

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

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004
		4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
		Case No.
LIABILITY LITIGATION	*	4:11-cv-5066 (K. Riley)

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O R D E R

Defendant Mentor Worldwide LLC ("Mentor") developed a suburethral sling product called ObTape Transobturator Tape ("ObTape"), which was used to treat women with stress urinary incontinence. Plaintiff Kathleen Riley ("Riley") was surgically implanted with ObTape. She alleges that she suffered serious injuries caused by ObTape's design and/or manufacturing defects. Riley also claims that Mentor failed to provide adequate warnings to her physicians about the risks associated with ObTape. Mentor seeks to dismiss Counts I, II and III of Riley's Complaint because she labeled those claims as "strict liability" claims, which are not recognized under Massachusetts law, instead of "breach of warranty" claims, which are recognized. Mentor also maintains that it is entitled to summary judgment as to all of Riley's claims because Riley has failed to point to sufficient evidence to create a genuine factual dispute as to whether the alleged ObTape defects proximately caused her injuries. For the reasons set forth below, the Court finds that Mentor's arguments

are without merit, and Mentor's Motion for Summary Judgment (ECF No. 62 in 4:11-cv-5066) is denied.

#### 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

Viewed in the light most favorable to Riley, the record reveals the following.

Riley, a resident of Massachusetts, was surgically implanted with ObTape in Massachusetts and received all of her subsequent related treatment there. She first consulted with a urologist in 2005 because she had problems with incontinence. On May 16, 2005, the urologist surgically implanted ObTape and also performed another surgical procedure. Riley's incontinence

symptoms improved after the surgery, but in August 2010, Riley returned to the urologist complaining that her stress incontinence had gotten worse. In September 2010, the urologist examined Riley and discovered a urethral erosion of the ObTape. The next month, the urologist performed surgery to remove the eroded ObTape and repair the urethral erosion. After the excision surgery, Riley continued to experience significant complications. She underwent an additional surgery in February 2011 and continues to experience stress incontinence and other symptoms.

#### DISCUSSION

Riley initially filed her action in this Court, but the Court found that venue was improper and transferred the case to the United States District Court for the District of Massachusetts, where it should have been filed initially. The Judicial Panel on Multidistrict Litigation transferred Riley's diversity action from the United States District Court for the District of Massachusetts back to this Court for pretrial proceedings. The Court applies the choice-of-law rules of Massachusetts, the transferor forum, to determine which state law controls. See *In re Volkswagen & Audi Warranty Extension Litig.*, 692 F.3d 4, 17 (1st Cir. 2012) ("Where a suit is consolidated and transferred under [28 U.S.C.] § 1407, courts typically apply the choice of law rules of each of the transferor courts."); see also

*Murphy v. Fed. Deposit Ins. Corp.*, 208 F.3d 959, 965 (11th Cir. 2000) (“Our system contemplates differences between different states’ laws; thus a multidistrict judge asked to apply divergent state positions on a point of law would face a coherent, if sometimes difficult, task.”) (internal quotation marks omitted). Riley and Mentor agree that Massachusetts law applies to Riley’s claims because Riley is a resident of Massachusetts and received all medical treatment relevant to this action in Massachusetts. See *Cosme v. Whitin Mach. Works, Inc.*, 632 N.E.2d 832, 834 (Mass. 1994) (noting that Massachusetts typically applies “the substantive laws of the jurisdiction wherein the tort occurred”).

**I. Are Riley’s “Strict Liability” Claims Cognizable Under Massachusetts Law?**

Mentor argues that Counts I, II and III of Riley’s Complaint should be dismissed because they are labeled as “strict liability” claims, and Massachusetts does not recognize product liability claims based on strict liability. Mentor is correct that Massachusetts law does not recognize strict liability in tort; however, Massachusetts does recognize product liability claims based on breach of warranty. See Mass. Gen. Laws ch. 106, § 2-318; *Swartz v. Gen. Motors Corp.*, 378 N.E.2d 61, 62 (Mass. 1978); accord *Mason v. Gen. Motors Corp.*, 490 N.E.2d 437, 442 (Mass. 1986). Moreover, the Massachusetts legislature “transformed warranty liability into a remedy intended to be

fully as comprehensive as the strict liability theory of recovery that has been adopted by a great many other jurisdictions." *Back v. Wickes Corp.*, 378 N.E.2d 964, 968 (Mass. 1978). The Massachusetts Supreme Judicial Court observed that the legislature "has made the Massachusetts law of warranty congruent in nearly all respects with the [strict liability] principles expressed in Restatement (Second) of Torts § 402A." *Id.* at 969; accord *Cigna Ins. Co. v. OY Saunatec, Ltd.*, 241 F.3d 1, 15 (1st Cir. 2001) ("Actions under Massachusetts law for breach of the implied warranty of merchantability are the functional equivalent of strict liability in other jurisdictions . . ."). Accordingly, Massachusetts regards strict liability cases of other jurisdictions as persuasive authority in considering cases under Massachusetts warranty law. See, e.g., *Back*, 378 N.E.2d at 969 ("[W]e find the strict liability cases of other jurisdictions to be a useful supplement to our own warranty case law.").<sup>1</sup>

The Court rejects Mentor's argument that Riley's claims must be dismissed simply because they are labeled as "strict liability" claims instead of claims for "breach of warranty." Instead, the Court must examine the factual allegations to determine whether they state claims for breach of warranty under Massachusetts law.

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<sup>1</sup> Although there are a few distinctions between traditional strict liability law and the Massachusetts law of warranty, those differences are not relevant to the pending motion.

Riley makes three "strict liability" claims in her Complaint. First, she asserts a claim for "strict liability - defective manufacture." Compl. 4, ECF No. 1 in 4:11-cv-5066. She alleges that ObTape "was defective in manufacture and unreasonably dangerous to the user or consumer when it left [Mentor's] possession or control in that it deviated materially from [Mentor's] design and manufacturing specifications in such a manner as to pose an unreasonable risk of serious bodily harm to [Riley]. *Id.* ¶ 15, ECF No. 1. Second, Riley asserts a claim for "strict liability - defective design." *Id.* at 5. She alleges that ObTape "was defective in design in that at the time it left [Mentor's] control, the foreseeable risks of harm associated with its design exceeded the benefits associated with said design." *Id.* ¶ 21. Third, Riley asserts a claim for "strict liability - inadequate warning or instruction." *Id.* at 7. She alleges that Mentor failed to provide the "warning or instruction that a manufacturer exercising reasonable care should have provided" regarding ObTape at the time it left Mentor's control and that Mentor did not provide the post-sale warnings that a reasonable manufacturer would have provided after learning of numerous complications in ObTape patients. *Id.* ¶¶ 30-31.

The question is whether these allegations support claims for breach of warranty under Massachusetts law. According to the Massachusetts courts, "the propensities of the product as sold"

must be compared "with those which the product's designer intended it to have" and decide whether a "deviation from the design rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes." *Back*, 378 N.E.2d at 970. The Court interprets this type of breach of warranty claim to encompass a breach caused by a manufacturing defect. And Riley certainly alleges that a manufacturing defect rendered ObTape unreasonably dangerous for users. Compl. ¶ 15 (alleging that ObTape "was defective in manufacture and unreasonably dangerous to the user or consumer when it left [Mentor's] possession or control in that it deviated materially from [Mentor's] design and manufacturing specifications in such a manner as to pose an unreasonable risk of serious bodily harm to [Riley]"). Therefore, based on Riley's factual allegations, Mentor was on notice that Riley's manufacturing defect claim fell within Massachusetts warranty law.

The same is true for Riley's design defect claim. Under Massachusetts warranty law, "a manufacturer must anticipate the environment in which its product will be used, and it must design against the reasonably foreseeable risks attending the product's use in that setting." *Back*, 378 N.E.2d at 969. In evaluating a design defect claim under Massachusetts warranty law, it must be determined whether the product's propensities that resulted "from conscious design choices of the manufacturer rendered the product

unreasonably dangerous to its users.” *Id.* at 970. Several factors must be considered to evaluate the adequacy of a product’s design, including “the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.” *Id.* (quoting *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 455 (Cal. 1978) (explaining factors for strict liability design defect claims under California law)). Riley alleges that a design defect made ObTape unreasonably dangerous for users. Compl. ¶ 21 (alleging that ObTape “was defective in design in that at the time it left [Mentor’s] control, the foreseeable risks of harm associated with its design exceeded the benefits associated with said design”). Therefore, based on Riley’s factual allegations, Mentor was on notice that Riley’s design defect claim was cognizable as a breach of warranty claim under Massachusetts law.

Finally, Riley’s failure to warn claim likewise states a claim under Massachusetts warranty law. Under Massachusetts warranty law, a manufacturer must warn or provide instructions about risks that are “reasonably foreseeable at the time of sale or could have been discovered by way of reasonable testing.” *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 923 (Mass.



1998). In addition, a manufacturer is "subject to a continuing duty to warn (at least purchasers) of risks discovered following the sale of the product." *Id.* In her Complaint, Riley alleges that Mentor failed to provide the warning or instruction "that a manufacturer exercising reasonable care would have provided" regarding ObTape at the time it left Mentor's control. Compl. ¶ 30. Riley also asserts that Mentor did not provide the post-sale warnings that a reasonable manufacturer would have provided to its purchasers after learning of numerous complications in ObTape patients. *Id.* ¶ 31. Therefore, based on Riley's factual allegations, Mentor was on notice that Riley's failure to warn claim would be cognizable under Massachusetts warranty law.

Riley's counsel could have likely avoided this unnecessary layer of litigation by crafting the Complaint in a manner that carefully followed the precise language of Massachusetts law, but failure to label the causes of action more accurately does not warrant dismissal of those claims when the factual allegations state claims under Massachusetts law. Accordingly, Mentor's summary judgment motion based on Riley's failure to label the claims as "warranty" claims is denied.

## **II. Did Riley Point to Sufficient Evidence of Causation?**

Mentor argues that Riley has failed to point to sufficient evidence that a defect in ObTape caused her injuries. In support of this argument, Mentor relies primarily upon the fact that

Riley suffered a urethral, instead of vaginal, erosion of the ObTape. It is undisputed that urethral erosions of ObTape are not as common as vaginal erosions. Mentor asserts that urethral erosions are commonly the result of surgical error. Mentor focuses on the fact that Riley's expert, Dr. Amanda White, acknowledged that she could not point to any literature documenting an increased risk of urethral erosion with ObTape as compared to other mesh products. Mentor's motion on causation is therefore akin to a motion to exclude Dr. White's testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The only ground Mentor asserts for excluding Dr. White's testimony is that Dr. White did not locate more than one article regarding a specific subset of ObTape erosion complications—urethral erosion. The lack of published studies on a specific topic (or a specific subset of that topic), however, is not necessarily dispositive of whether an expert's testimony is minimally reliable. *United Fire & Cas. Co. v. Whirlpool Corp.*, No. 11-15011, 2013 WL 174064, at \*4 (11th Cir. Jan. 17, 2013); accord *Daubert*, 509 U.S. at 593 ("Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability[.]"). Here, the Court concludes that the lack of published studies on a subset of ObTape erosion complications does not render Dr. White's testimony unreliable. Mentor has pointed to no other

grounds for excluding Dr. White's testimony, and the Court will therefore consider her testimony.

Based on the Court's previous findings and on the testimony of Dr. White, the Court finds that it cannot decide the causation issue *as a matter of law*. To do so, the Court would have to conclude that no reasonable juror could find that the erosion of the ObTape through Riley's urethra was caused by a manufacturing or design defect in ObTape. The Court has previously concluded that a genuine fact dispute exists as to whether there is an increased risk of complications such as erosion and infection with ObTape as compared to other mesh products. *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1369-71 (M.D. Ga. 2010). The Court also concluded that a genuine fact question exists on whether ObTape has a propensity to degrade that renders it unsuitable as an implantable material. *Id.* at 1374-75. Mentor has presented no basis for having the Court reconsider these previous findings. Mentor simply argues that the fact that the ObTape eroded through the urethra instead of the vagina makes all the difference. This argument ignores the testimony of Dr. White. When Dr. White's testimony is construed with all reasonable inferences drawn in Riley's favor, it establishes for purposes of summary judgment that the same allegedly defective qualities of ObTape that cause it to erode into the vagina likewise cause the erosion into the

urethra. Specifically, Dr. White testified that “[t]he rate of erosion in general due to the properties of the ObTape are increased.” White Dep. 61:1-2, ECF No. 62-6 at 11 in 4:11-cv-5066. She further testified that whether ObTape “erodes into the vagina or whether it erodes into the urethra . . . is irrelevant.” *Id.* at 61:3-5. Finally, Dr. White testified, “I think we can take from the literature that the increased risk of vaginal erosions portends an increased risk of urethral erosions with [ObTape].” *Id.* at 61:10-12. Based on this evidence, the Court finds that a genuine fact dispute exists as to whether a defect in ObTape caused Riley’s injuries. Mentor’s summary judgment motion on the causation issue is therefore denied.

#### CONCLUSION

For the reasons set forth above, Mentor’s Motion for Summary Judgment as to Kathleen Riley (ECF No. 62 in 4:11-cv-5066) is denied.

IT IS SO ORDERED, this 24th day of January, 2013.

S/Clay D. Land

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CLAY D. LAND

UNITED STATES DISTRICT JUDGE