IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

ELIZABETH BUCKNER, *

Plaintiff, *

vs. * CASE NO. 4:22-CV-21 (CDL)

BOSTON SCIENTIFIC CORPORATION, *

Defendant. *

O R D E R

Boston Scientific Corporation developed a product called Obtryx transobturator midurethral sling, which is used to treat stress urinary incontinence. Elizabeth Buckner was implanted with Obtryx and asserts that she suffered injuries caused by Obtryx. Buckner brought this product liability action against Boston Scientific, contending that Obtryx had design defects that proximately caused her injuries. Buckner also asserts that Boston Scientific did not adequately warn her physician about the risks of Obtryx. Presently pending before the Court are Boston Scientific's motions to exclude Buckner's causation experts and its summary judgment motion. Also before the Court is Buckner's motion for partial summary judgment on some of Boston Scientific's affirmative defenses. For the reasons set forth below, the Court grants in part and denies in part Boston Scientific's motion to exclude Jimmy Mays (ECF No. 17), grants

in part and denies in part Boston Scientific's motion to exclude Bruce Rosenzweig (ECF No. 19),grants in part and denies in part Boston Scientific's summary judgment motion (ECF No. 20), and grants in part and denies in part Buckner's partial summary judgment motion (ECF No. 21).

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "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." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

Boston Scientific Corporation manufactures and markets the Obtryx transobturator midurethral sling, a polypropylene sling used to treat stress urinary incontinence. It is a prescription medical device that was cleared by the Food and Drug Administration in 2004 under the 510(k) regulatory process. In

2019, Elizabeth Buckner visited Dr. Edward Killorin complaining of incontinence. Dr. Killorin and another doctor, Dr. Sylvester McRae, recommended that Buckner be implanted with a polypropylene midurethral sling. Dr. Killorin told Buckner about the risks of polypropylene midurethral slings that Boston Scientific had disclosed to him. He did not inform her about risks that Boston Scientific had not disclosed to him, such as the risks that Obtryx could degrade, contract, cause debilitating chronic pain, or cause delayed-onset pudendal and obturator neuralgia (chronic pelvic and thigh pain caused by an irritated or damaged nerve). Killorin Dep. 101:3-102:1, 103:3-10, 104:16-23, ECF No. 28-24.

Boston Scientific points out that the Obtryx "Directions for Use" package insert lists several "Known risks of surgical procedures for the treatment of incontinence," including ongoing pain ("pelvic, vaginal, groin/thigh, dyspareunia") and states that these "events may persist as a permanent condition" even after surgical intervention. Def.'s Mot. Summ. J. Ex. B, Obtryx System Directions for Use 7 ("Obtryx DFU"), ECF No. 20-3.[1] Dr. Killorin testified that he was satisfied in January of 2020 and

[1] Boston Scientific also points out that a 2004 Material Safety Data Sheet for Marlex polypropylene, which was used in the Obtryx sling, states, "Do not use this . . . material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." Killorin Dep. 96:23-97:23, ECF No. 20-5. There is no evidence that Boston Scientific disclosed this information to Dr. Killorin or that he knew what kind of polypropylene was used to make Obtryx.

remained satisfied that Obtryx was a solution for stress urinary incontinence that was within the standard of care. Killorin Dep. at 128:1-17, ECF No. 20-5. But he also testified that if he had been warned that the polypropylene used in Obtryx could degrade or contract or that Obtryx would cause Buckner to be in pain for the rest of her life, he would not have recommended the product for Buckner. Killorin Dep. 101:8-18, 110:22-111:1, ECF No. 28-24. Dr. Killorin further testified that if Boston Scientific had warned him about some of the risks that Buckner experienced—risks like debilitating lifelong chronic pain, dyspareunia so painful that it made intercourse impossible, or nerve irritation and damage—he would have warned Buckner about these risks as part of the informed consent process. *Id.* at 103:3-10, 108:17-109:5, 109:17-111:1. If Dr. Killorin had told Buckner about these risks, she would not have consented to the procedure.

Dr. Killorin implanted Buckner with Obtryx on January 28, 2020. There were no complications with the surgery. After the surgery, Buckner was diagnosed with chronic pelvic pain, pudendal neuralgia, and obturator neuralgia. Buckner underwent a sling revision surgery in 2021, and her doctor observed that the Obtryx mesh "was cording and banding like a guitar string." Miklos Dep. 82:21-22, ECF No. 28-3. The revision surgery did not resolve Buckner's symptoms.

Buckner brought claims against Boston Scientific for negligence, negligence – design defect, negligence – failure to warn, strict liability – failure to warn, strict liability – defective design, and fraud.[2]

DISCUSSION

Boston Scientific seeks to exclude the expert testimony of two Buckner's causation experts, Jimmy Mays, Ph.D. and Bruce Rosenzweig, M.D. Without the testimony of these experts, Buckner cannot create a genuine fact dispute on any of her claims. Therefore, the Court must begin its analysis by addressing the motions to exclude these two experts.

I. Motions to Exclude Buckner's Experts

Boston Scientific argues that Dr. Mays and Dr. Rosenzweig should not be permitted to offer opinion testimony under Federal Rule of Evidence 702. "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if" his "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;" his "testimony is based on sufficient facts or data" and "is the product of reliable principles and methods;"

[2] Buckner withdrew her claims for negligent misrepresentation (Count 8), breach of warranty (Counts 9 & 10), and violation of consumer protection laws (Count 11).

and he "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

In evaluating the admissibility of expert testimony, the Court must consider whether "the expert is qualified to testify competently regarding the matters he intends to address," whether his methodology "is sufficiently reliable," and whether his testimony will help the trier of fact "understand the evidence or to determine a fact in issue." *Knepfle v. J-Tech Corp.*, 48 F.4th 1282, 1294 (11th Cir. 2022) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). The Court's goal is to ensure "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). To allow the testimony to be considered by the jury, the Court must find that "'it is properly grounded, well-reasoned, and not speculative.'" *Id.* (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments).

A. Motion to Exclude Jimmy Mays, Ph.D. (ECF No. 17)

Dr. Mays has a Ph.D. in Polymer Science. He spent several years as a research chemist before becoming a chemistry

professor, first at the University of Alabama at Birmingham and then at the University of Tennessee. For more than thirty-five years, Dr. Mays has studied the synthesis and analytical characterization of polymers, including polypropylene. He has published more than 400 peer-reviewed papers and co-edited a book on polymer characterization techniques. He is also a member of the Society of Biomaterials, and his work includes development of polypropylene pelvic mesh. The main purpose of Dr. Mays's testimony is to explain (1) the chemical structure and properties of polypropylene and (2) how and why polypropylene degrades in the human body. Boston Scientific seeks to exclude Dr. Mays's testimony in its entirety.

First, Boston Scientific seeks to exclude Dr. Mays's opinions about clinical complications caused by polypropylene degradation because he is not a doctor or a biomaterials engineer. But Dr. Mays specializes in polymer chemistry and has spent years studying polymeric biomaterials. He understands, based on his own research and his review of scientific literature, how polypropylene undergoes oxidative degradation when it is implanted into a living organism (like a human). Boston Scientific's central argument on this point is that Dr. Mays should not be permitted to connect the properties of the mesh to clinical symptoms like pain because he is not a medical expert. Plaintiffs argue, though, that Dr. Mays does not intend

to offer an opinion on medical complications associated with degradation (*e.g.*, pain and bleeding). Instead, his testimony is tied to his experience with polypropylene and his research on how the human body responds to it when it undergoes oxidative degradation and can cause complications at a molecular level. The Court finds that Dr. Mays is qualified to testify on what happens to polypropylene when it undergoes oxidative degeneration. Boston Scientific's motion to exclude his testimony on this ground is denied.

Second, Boston Scientific objects to Dr. Mays's opinions on oxidative degradation of polypropylene mesh. Boston Scientific's first argument on this point is that Dr. Mays's opinions should be excluded to the extent that they are based on thermogravimetric analysis, which involved subjecting polypropylene samples to higher temperatures than exist in the human body. Boston Scientific points out that nearly nine years ago, another court excluded Dr. Mays's testimony that was based in part on thermogravimetric analysis because Dr. Mays did not include the protocol or results of the analysis in his expert report—he simply produced some handwritten lab notes that did not reveal whether he had sufficiently controlled for error or bias. *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 535 (S.D.W.

Va. 2014), as amended (Oct. 29, 2014).[3] Since then, though, Dr. Mays has conducted additional research on explanted Boston Scientific meshes and co-authored a peer-reviewed article that appeared in the journal *Biomaterials*. That peer-reviewed study used a combination of analysis techniques, including thermogravimetric analysis. And, there is more published scientific literature on degradation of polypropylene *in vivo*, which Dr. Mays also relied on in reaching his opinions. The Court is not convinced that Dr. Mays's consideration of thermogravimetric analysis—in addition to other analysis techniques—renders his opinion unreliable, and the Court declines to exclude his degradation opinion on this ground.

The Court understands that Boston Scientific also finds fault with Dr. Mays's *Biomaterials* article for other reasons, including the method for selecting which explanted meshes to study, his statements during a 2014 deposition regarding test protocols (before the 2015 *Biomaterials* article was published), and the fact that some biologic material remained on some of the tested samples. In the Court's view, the flaws Boston Scientific perceives in Dr. Mays's analysis go to the weight of his testimony, not its admissibility, and Boston Scientific may

[3] General discovery for this action was done in a multidistrict litigation proceeding before the "MDL court," which also shepherded many individual cases through case-specific discovery and dispositive motions. In those individual cases, like *Tyree*, the MDL court ruled on *Daubert* motions based on the record that was presented to the MDL court. The record before this Court is different.

address these issues on cross-examination. The Court declines to exclude Dr. Mays's opinions regarding oxidative degradation of polypropylene mesh.

Third, Boston Scientific criticizes Dr. Mays's opinions on safer alternative designs, arguing that his opinions on proposed safer materials are unreliable because Dr. Mays testified in depositions several years ago that more biocompatibility testing needed to be performed. Since those depositions, there has been additional research on certain alternative materials like polyethylene and PVDF, and Dr. Mays relies on the scientific studies on the biocompatibility of those materials—in addition to his own experience, knowledge, and training—in reaching his conclusions on safer alternative designs. The Court finds that Boston Scientific's criticisms go to the weight and not admissibility of Dr. Mays's safer alternative opinions. The Court thus declines to exclude these opinions.

Finally, Boston Scientific argues that Dr. Mays should not be allowed to offer "state-of-mind" opinions and legal conclusions—such as his opinion that Boston Scientific was negligent and was driven by money. Buckner acknowledges these types of opinions are not proper expert testimony and represents that Dr. Mays will not attempt to offer such opinions or legal conclusions at trial. This portion of the motion to exclude Dr. Mays's testimony is granted.

B. Motion to Exclude Bruce Rosenzweig, M.D. (ECF No. 19)

Boston Scientific also seeks to exclude Buckner's urogynecology expert, Bruce Rosenzweig, M.D. Dr. Rosenzweig is a urogynecologist with more than thirty years of experience in obstetrics and gynecology. He has performed more than 350 surgeries to correct complications related to synthetic mesh products, including Boston Scientific devices. In this case, Dr. Rosenzweig reviewed Buckner's medical records and opines that she sustained injuries caused by Obtryx. Boston Scientific objects to Dr. Rosenzweig's opinions for several reasons, which the Court addresses in turn.

First, Boston Scientific criticizes Dr. Rosenzweig's differential diagnosis opinion, arguing that he did not correctly rule in a pudendal neuralgia diagnosis and did not adequately rule out other causes of Buckner's injuries. Boston Scientific does not dispute that differential diagnosis is a reliable methodology that is commonly used to determine the medical cause of a patient's injuries. In conducting a differential diagnosis, a physician generally makes a list of possible causes of a patient's condition and then uses a process of elimination to rule out possible causes until only one cause remains.

Boston Scientific argues that Dr. Rosenzweig did not correctly diagnose Buckner with pudendal neuralgia caused by

Obtryx because she did not meet certain criteria for such a diagnosis. But both Dr. Rosenzweig and another physician (Dr. Anthony Gyang) concluded that Buckner had symptoms consistent with pudendal neuralgia. Dr. Rosenzweig explained why, based on his experience and training, all five "Nantes Criteria" are not necessary for a pudendal neuralgia diagnosis, and he explained that Buckner had four of the five "Nantes Criteria" symptoms. Boston Scientific points out that Buckner's pain physician, Dr. Gyang, did not conclude that Obtryx caused Buckner's pudendal neuralgia and that Dr. John Miklos, who performed her Obtryx revision surgery, did not diagnose Buckner with pudendal neuralgia. The fact that different physicians had different opinions goes to the weight of Dr. Rosenzweig's testimony, not its admissibility.[4] Based on the present record, the Court declines to exclude Dr. Rosenzweig's opinion on pudendal neuralgia.

Boston Scientific also contends that Dr. Rosenzweig did not conduct a reliable differential diagnosis because he did not adequately consider Buckner's medical history and rule out potential causes of her injuries (like her hysterectomy and pelvic organ prolapse). Boston Scientific points out that a panel of the Eleventh Circuit concluded, in an unpublished

[4] Boston Scientific also argues that it is not possible to tell if pudendal neuralgia is caused by mesh or something else without nerve decompression surgery, but the evidence Boston Scientific cited in support of that argument does not clearly establish this point.

opinion, that the district court did not abuse its discretion in excluding Dr. Rosenzweig's differential diagnosis opinion in another case because Dr. Rosenzweig did not adequately rule out three potential causes of the plaintiff's symptoms. *Arevalo v. Mentor Worldwide LLC*, No. 21-11768, 2022 WL 16753646, at *5 (11th Cir. Nov. 8, 2022). In *Arevalo*, Dr. Rosenzweig ruled out three potential causes of the plaintiff's injuries by simply stating that the conditions did not lead to the plaintiff's injuries. Here, in contrast, Dr. Rosenzweig provided specific explanations of why he ruled out certain potential causes of Buckner's injuries. *See* Mot. to Exclude Rosenzweig Ex. A, Rosenzweig Report 31-32, ECF No. 19-1. So, although Buckner's medical history may provide fodder for a thorough and sifting cross-examination of Dr. Rosenzweig, the Court is not convinced that Dr. Rosenzweig's differential diagnosis testimony should be excluded as unreliable.

In addition to its criticisms of Dr. Rosenzweig's differential diagnosis, Boston Scientific contends that Rosenzweig's general causation testimony—that Obtryx *can* cause certain injuries—should be excluded. Boston Scientific argues that Rosenzweig's opinion that Obtryx can cause obturator and pudendal neuralgia is nothing but *ipse dixit*. But Dr. Rosenzweig explained why, based on his medical training and his knowledge of human anatomy, midurethral transobturator slings

like Obtryx can cause obturator and pudendal neuralgia. Rosenzweig also relied on medical literature to support his opinion.[5] Boston Scientific's motion to exclude Dr. Rosenzweig's opinions on this ground is denied.

Next, Boston Scientific argues that the Court should not let Dr. Rosenzweig opine that polypropylene mesh can degrade in the human body due to its chemical properties. The basis for this portion of Boston Scientific's motion is that Dr. Rosenzweig is not a biomedical engineer and thus (in Boston Scientific's view) is not qualified to render such an opinion. In reaching his opinion that polypropylene mesh degrades, Dr. Rosenzweig conducted extensive research in the medical and scientific literature, and he relied on his significant clinical experience treating hundreds of patients who needed revision surgeries for their polypropylene mesh slings. So, even if Dr. Rosenzweig's knowledge of the precise biochemical interactions that cause degradation is not as extensive as that of another type of expert, the Court is not convinced that his opinion on this issue should be excluded.

Boston Scientific also objects to Dr. Rosenzweig's testimony on the sufficiency of its testing of Obtryx. Buckner

[5] Boston Scientific contends that Dr. Rosenzweig admitted that there is no scientific literature linking pudendal or obturator neuralgia to Obtryx or other transobturator tape slings, but that portion of his deposition focuses on literature other than case studies and case reports. Boston Scientific did not argue that Dr. Rosenzweig may not consider such studies and reports.

acknowledges that Dr. Rosenzweig may not testify about what tests Boston Scientific should have performed or could have performed on Obtryx because Dr. Rosenzweig does not have experience or training about appropriate pre-market medical device testing. The Court thus grants this portion of Boston Scientific's motion to exclude Dr. Rosenzweig.

Next, Boston Scientific contends that Dr. Rosenzweig should not be permitted to offer an opinion about the biocompatibility warnings contained in the material safety data sheet for polypropylene used to make Obtryx—warnings that the polypropylene resin should not be used in medical applications involving permanent implantation in the human body and that the material may react with oxygen and strong oxidizing agents. Boston Scientific's specific argument is that Dr. Rosenzweig is not qualified to testify on what biocompatibility testing Boston Scientific should have done in light of the biocompatibility warnings. As discussed above, Dr. Rosenzweig shall not be permitted to testify on the sufficiency of Boston Scientific's testing of Obtryx or its components, so that portion of the motion to exclude is granted. But Boston Scientific did not clearly move to exclude any other opinions Dr. Rosenzweig has based on the material data safety sheet (e.g., that Boston Scientific should not have used Marlex polypropylene or should

have warned doctors of the biocompatibility risks), so this ruling does not exclude such opinions.

Finally, Boston Scientific asserts that Dr. Rosenzweig should not be allowed to offer "state-of-mind" opinions and legal conclusions—such as his opinion that Boston Scientific failed to act as a reasonable and prudent manufacturer. Buckner acknowledges these types of opinions are not proper expert testimony and represents that Dr. Rosenzweig will not attempt to offer such opinions or legal conclusions at trial. This portion of the motion to exclude Dr. Rosenzweig is granted. Nothing in this ruling shall prohibit Dr. Rosenzweig from testifying about Boston Scientific's internal documents to the extent that they explain a basis for his opinions.

II. Boston Scientific's Summary Judgment Motion (ECF No. 20)

Boston Scientific acknowledges that if the Court permits the expert testimony of Dr. Mays and Dr. Rosenzweig, genuine fact disputes exist on Buckner's claims for negligence and design defect. Boston Scientific contends, though, that the rest of Buckner's claims fail as a matter of law. Georgia law applies in this diversity action. *See, e.g., Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996) ("Under the *Erie* [*R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)] doctrine, federal courts sitting in diversity apply state substantive law[.]"). The Court addresses each claim in turn.

A. Buckner's Failure to Warn Claims

A medical device manufacturer has a duty to warn the patient's doctor of the device's dangers, and "the manufacturer's warnings to the physician must be adequate or reasonable under the circumstances of the case." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003).[6] Boston Scientific emphasizes that the Obtryx "Directions for Use" package insert lists several "Known risks of surgical procedures for the treatment of incontinence," including ongoing pain ("pelvic, vaginal, groin/thigh, dyspareunia") and states that these "events may persist as a permanent condition." Obtryx DFU 7. Boston Scientific contends that these are the basic types of injuries Buckner claims, so the Obtryx warnings were adequate as a matter of law.

It is true that when a medical device's package insert warns of the precise risk that the plaintiff suffered, the warning is adequate and reasonable as a matter of law. *See McCombs v. Synthes (U.S.A.)*, 596 S.E.2d 780, 780 (Ga. Ct. App. 2004) (concluding that a manufacturer's warning that a medical device could break under certain circumstances was sufficient in a case where the plaintiff's medical device broke under those circumstances). But a warning is not sufficient if it does not

[6] Buckner acknowledges that she may not pursue a failure to warn claim based on Boston Scientific's failure to warn her directly of the risks associated with Obtryx.

"provide a complete disclosure of the existence and extent of the risk involved." *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1220 (11th Cir. 1999) (quoting *Thornton v. E.I. DuPont De Nemours & CO.*, 22 F.3d 284, 289 (11th Cir. 1994)) (finding a genuine fact dispute on whether a more detailed warning was required given a vehicle model's propensity to roll over).

Here, Buckner asserts that she suffers from chronic debilitating pain, obturator neuralgia (chronic thigh pain caused by irritation or damage to the obturator nerve), pudendal neuralgia (chronic pelvic pain caused by irritation or damage to the pudendal nerve), and dyspareunia that makes intercourse impossible. Although the Obtryx DFU warns that known complications of surgical procedures to treat incontinence include some ongoing pain (including, pelvic, vaginal, thigh, groin, and dyspareunia), there is evidence from which a jury could conclude that Boston Scientific did not warn that the polypropylene used in Obtryx could degrade or contract and cause problems like debilitating chronic pain and delayed onset nerve damage/irritation. In addition, Buckner presented evidence from which a jury could conclude that Boston Scientific did not disclose the true complication rate of polypropylene sling products like Obtryx. The Court thus finds that a genuine fact dispute exists on whether Boston Scientific adequately disclosed the nature and the extent of Obtryx's risks.

Boston Scientific argues that even if there are genuine fact disputes on the adequacy of the Obtryx warning, Buckner cannot establish causation on her failure to warn claims because Dr. Killorin testified that he believes that Obtryx was a solution for stress urinary incontinence that was within the standard of care. Again, though, Dr. Killorin also testified that if Boston Scientific had warned that the polypropylene used in Obtryx could degrade or contract or that Obtryx would cause a patient to be in debilitating pain for the rest of her life, he would not have recommended the product for Buckner. Dr. Killorin further testified that if Boston Scientific had warned him about some of the risks that Buckner experienced—risks like debilitating lifelong chronic pain, dyspareunia so painful that it made intercourse impossible, or nerve damage—he would have warned Buckner about these risks as part of the informed consent process. And, if Dr. Killorin had told Buckner about the nature and extent of these risks, she would not have consented to the procedure. For these reasons, genuine fact disputes remain on Buckner's failure to warn claims, and Boston Scientific's summary judgment motion on these claims is denied.

B. Buckner's Fraud Claims

In addition to her design defect and failure to warn claims, Buckner asserts claims for fraudulent misrepresentation (including misrepresentation by omission). Boston Scientific

argues that these claims are subsumed into Plaintiffs' failure-to-warn claims. Buckner did not clearly respond to this argument, and she did not explain how her fraudulent misrepresentation claims are different from her failure to warn claims. Buckner's failure to warn claims are based on Boston Scientific's allegedly inadequate warnings about the true risks of Obtryx—and the implication that Obtryx was safe and had no higher risk of adverse events than other procedures to treat stress urinary incontinence. Buckner did not point to any separate statements that form the basis of her fraud claims. Accordingly, the Court finds that Buckner's fraud claims are subsumed into her failure-to-warn claims. Boston Scientific is entitled to summary judgment to the extent that Buckner shall not be permitted to pursue separate fraud claims.

C. Buckner's Punitive Damages Claim

Boston Scientific argues that even if genuine fact disputes preclude summary judgment on Buckner's negligence, design defect, and failure to warn claims, she cannot present enough evidence to create a genuine fact dispute on punitive damages. "Punitive damages may be awarded only in such tort actions in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would

raise the presumption of conscious indifference to consequences." O.C.G.A. § 51-12-5.1(b).

Here, Buckner pointed to evidence from which a jury could conclude that Boston Scientific was warned well before her Obtryx implant surgery that the polypropylene used in Obtryx should not be used in "medical applications involving permanent implantation in the human body." Pl.'s Resp. to Def.'s Mot. Summ. J. Ex. I, Marlex Material Safety Data Sheet 1, ECF No. 28-10. She also pointed to evidence that Boston Scientific was warned that before it used certain polypropylene products, it should make its own determination of the safety and suitability of that polypropylene product for Boston Scientific's specific application. Pl.'s Resp. to Def.'s Mot. Summ. J. Ex. J, Agreement (Oct. 1, 2004) § I.C, ECF No. 28-11. And she pointed to evidence that Boston Scientific did not do testing to determine that the polypropylene was safe for use in an implantable medical device. Smith Dep. 32:15-33:7, ECF No. 28-12. From this evidence, a reasonable jury could conclude that Boston Scientific ignored safety warnings about the polypropylene it used in Obtryx and that this conduct warrants punitive damages under Georgia law. Boston Scientific's summary judgment motion on this ground is denied.

III. Buckner's Partial Summary Judgment Motion (ECF No. 21)

Boston Scientific raised more than two dozen affirmative defenses. Buckner moved for partial summary judgment on thirteen of them, then Boston Scientific withdrew seven of them. The question before the Court is thus whether Buckner established that Boston Scientific should not be permitted to pursue six of its affirmative defenses at trial.[7] As a preliminary matter, Boston Scientific contends that Buckner's motion should be denied because she did not follow the Court's local rules and submit a separate statement of material facts. The Court finds that Buckner's motion raises purely legal questions and that the Court has a sufficient understanding of the facts to address them.

First, Buckner contends that Boston Scientific should not be able to pursue its fifth, sixth, and eighteenth affirmative defenses because the issues (state-of-the-art, compliance with regulations, and lack of a safer alternative design) are all part of the risk-utility factors that the jury may consider in determining whether a product is defectively designed. *See Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 674-75 & n.6 (Ga. 1994) (listing risk-utility factors, including whether "an alternative design would have made the product safer than the

[7] This order obviously does not address the affirmative defenses on which Buckner did not seek summary judgment.

original design and was a marketable reality and technologically feasible"). Under Georgia law, compliance with regulations and state of the art "does not eliminate conclusively" a manufacturer's liability for defective design. *Id.* at 675 n.6. Accordingly, even if Boston Scientific established its fifth and sixth affirmative defenses, it could still be liable for design defect under Georgia's risk-utility test, so success on these "affirmative defenses" would not mandate judgment in Boston Scientific's favor. This ruling shall not prohibit Boston Scientific from presenting evidence on these issues (if it is otherwise admissible) to refute Buckner's design defect claims.

Regarding the eighteenth defense—lack of a safer alternative—Boston Scientific notes that in pharmaceutical cases, some courts have relied on Comment k to § 402A of the Restatement (Second of Torts) to find that absence of a safer alternative design is an affirmative defense on a strict liability design defect claim. *See, e.g., Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003) ("[O]nce a prima facie case for design defect is established, we hold that a pharmaceutical manufacturer will be relieved from strict liability only when it demonstrates that it has met the requirements of Comment k."). Buckner's summary judgment motion on this defense is denied. The Court notes that Boston Scientific suggests that it simply intends to introduce evidence

and argument on the absence of a safer design to *refute* the elements of Buckner's claims—not that it intends to pursue this defense as an affirmative defense on which it bears the burden of proof. If Boston Scientific intends to pursue its eighteenth defense as an affirmative defense on which it bears the burden of proof at trial, Boston Scientific shall so state in its portion of the proposed pretrial order.

Next, Buckner objects to Boston Scientific's seventeenth affirmative defense, which invokes the Restatement (Third) of Torts: Products Liability § 6 – "Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices." The defense articulated in Boston Scientific's answer is that Buckner's claims are barred "because the foreseeable risks of harm posed by the medical device are not sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients." Answer 31 ¶ 17, ECF No. 3. In its response to Buckner's motion, Boston Scientific clarifies that it intends to rely on § 6(d)(1): "A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-

care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings[.]" Restatement (Third) of Torts: Prod. Liab. § 6(d)(1) (1998).

It is not clear to the Court how this is an affirmative defense. Certainly, "under the learned intermediary doctrine, the manufacturer's warnings to the physician must be adequate or reasonable under the circumstances of the case." *McCombs*, 587 S.E.2d at 595. So to prevail on her failure to warn claims, Buckner has the burden to prove that Boston Scientific's warnings to her physician were not adequate or reasonable. Boston Scientific may refute Buckner's claims by presenting argument and evidence that its Obtryx warnings were adequate and reasonable, but the burden of proof on this issue would remain with Buckner. Nonetheless, if Boston Scientific intends to pursue its seventeenth defense as an affirmative defenses on which it bears the burden of proof, Boston Scientific shall so state in its portion of the proposed pretrial order.

Buckner also objects to Boston Scientific's twenty-fourth affirmative defense, that Buckner's claims are barred by the doctrine of federal preemption. The Court understands that state requirements are expressly preempted under the Medical Device Amendments to the federal Food Drug and Cosmetic Act if "they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel v. Medtronic, Inc.*, 552 U.S.

312, 330 (quoting 21 U.S.C. § 360k(a)(1)). But, as Boston Scientific acknowledges, "duties imposed by state law are preempted only to the narrow extent that they add different or extra requirements to the safety and effectiveness of the medical device beyond those required by the federal scheme." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1326 (11th Cir. 2017) (citing *Riegel*, 552 U.S. at 330). The Court also understands that the Food Drug and Cosmetic Act impliedly preempts fraud-on-the-FDA claims, even if they are labeled as something else, like a negligence claim based on a manufacturer's failure to investigate adverse events and report them to the FDA. *Id.* at 1327, 1330 (discussing 21 U.S.C. § 337(a) and *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341 (2001)). But, "traditional state-law tort claims survive implied preemption so long as they don't seek to enforce a duty owed to the FDA." *Id.* at 1327. Whether a claim is preempted by federal law is a question of law for the Court, not a fact question for a jury, so the proper way to raise a preemption defense is to file a dispositive motion before trial. Boston Scientific did not move to dismiss or seek summary judgment on any of Buckner's claims based on a preemption defense, and its response to Buckner's summary judgment motion on this defense does not clearly explain why any of Buckner's claims are preempted. So, while the Court does not reach the merits of the

defensive preemption affirmative defense, the Court finds that Boston Scientific did not raise it by the dispositive motion deadline and has thus waived it.

Finally, Buckner objects to Boston Scientific's tenth affirmative defense, assumption of the risk. The defense "applies when the plaintiff, with a full appreciation of the danger involved and without restriction of [her] freedom of choice either by the circumstances or by coercion, deliberately chooses an obviously perilous course of conduct." *Bodymasters Sports Indus., Inc. v. Wimberley*, 501 S.E.2d 556, 560 (Ga. Ct. App. 1998). "A defendant asserting an assumption of the risk defense must establish that the plaintiff (1) had knowledge of the danger; (2) understood and appreciated the risks associated with such danger; and (3) voluntarily exposed [herself] to those risks." *Id.* Buckner contends that Boston Scientific will be unable to establish assumption of the risk as a matter of law because she did not have actual and subjective knowledge of the risks of Obtryx. That is a fact question. If the jury believes Buckner's evidence that Boston Scientific failed to adequately warn Dr. Killorin of Obtryx's true risks, then Boston Scientific cannot prevail on this defense. But if the jury concludes that Boston Scientific's warnings were sufficient *and* that Buckner fully understood and appreciated the risks of Obtryx before consenting to the procedure, the jury could find that she

assumed the risk. Buckner's summary judgment motion on this issue is denied. Boston Scientific, of course, bears the burden of proof on this affirmative defense.

CONCLUSION

For the reasons set forth above, the Court grants in part and denies in part Boston Scientific's motion to exclude Jimmy Mays (ECF No. 17), grants in part and denies in part Boston Scientific's motion to exclude Bruce Rosenzweig (ECF No. 19), grants in part and denies in part Boston Scientific's summary judgment motion (ECF No. 20), and grants in part and denies in part Buckner's partial summary judgment motion (ECF No. 21).

The Court will try this action during the Court's September 2023 trial term, which is scheduled to begin on September 11, 2023. The Court will issue a notice of pretrial conference by the end of June 2023. The parties are instructed to nail down precisely which claims and defenses they intend to pursue at trial and to include the elements of each claim or defense in their joint proposed pretrial order.[8]

IT IS SO ORDERED, this 22nd day of June, 2023.

S/Clay D. Land
CLAY D. LAND
U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA

[8] For example, before trial, Buckner's counsel should be able to articulate the difference between Buckner's general negligence claim and her negligence claims for design defect and failure to warn.