

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	*
LIABILITY LITIGATION	Case No. * 4:14-cv-113 (Morgan)

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O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Doris Morgan was implanted with ObTape and claimed that she suffered injuries caused by ObTape. Morgan brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Morgan also asserted that Mentor did not adequately warn her physicians about the risks associated with ObTape. Morgan died after she filed this action. Her daughters Vickie Thomas and Sandra F. Johnston, as representatives for the Estate of Doris Morgan, were substituted as the Plaintiffs in this action. Mentor seeks summary judgment as to Plaintiffs' breach of warranty and continuing duty to warn claims. As discussed below, Mentor's partial summary judgment motion (ECF No. 33 in 4:14-cv-113) is granted.

#### 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

On May 9, 2005, Dr. Lane Mercer implanted Morgan with ObTape to treat her stress urinary incontinence. Dr. Mercer does not recall treating Morgan after her implant surgery. Mercer Dep. 29:9-17. According to Morgan's daughter, Morgan did follow up with Dr. Mercer a few months after the implant procedure. Johnston Dep. 16:2-21, ECF No. 35-3 in 4:14-cv-113. Morgan's daughter also testified that Morgan saw Dr. Mercer in 2009 when she began nerve stimulation treatment to treat her recurrent stress urinary incontinence. *Id.* at 18:6-24; accord Mercer Dep. 29:9-24, ECF No. 35-5 in 4:14-cv-113. When Morgan

saw Dr. Mercer in 2009, Dr. Mercer "didn't mention the - the tape at all. He said it was more of a problem between maybe [Morgan's] brain and her bladder not communicating." Johnston Dep. 18:6-16.<sup>1</sup>

In 2013, Morgan sought treatment from Dr. Rakesh Patel. Dr. Patel diagnosed Morgan with an erosion of her ObTape. Dr. Patel removed Morgan's entire ObTape on October 25, 2013, and he was able to remove it as one piece. Dr. Patel's practice was to remove the entire ObTape in the event of an erosion. Patel Dep. 43:16-44:10, 93:18-94:17, ECF No. 33-6 in 4:14-cv-113. Dr. Mercer's practice was also to remove any eroded tape in the event of an erosion. Mercer Dep. 95:14-19, ECF No. 33-5 in 4:14-cv-113. Dr. Mercer testified that an additional warning to remove as much ObTape as possible in the event of an erosion would not have changed his practice because he would remove any eroded tape, anyway. *Id.*

Plaintiffs assert claims for negligence, strict liability - design defect, strict liability - manufacturing defect, strict liability - failure to warn, breach of implied warranties, breach of express warranties, fraudulent misrepresentation,

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<sup>1</sup> Plaintiffs assert that Morgan sought treatment from Dr. Mercer for a bladder infection, but they did not present evidence to prove this point. They cited Johnston's deposition at page 18:22-25, which states that Morgan was experiencing stress urinary incontinence in 2009. They also cited Johnston's deposition at page 19:1-6, but they did not include that page with the deposition excerpt they submitted, so the Court cannot determine whether it supports Plaintiffs' claim that Morgan sought treatment from Dr. Mercer for a bladder infection.

fraudulent concealment, and negligent misrepresentation. Mentor seeks summary judgment on Plaintiffs' warranty claims, as well as any claims based on Mentor's alleged breach of a post-sale duty to warn. Plaintiffs do not contest Mentor's summary judgment motion as to the warranty claims, and Mentor's summary judgment motion is therefore granted as to those claims.

#### DISCUSSION

Morgan filed her action in this Court on May 8, 2014 under the Court's direct filing order. The parties agreed that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. Morgan was a Florida resident, and all of her ObTape-related treatment took place in Florida. The parties agree that Florida law applies to the Plaintiffs' claims.

Florida law recognizes a continuing duty to warn. See *Sta-Rite Indus., Inc., v. Levey*, 909 So. 2d 901, 905-06 (Fla. Dist. Ct. App. 2004) (finding that swimming pool pump manufacturer could be liable for injuries caused by inadequate warnings because it did not send updated warnings to its distributors). The Court previously concluded that to state a continuing duty to warn claim under Florida law, an ObTape plaintiff must present some evidence that a different post-sale warning would

have made a difference in her treatment. *Burch v. Mentor*, Case No. 4:12-cv-279, 2015 WL 5722799, at \*3-\*4 (M.D. Ga. Sept. 29, 2015). Plaintiffs did not point to any authority suggesting that Florida courts have since adopted a different causation standard for continuing duty to warn claims.

Plaintiffs do not appear to dispute that it would not have made a difference to Morgan's post-implant treatment if Mentor had instructed physicians to remove as much of the ObTape as possible in the event of an erosion. Dr. Mercer never diagnosed Morgan with an erosion of her ObTape; if he had, he would have removed any eroded ObTape. And Dr. Patel's practice was to remove the entire ObTape in the event of an erosion, which is what he did for Morgan.

Rather, Plaintiffs' chief argument appears to be that Mentor should have warned Dr. Mercer of the risk of delayed onset infections and that the Court may presume that Dr. Mercer would have diagnosed Morgan with a failed sling in 2009 and taken some unspecified action to treat it. But Plaintiffs did not point to any *evidence* of what Dr. Mercer would have done with an additional warning. There must be some evidence that Mentor's failure to issue adequate post-sale warnings actually caused Morgan's injuries. Citing *Sta-Rite*, Plaintiffs contend that the Court may simply presume that a different post-sale warning would have made a difference to Morgan's treatment. As

the Court previously observed, *Sta-Rite* "stand[s] for the proposition that under Florida law, the courts may assume that an adequate warning would have been heeded." *Id.* at \*3. But *Sta-Rite* "did not dispense with the causation requirement entirely." *Id.* "In *Sta-Rite*, the court presumed that the pool owner would have heeded a more stringent warning regarding the hazards of a pool pump and would have fixed the grate over the pump in time to avoid the plaintiff's injuries." *Id.* (citing *Sta-Rite*, 909 So. 2d at 906). "Thus, all *Sta-Rite* . . . allow[s] the Court to presume is that Dr. [Mercer] would have paid attention to an additional warning that ObTape may have a higher rate of infection than other slings." *Id.* *Sta-Rite* does not, "however, permit the Court to speculate as to what Dr. [Mercer] would have done with those warnings." *Id.*

"[I]n *Sta-Rite*, there was enough evidence for a jury to find that the pool owner would have heeded a warning to fix the grate over the pump in time to prevent the plaintiff's injuries." *Id.* at \*4 (citing *Sta-Rite*, 909 So. 2d at 906). But this case, unlike *Sta-Rite*, involves a complex decision regarding a medical device that had already been implanted in Morgan's body. Though Plaintiffs did present evidence that Morgan had two post-implant visits with Dr. Mercer, they did not point to any evidence that he treated her for an infection. Even if they had pointed to evidence that Dr. Mercer treated

Morgan for an infection, they did not point to any evidence of how a different warning regarding delayed onset ObTape-related infections would have affected his treatment of Morgan. Without such evidence, "the Court finds it highly unlikely that the Florida courts would presume causation under the circumstances of this case." *Id.* "Absent a presumption that relies on pure speculation, no reasonable juror could conclude based on the present record that any post-implant failure to warn caused any of [Morgan's] injuries." *Id.* For these reasons, Mentor is entitled to summary judgment on Plaintiffs' continuing duty to warn claims based on Mentor's alleged failure to provide adequate post-implant warnings to Morgan's physicians.

Plaintiffs also argue that they can assert a continuing duty to warn claim based on Mentor's failure to provide an adequate post-implant warning directly to Morgan. This argument fails for two reasons. First, under Florida's learned intermediary rule, Mentor's duty to warn was directed to Morgan's physicians and not to Morgan herself; Mentor did not have a duty to warn Morgan directly. *See Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009) (explaining Florida's learned intermediary rule). Second, though Plaintiffs speculate that Morgan might have been able to connect her infection symptoms to her ObTape and then might have sought more targeted treatment, Plaintiffs did not point to any

evidence of what Morgan actually would have done with a different post-implant warning. Thus, Mentor is entitled to summary judgment on Plaintiffs' continuing duty to warn claims based on Mentor's alleged failure to provide adequate post-implant warnings directly to Morgan.

#### CONCLUSION

As discussed above, the Court grants Mentor's summary judgment motion as to Plaintiffs' warranty claims and any claims based on Mentor's alleged breach of a post-sale duty to warn. Plaintiffs' other claims remain pending for trial.

This action is ready for trial. Within seven days of the date of this Order, the parties shall notify the Court whether they agree to a *Lexecon* waiver.

IT IS SO ORDERED, this 9th day of December, 2016.

s/Clay D. Land

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CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE  
MIDDLE DISTRICT OF GEORGIA