

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	*	4:13-cv-345 (Stewart)

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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. Plaintiff Paula Stewart was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Stewart brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Stewart also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor seeks summary judgment on several of Stewart's claims. For the reasons set forth below, Mentor's partial summary judgment motion (ECF No. 37 in 4:13-cv-345) 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

Stewart developed symptoms of stress urinary incontinence and discussed her treatment options with Dr. Christopher Minott. On August 17, 2004, Dr. Minott implanted Stewart with ObTape. Before the procedure, Dr. Minott discussed ObTape with Stewart, and Stewart reviewed a Mentor ObTape brochure with Dr. Minott. The brochure discusses serious complications that may occur with ObTape and states that the patient's doctor should discuss these matters with the patient. Stewart Dep. 202:14-203:6, ECF No. 38-3. Based on her discussion with Dr. Minott, Stewart was under the impression that any complications, such as infections and pain, would occur during the recovery period; she did not understand that these complications could occur after that. *Id.* at 206:9-207:9. Stewart was also under the impression based on her discussion with Dr. Minott and her review of the brochure that a revision surgery might be necessary, but only to tighten

or loosen the sling—not in the event of an erosion. *Id.* 202:19-203:24. Stewart testified that if Dr. Minott or the brochure had informed her of certain risks of ObTape—such as the risk of long-term painful intercourse and the risk of additional surgery years after the initial implant—she would not have undergone the ObTape procedure.

Stewart's incontinence improved for a while but recurred in 2006. Stewart asserts that she suffered adverse symptoms related to ObTape, including pelvic pain and dyspareunia. In 2008 and 2013, Stewart underwent procedures to remove portions of her ObTape, although she did not realize in 2008 that some of her ObTape had been removed. Stewart is a Nevada resident whose ObTape-related medical treatment occurred in Nevada.

Stewart asserts claims for strict liability (design defect, manufacturing defect, and failure to warn); negligence; breach of express warranty; breach of implied warranty; common law fraud; constructive fraud; and negligent and intentional misrepresentation. Mentor seeks summary judgment on Stewart's strict liability, fraud, and misrepresentation claims to the extent that they are based on Stewart's allegation that Mentor did not provide adequate or truthful warnings regarding ObTape.<sup>1</sup>

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<sup>1</sup> Stewart contends that her fraud and misrepresentation claims are different from her strict liability - failure to warn claim and that Mentor only seeks summary judgment on the strict liability claim. While these claims do have some different elements, Mentor's present argument is that Stewart cannot establish causation on any of these

Mentor also seeks summary judgment on Stewart's warranty claims. Stewart does not contest summary judgment on her warranty claims, so Mentor is entitled to summary judgment on those claims. The only issue remaining is whether Stewart presented enough evidence to create a genuine fact dispute on her failure to warn claims.

#### DISCUSSION

On July 12, 2013, Stewart served Mentor with a Complaint captioned in the Hennepin County District Court of the State of Minnesota. Mentor removed the action to the United States District Court for the District of Minnesota. The case was later transferred to this Court as part of a multidistrict litigation proceeding regarding ObTape. The parties agree for purposes of summary judgment that Minnesota law applies to Stewart's claims. See *Cline v. Mentor*, No. 4:10-cv-5060, 2013 WL 286276, at \*7 (M.D. Ga. Jan. 24, 2013) (concluding that Minnesota law applied to claims of non-Minnesota ObTape plaintiffs who brought their actions in Minnesota).

Stewart asserts that Mentor did not provide Dr. Minott accurate information with regard to ObTape's risks, including the true risks of complications like erosion, infection, and inadequate tissue ingrowth. "Under Minnesota law, a plaintiff

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claims. And causation for these claims rests on the same basic question: did Mentor's fraud, misrepresentations, or failure to warn regarding the true risks of ObTape cause Stewart's injuries?

claiming a failure to warn must show that the lack of an adequate warning caused plaintiff[']s injuries." *Prairie v. Mio Mech. Corp.*, No. 27-CV-12-14077, 2013 WL 3869264, at \*6 (Minn. Dist. Ct. June 25, 2013) (citing *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004)). "To establish causation, a plaintiff must show that a warning would have caused him to act in a way that would have avoided the injury." *Id.* Here, Stewart contends that Mentor, intending to defraud her and induce her to undergo the ObTape procedure, made misrepresentations to Dr. Minott that induced Dr. Minott to recommend ObTape to Stewart.

Stewart's implanting physician, Dr. Minott, died before he could testify in this action, and there is no direct evidence that different warnings would have changed how Dr. Minott treated Stewart. Stewart nonetheless contends that she can establish causation because Minnesota courts apply a "heeding presumption" - "a rebuttable presumption that the injured person would have heeded an adequate warning, had one been provided." *Prairie*, 2013 WL 3869264, at \*6. The Court previously considered this issue in *Bromley v. Mentor Corp.*, Case No. 4:13-cv-17, 2015 WL 7313394 (M.D. Ga. Nov. 19, 2015). The Court noted that "in *Prairie*, the Minnesota trial court presumed that a window washer who died after falling from the defendant's roof rigger platform product would have heeded an adequate

instruction regarding the proper way to secure the platform had one been given." *Id.* at \*6 (citing *Prairie*, 2013 WL 3869264 at \*6). But the Court found that "all *Prairie* allows the Court to presume is that Plaintiffs' physicians would have paid attention to an additional warning about the risks of ObTape." *Id.* "In other words, *Prairie* allows the Court to presume that the physicians would have considered the infection and erosion rates—among other considerations—in determining which product to select for their patients." *Id.* *Prairie* did "not, however, permit the Court to speculate about how the physicians would have weighed the additional warnings." *Id.*

Stewart did not point the Court to any authority suggesting that the Minnesota courts have expanded the heeding presumption since the Court decided this issue in *Bromley*. The Court again concludes that it cannot apply the heeding presumption here, where there is no evidence of how Dr. Minott would have weighed the additional warnings or the true complication rates had Mentor provided them. Thus, Stewart cannot establish causation for her failure to warn, fraud, and misrepresentation claims under the heeding presumption.

Stewart points out that Mentor provided some information about ObTape directly to consumers, including her, via a brochure that provides a short description of ObTape's potential complications and states that the patient's doctor should

discuss these matters with the patient. Stewart argues that the brochure did not adequately warn her about ObTape's true risks. But the record here reveals that Stewart did not rely solely on the brochure in deciding to undergo the ObTape procedure. Stewart reviewed the brochure *and* discussed it with Dr. Minott; her impressions about ObTape were based on Dr. Minott's explanation of the brochure and his description of the procedure and potential complications. As discussed above, there is no evidence of how Dr. Minott would have weighed the additional warnings or the true complication rates had Mentor provided them. There is also no evidence of how Dr. Minott might have approached his doctor-patient discussion of the brochure had he been given additional warnings about ObTape. Stewart thus cannot establish causation for her failure to warn, fraud, and misrepresentation claims based on the brochure.

#### CONCLUSION

For the reasons set forth above, the Court concludes that Stewart has not presented enough evidence to establish a genuine fact dispute on causation for her failure to warn, fraud, and misrepresentation claims. Mentor's Motion for Partial Summary Judgment (ECF No. 37 in 4:13-cv-345) is therefore granted. Mentor is entitled to judgment as a matter of law on Stewart's strict liability, fraud, and misrepresentation claims to the extent that they are based on Stewart's contention that Mentor

did not provide adequate or truthful warnings regarding ObTape. Mentor is also entitled to judgment as a matter of law on Stewart's warranty claims. Stewart's design defect, manufacturing defect, and negligence claims remain pending for trial.

This action is now 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 2nd day of September, 2016.

s/Clay D. Land

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CLAY D. LAND

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