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

KIMBERLY WILICHOWSKI and
KENT WILICHOWSKI **PLAINTIFFS**

V. **CASE NO. 5:21-CV-5024**

BOSTON SCIENTIFIC CORPORATION **DEFENDANT**

MEMORANDUM OPINION AND ORDER

Before the Court are a Motion for Summary Judgment (Doc. 40) filed by Defendant Boston Scientific Corporation ("BSC") and a Response and Brief in Opposition (Docs. 43 & 44) filed by Plaintiffs Kimberly and Kent Wilichowski. 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 is related to one of the seven MDLs. *See* Transfer Order, Doc. 53. 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

Plaintiffs filed this action in the MDL on December 18, 2014 (Doc. 1). They bring 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 (by separate Plaintiff Kent Wilichowski only), loss of consortium; Count VIII, discovery rule/tolling/fraudulent concealment; and Count IX, punitive

damages. The parties agree that all claims arise 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–IX. Nevertheless, the Court has determined, *sua sponte*, that Counts VIII and IX merit dismissal. Count VIII alleges that the discovery rule should be applied to toll the running of the statute of limitations. 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 VIII is moot and will be dismissed on the Court's own motion. As for Count IX'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 IX will not preclude Plaintiffs 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 the claims at issue here. Mrs. Wilichowski contends that she suffered injuries following her implantation with a medical device made by BSC called the Obtryx Transobturator Mid-Urethral Sling System (referred to by the parties as the "Obtryx"). Her implantation surgery took place on January 21, 2009, and was performed by Dr. Lawrence Schmitz at the Northwest Medical Center in Bentonville, Arkansas. The Obtryx is used to treat symptoms of stress urinary incontinence. According to Mrs. Wilichowski, she suffered from stress urinary incontinence and uterine prolapse prior to surgery, and she trusted her doctor's recommendation that the Obtryx would eliminate those conditions once implanted. Unfortunately, Mrs. Wilichowski complained that after surgery she suffered

from pain, infection, urinary and bowel problems, neuromuscular problems, vaginal scarring, dyspareunia (painful intercourse), and continued urinary incontinence. She underwent a second surgery to remove the Obtryx on February 27, 2015, at Mercy Medical Hospital in St. Louis, Missouri, 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 Mrs. Wilichowski's breach-of-warranty claims, which appear in Counts V and VI.[1]

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).

[1] Count VII, a claim for loss of consortium brought by Mr. Wilichowski, will not be discussed, since it is not mentioned in the Motion.

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 Plaintiffs' design-defect claim should be dismissed because they cannot establish that the Obtryx was supplied to Mrs. Wilichowski in a defective condition that rendered it unreasonably dangerous, or that this defective condition was the proximate cause of her injuries. BSC points out that "[e]ven Plaintiff's expert testified that midurethral slings are the standard of care to treat [stress urinary incontinence] when Mrs.

Wilichowski had her Obtryx implant and the Obtryx was commonly used in the surgical treatment of [stress urinary incontinence]." (Doc. 40, p. 8). 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, Plaintiffs point out that although polypropylene midurethral slings are commonly used to treat stress urinary incontinence, these products are not all the same. The Obtryx is a transobturator sling, rather than a retropubic sling, and Plaintiffs' experts have opined that other products, including retropubic slings, are safer than the Obtryx—meaning that the Obtryx was not the only treatment option available for stress urinary incontinence at the time of Mrs. Wilichowski's surgery. Second, Plaintiffs' and BSC's experts apparently disagree about the safety and efficacy of Marlex polypropylene, which is a material that is present in the Obtryx device. One of Plaintiffs' experts testified that this substance is not suitable for permanent human implantation and degrades over time—something BSC either knew or should have known. (Doc. 44, p. 9). The Court is therefore persuaded that summary judgment should be denied on Count II.

2. Count III: Manufacturing Defect

Plaintiffs state in their brief that they do not oppose the entry of summary judgment on the manufacturing-defect claim. *See* Doc. 43, p. 2. The Court will therefore dismiss this claim and not discuss its merits further in this Order.

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. Wilichowski's implanting physician, Dr. Schmitz. The brochure and associated written materials warned Dr. Schmitz of the post-implantation risk of pain, dyspareunia, bleeding, incontinence, infection, erosion, and the possible migration of the device from the desired location, and Mrs. Wilichowski agrees that Dr. Schmitz advised her of certain risks, complications, and benefits of the surgery. In spite of all that, however, she maintains that she suffered some injuries that were not contemplated in the product brochure and written materials. She claims that BSC failed to provide her doctor 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. Mrs. Wilichowski 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 Mrs. Wilichowski, the Court finds there is proof that Dr. Schmitz was not provided clear and complete warnings of the risks associated with the Obtryx. If Mrs. Wilichowski 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. Schmitz testified

that he was unaware that the Obtryx contained Marlex polypropylene and that the manufacturer of this substance allegedly stated that it was not intended for permanent implantation. (Doc. 43-7, pp. 63–66). He admits he did not receive but would have liked to receive the testing data on Marlex polypropylene prior to implanting the Obtryx in Mrs. Wilichowski. *Id.* at p. 66. He also testified that if he had been warned by BSC about possible dangers associated with Marlex polypropylene, he would have shared that information with Mrs. Wilichowski. *Id.* at p. 67. He agreed that "[i]f the material being used in a device wasn't intended by its manufacturer to be implanted into humans," that information would have "helped [him] in making an informed decision on using that device." *Id.*

Mrs. Wilichowski has raised a triable question of fact as to whether BSC failed to warn Dr. Schmitz 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. Schmitz 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. Schmitz's decision to recommend the product for implantation. Therefore, summary judgment as to Count IV is denied.

B. Count I: Negligence

BSC contends that the negligence claim should be dismissed for the same reasons that the APLA claims should be dismissed. As explained above, two of the APLA claims will be preserved for trial. For the same reasons, the Court concludes there is a triable question of fact as to whether BSC was negligent. Arkansas law permits Mrs.

Wilichowski 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)).[2] Summary judgment is therefore denied as to Count I.

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

Plaintiffs state in their brief that they do not oppose the entry of summary judgment on the breach-of-warranty claims. *See* Doc. 43, p. 2. The Court will therefore dismiss Counts V and VI.

IV. CONCLUSION

For the reasons described herein, **IT IS ORDERED** that Defendant Boston Scientific Corporation's Motion for Summary Judgment (Doc. 40) is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** as to Count III, Count V, and Count VI and **DENIED** as to Counts I, II, and IV.

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

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[2] 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)."

To recap, the following claims remain for trial: Count I, negligence; Count II, strict liability—design defect; Count IV, strict liability—failure to warn; and Count VII (by separate Plaintiff Kent Wilichowski only), loss of consortium.

IT IS SO ORDERED on this 1st day of March, 2021.

TIMOTHY L. BROOKS
UNITED STATES DISTRICT JUDGE