IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

KORTNEY R. CLINE **PLAINTIFF**

V. **CASE NO. 5:14-CV-5090**

BOSTON SCIENTIFIC CORPORATION **DEFENDANT**

MEMORANDUM OPINION AND ORDER

Before the Court are a Motion for Summary Judgment (Doc. 71) filed by Defendant Boston Scientific Corporation ("BSC") and a Response in Opposition (Doc. 72) filed by Plaintiff Kortney R. Cline. This case was recently transferred to this Court from the District Court for the Southern District of West Virginia, where the Honorable Joseph R. Goodwin was presiding over seven separate multi-district litigations ("MDL") concerning products sold by BSC. This case was related to one of the seven MDLs. *See* Transfer Order, Doc. 30. The Court has now considered the parties' briefing and finds that the Motion for Summary Judgment should be **GRANTED IN PART AND DENIED IN PART**.

I. BACKGROUND

Ms. Cline's original complaint was filed in this Court on March 14, 2014 (Doc. 1). An amended complaint was filed on April 4, 2014 (Doc. 11). BSC answered the amended complaint on April 18, 2014 (Doc. 14); however, on June 10, 2014, the entire case was removed to the MDL, and a Master Long Form Complaint (Doc. 32) and Amended Short Form Complaint (Doc. 81) were subsequently filed in that forum. The Court understands that the Amended Short Form Complaint and Master Long Form Complaint are the joint operative pleadings in this case.

Ms. Cline brings the following causes of action against BSC: Count I, negligence; Count II, strict liability—design defect; Count III, strict liability—manufacturing defect; Count IV, strict liability—failure to warn; Count V, breach of express warranty; Count VI, breach of implied warranty; Count VII, discovery rule/tolling/fraudulent concealment; Count VIII, punitive damages; Count IX, violations of the Arkansas Deceptive Trade Practices Act ("ADTPA"), and Count X, fraud/deceit. The parties agree that all claims are brought under Arkansas law, and the Court concurs with that assessment.

BSC's Motion for Summary Judgment seeks the dismissal of Counts I–VI and does not mention Counts VII–X. Nevertheless, the Court has determined, *sua sponte*, that Counts VII and VIII merit dismissal. Count VII alleges "that the discovery rule should be applied to toll the running of the statute of limitations." (Doc. 32, p. 28). This tolling argument is not a separate tort claim but is instead a preemptive response to a statute-of-limitations defense—which BSC has failed to pursue on summary judgment. The Court therefore finds that Count VII is moot and will be dismissed on the Court's own motion. As for Count VIII's claim for punitive damages, this is a remedy and not a standalone cause of action under Arkansas law. *See Bergan v. Ocwen Fin. Corp.*, 2018 WL 9986722, at *3 (E.D. Ark. Nov. 1, 2018). To be clear, the Court's dismissal of Count VIII will not preclude Ms. Cline from seeking a jury instruction on punitive damages at trial.

With those housekeeping matters out of the way, the Court now turns to a summary of Ms. Cline's claims. She contends that she suffered injuries following her implantation with a medical device made by BSC called a transobturator mid-urethral sling (referred to by the parties as the "Obtryx" device). Her implantation surgery took place on July 22, 2009, and was performed by Dr. Gregory D. Reiter in a hospital in Johnson, Arkansas.

The Obtryx is used to treat symptoms of stress urinary incontinence. According to Ms. Cline, she suffered from stress urinary incontinence prior to surgery, and she trusted her doctor's recommendation that the Obtryx would eliminate that condition once implanted. Unfortunately, Ms. Cline complained that after surgery she suffered from "burning" pelvic pain, cramping, urinary incontinence, an inability to engage in sexual intercourse due to pain, and various other injuries. She underwent a second surgery to remove the Obtryx on June 11, 2018, but she maintains that her injuries never fully resolved and that she lives with permanent pain and damage.

In the discussion below, the Court will first address Counts II–IV, which are strict-liability claims brought under the Arkansas Products Liability Act ("APLA"). Next, the Court will consider BSC's request for dismissal of Count I, which is a claim for common-law negligence. Lastly, the Court will take up Ms. Cline's breach-of-warranty claims, which appear in Counts V and VI.

II. LEGAL STANDARD

The standard for summary judgment is well established. Under Federal Rule of Civil Procedure 56(a), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The Court must review the facts in the light most favorable to the opposing party and give that party the benefit of any inferences that can be drawn from those facts. *Canada v. Union Elec. Co.*, 135 F.3d 1211, 1212–13 (8th Cir. 1997). The moving party bears the burden of proving the absence of a genuine dispute of material fact and that it is entitled to judgment as a matter of law. *See* Fed. R. Civ. P.

56(c); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Nat'l. Bank of Com. of El Dorado v. Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999).

Once the moving party has met its burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(c)). However, "the mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient" to survive summary judgment. *Anderson v. Durham D&M, L.L.C.*, 606 F.3d 513, 518 (8th Cir. 2010) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)). Rather, in order for there to be a genuine issue of material fact that would preclude summary judgment, the non-moving party must produce evidence "such that a reasonable jury could return a verdict for the nonmoving party." *Allison v. Flexway Trucking, Inc.*, 28 F.3d 64, 66 (8th Cir. 1994) (quoting *Anderson*, 477 U.S. at 248).

III. DISCUSSION

A. APLA Claims

Counts II, III, and IV are brought pursuant the APLA. According to that statute, a "'[p]roduct liability action' includes all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparations, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product." Ark. Code Ann. § 16-116-202(5).

1. Count II: Design Defect

BSC argues that Ms. Cline's design-defect claim should be dismissed "for lack of evidence." (Doc. 71, p. 9). Specifically, BSC maintains that Ms. Cline cannot establish that the Obtryx was supplied to her in a defective condition that rendered it unreasonably

dangerous or that this defective condition was the proximate cause of her damages. BSC points out that "[e]ven Plaintiff's expert concedes that the Obtryx was the standard of care to treat [stress urinary incontinence] when [she] had her Obtryx implant." *Id.* Further, BSC contends that there is no surgical alternative treatment for stress urinary incontinence that is without risk, and pursuant to the "comment k defense" located in Section 402A of the Restatement (Second) of Torts—which Arkansas has adopted—a manufacturer will not be liable for selling so-called "unavoidably unsafe products" that carry "a medically recognizable risk" if the products are marketed and sold with proper warnings of the risk.

The Court finds that there are genuine, material disputes of fact as to Count II, such that summary judgment must be denied. First, Ms. Cline points out that the Obtryx is made of a material called Marlex polypropylene, which she believes should not be used for permanent human implantation. It appears that Ms. Cline's experts and BSC's experts disagree as to the safety and efficacy of this material. Second, with respect to the comment k defense, Ms. Cline offers proof that BSC knew the Obtryx contained an unsafe material—Marlex polypropylene—and did not provide proper product warnings about that material. Third, Ms. Cline presents evidence that the Obtryx was not the only treatment option available for stress urinary incontinence. The Court is therefore persuaded that summary judgment should be denied on Count II.

2. Count III: Manufacturing Defect

Ms. Cline states in her Brief in Response to Summary Judgment that she "hereby dismisses her strict liability—manufacturing defect cause of action." (Doc. 72, p. 2 n.1).

The Court interprets this to mean that Ms. Cline does not oppose the entry of summary judgment on Count III, and the Court will not consider the merits of the claim further.

3. Count IV: Failure-to-Warn

Under Arkansas law, "the manufacturer of a product has a duty to warn the user of dangers inherent in that product under the theories of strict liability, negligence and breach of warranty, and the comment k defense." *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989). However, Arkansas law also acknowledges that one of the exceptions to a manufacturer's duty to warn is "the learned intermediary rule, which assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the . . . products, any warnings regarding their possible side effects." *Id.* This rule recognizes that "medical ethics and practice dictate that the doctor must be an intervening and independent party between patient and [device] manufacturer," that "the information regarding risks is often too technical for a patient to make a reasonable choice," and that "it is virtually impossible in many cases for a manufacturer to directly warn each patient." *Id.* "Thus, a warning to the [physician] is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of [medical devices]." *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985). "Courts are generally in agreement that a warning is adequate where it is reasonable under the circumstances." *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1196 (D.N.D. 2002).

Here, BSC argues that it satisfied its duty to warn by providing clear warnings of the risks associated with the Obtryx in the product brochure, which was provided to Ms. Cline's implanting physician, Dr. Reiter. The brochure and associated written materials

warned Dr. Reiter of the post-implantation risk of pain, dyspareunia (painful intercourse), bleeding, incontinence, infection, erosion, and the possible migration of the device from the desired location, and Ms. Cline agrees that Dr. Reiter advised her of certain risks, complications, and benefits of the surgery. In spite of all that, however, Ms. Cline maintains that she suffered some injuries that were not contemplated in the product brochure and written materials. She claims that BSC failed to provide Dr. Reiter with information about all the possible risks associated with the Obtryx, such that he was unable to make a knowledgeable risk assessment and could not adequately advise her. Ms. Cline posits that when a doctor does not receive full and appropriate warnings about a product from the manufacturer and would have changed his advice to a patient had he received adequate warnings, the learned intermediary exception should not shield the manufacturer from liability for failure to warn.

After reviewing the evidence in the light most favorable to Ms. Cline, the Court finds there is proof that Dr. Reiter was not provided clear and complete warnings of the risks associated with the Obtryx. If Ms. Cline is correct about those risks, the learned-intermediary exception would not be available to BSC to protect it from liability on the failure-to-warn claim. "Once a plaintiff proves the lack of an adequate warning or instruction, a presumption arises that the user"—or in this case, the implanting physician—"would have read and heeded adequate warnings or instructions." *Bushon v. Garman Co.*, 843 S.W.2d 807, 811 (Ark. 1992). In the case at bar, Dr. Reiter testified that he was unaware that the Obtryx contained Marlex polypropylene. (Doc. 72-2, pp. 15–16). He admits he did not receive warnings about certain studies that had concluded Marlex polypropylene was not recommended for permanent use in humans. *Id.* at p. 12.

He also testified that if he had been warned by BSC about possible dangers associated with Marlex polypropylene, this knowledge might have affected his product recommendation to Ms. Cline. *Id.* at p. 44–45 ("I think I would like to see more material or more information on any of the meshes now. If there's things like this being said, I'd like to see more information period.").

Ms. Cline has raised a triable question of fact as to whether BSC failed to warn Dr. Reiter of a risk associated with the Obtryx that was not otherwise known to him. She has also raised a genuine, material dispute of fact as to whether a failure to warn Dr. Reiter of certain risks associated with the Obtryx was a cause in fact and the proximate cause of her injuries. Finally, she has identified a material dispute about whether certain warnings about the Obtryx—if true—would have changed Dr. Reiter's decision to recommend the product for implantation. Summary judgment as to Count IV is denied.

B. Count I: Negligence

BSC contends that Ms. Cline's negligence claim should be dismissed for the same reasons that her APLA claims should be dismissed. As explained above, two of Ms. Cline's APLA claims will be preserved for trial. Moreover, Arkansas law permits Ms. Cline to simultaneously maintain both her negligence claim under Count I and her strict liability claims under Counts II and IV. According to the Arkansas Supreme Court, "[n]egligence and strict liability are not mutually exclusive claims. More than one theory of liability is permissible in a products liability claim." *Nationwide Rentals Co. v. Carter*, 765 S.W.2d

931, 933 (Ark. 1989) (citing *W.M. Bashlin Co. v. Smith*, 643 S.W.2d 526, 529 (Ark. 1982)).[1] Summary judgment is therefore denied as to Count I.

C. Counts V and VI: Breach of Express and Implied Warranties

BSC's final arguments concern Ms. Cline's warranty of merchantability claims. As to the express warranty claim, BSC contends that Ms. Cline has failed to identify an express warranty that she relied on in making her decision to be implanted with the Obtryx device. According to BSC, Ms. Cline admitted in her deposition that she never relied on any written materials authored by BSC, nor did any written materials influence her to proceed with the implantation surgery. At the same time, BSC acknowledges that the learned intermediary doctrine applies in this case, and it is undisputed that Ms. Cline relied on the representations and recommendations of her doctor regarding the safety and efficacy of the Obtryx product when she made the decision to go forward with her surgery. As the Court previously explained, a warning—express or implied—issued to a physician "is deemed a warning to the patient" and "the manufacturer need not communicate directly with all ultimate users of [medical devices]." *Kirsch*, 753 F.2d at 671. The learned intermediary doctrine applies to all theories of products liability including breach of warranty. *Hill,* 884 F.2d at 1070.

Dr. Reiter relied on BSC's written materials about the Obtryx, including the written product brochures, and shared that information with Ms. Cline. There is a genuine,

[1] Arkansas Model Civil Jury Instruction 1013, titled "Products Liability—Issues—Claims Involving Two or More Theories of Liability," explains in the "Note on Use" that it "can be used to submit to the jury any combination of five separate causes of action in the field of products liability: strict liability (AMI 1008); negligence (AMI 203); breach of implied warranty of merchantability (AMI 1010); breach of implied warranty of fitness for a particular purpose (AMI 1011); and breach of an express warranty (AMI 1012)."

material dispute of fact as to whether the product brochures or other writings provided to Dr. Reiter contained complete, truthful information about the fitness and merchantability of the device for permanent implantation in human patients. For these reasons, the breach-of-express-warranty claim will go to trial.

As for the breach-of-implied-warranty claim, to survive summary judgment Ms. Cline must provide evidence that the Obtryx was unsuited for its ordinary purpose, Ark. Code Ann. § 4-2-314, or unfit for the purpose for which it was required, Ark. Code Ann. § 4-2-315. To do this, she identifies expert witnesses who will testify that the Obtryx is not fit for its ordinary purpose or for a particular purpose due to the presence of Marlex polypropylene in the product. BSC responds that the Obtryx was considered the "standard of care" at the time of Ms. Cline's surgery, and her implanting doctor believed it would provide the correct treatment for Ms. Cline's symptoms. BSC also notes that wide usage of the Obtryx to treat stress urinary incontinence was not "objected to within the trade." (Doc. 71, p. 13).

After considering the parties' arguments and reviewing the proposed evidence, the Court concludes that despite the fact that the Obtryx was recommended for use by doctors—including Ms. Cline's own doctor—at the time of her surgery, this does not necessarily mean that the product was suited for its ordinary purpose or for the purpose for which it was required. There are genuine, material disputes of fact regarding whether the Obtryx was a product suitable for permanent implantation in women and whether, given its materials and design, it was fit for use as a medical device to treat stress urinary incontinence. Accordingly, the implied breach-of-warranty claim will be preserved for trial.

IV. CONCLUSION

For the reasons described herein, **IT IS ORDERED** that Defendant Boston Scientific Corporation's Motion for Summary Judgment (Doc. 71) is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** as to Count III and **DENIED** as to Counts I, II, IV, V, and VI.

IT IS FURTHER ORDERED that Counts VII and VIII are **DISMISSED** on the Court's own motion.

To recap, the following claims remain for trial: Count I, negligence; Count II, strict liability—design defect; Count IV, strict liability—failure to warn; Count V, breach of express warranty; Count VI, breach of implied warranty; Count IX, violations of the ADTPA, and Count X, fraud/deceit.

IT IS SO ORDERED on this 11th day of February, 2021.

TIMOTHY L. BROOKS
UNITED STATES DISTRICT JUDGE