantability; (2) that the goods did not comply with the warranty in that the goods were defective at the time of sale; (3) that his injury was due to the defective nature of the goods; and (4) that damages were suffered as a result.

DeWitt, 355 N.C. at 683 (quotation omitted). "[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.

North Carolina common law requires privity of contract to assert an implied warranty claim. Atl. Coast Mech., Inc. v. Arcadis, Geraghty & Miller of N.C., Inc., 175 N.C. App. 339, 345 (2006); Crews v. W.A. Brown & Son, Inc., 106 N.C. App. 324, 332 (1992); see, e.g., Terry v. Double Cola Bottling Co., 263 N.C. 1, 2 (1964); Thomason v. Ballard and Ballard Co., 208 N.C. 1, 4 (1935). However, upon passage of North Carolina's Products Liability Act, N.C. Gen. Stat. 99B-1 et seq., "privity is not required" where "claimant . . . is a buyer, as defined in the Uniform Commercial Code, of the product involved," and he or she brings "a product liability action directly against the manufacturer of the product involved for breach of implied warranty." Bernick v. Jurden, 306 N.C. 435, 449 & n.8 (1982) (quoting N.C. Gen. Stat. § 99B-2(b)); DeWitt, 355 N.C. at 682; see also Tetterton v. Long Mfg. Co., 314 N.C. 44, 51 (1985) ("[O]ur products liability chapter[] expressly abrogates this privity requirement in certain cases based on implied warranty." (emphasis added)).

Under North Carolina's Uniform Commercial Code, a buyer is "a person who buys or contracts to buy goods." N.C. Gen. Stat. § 25-2-103(1)(a). "Goods" include "all things (including specially manufactured goods) which are movable at the time of identification to the contract for

sale." Id. § 25-2-105(a). "In the context of the Uniform Commercial Code, [the North Carolina Court of Appeals] has held that medical professionals do not engage in the sale of 'goods' when they either issue a prescription for a drug, or prepare and fit dentures." Cameron v. New Hanover Mem'l Hosp., Inc., 58 N.C. App. 414, 445 (1982) (first citing Batiste v. Am. Home Prods. Corp., 32 N.C. App. 1 (1977); and then citing Preston v. Thompson, 53 N.C. App. 290 (1981)); see also id. (holding that a public hospital, its trustees, administrator, and medical doctors on its staff were not "sellers" within the meaning of North Carolina's unfair competition statute).

Here, plaintiff only alleges that "[p]laintiff and/or her physicians were at all relevant times in privity with defendants." (Compl. ¶ 102). However, this amounts to assertion of a legal conclusion, not a sufficient factual allegation. No other relevant factual allegations are provided in the complaint. Given that generally "a physician is neither a merchant nor a seller of goods under the [Uniform Commercial Code]," Preston, 53 N.C. App. at 296, no reasonable inference arises from the complaint that plaintiff was a "a buyer, as defined in the Uniform Commercial Code, of the product involved," the TVTA product. N.C. Gen. Stat. § 99B-2(b). Accordingly, "privity of contract" may "be grounds for dismissal" of this type of action. See N.C. Gen. Stat. § 99B-2(b); see, e.g., McLaurin v. Vulcan Threaded Prod., Inc., 410 F. App'x 630, 634 (4th Cir. 2011).

Accordingly, defendants' motion for judgment on the pleadings on this basis is granted in this part. Plaintiff's claim for breach of implied warranty is dismissed without prejudice.

CONCLUSION

Based on the foregoing, defendants' motion for judgment on the pleadings (DE 14) is GRANTED IN PART and DENIED IN PART as set forth herein. Plaintiff's design defect and

failure-to-warn claims may proceed. Plaintiff's claim for breach of implied warranty is DISMISSED WITHOUT PREJUDICE.

Where the court's case management order entered June 8, 2021, enumerates a May 20, 2022, deadline for all discovery as well as deadlines contemplated by Federal Rule of Civil Procedure 26(a)(2) that soon terminate (DE 18), the parties are invited to confer and file suggested proposed changes, if any, to the court's case management order now in effect within 14 days of entry of this order.

SO ORDERED, this the 5th day of January, 2022.

LOUISE W. FLANAGAN
United States District Judge