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. 4:13-cv-229 (Burke)

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 Vivian Burke was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Burke brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Burke also asserts that Mentor did not adequately warn her physician about the risks associated with ObTape. Mentor seeks summary judgment on several of Burke's claims. For the reasons set forth below, Mentor's partial summary judgment motion (ECF No. 47 in 4:13-cv-229) 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 February 2, 2005, Dr. Bernhardt Rothschild implanted Burke with ObTape to treat her stress urinary incontinence. Burke did not review any materials from Mentor in deciding to undergo the sling procedure, and she did not speak to Mentor representatives about the procedure. Burke did speak with Dr. Rothschild before she decided to undergo the procedure. Burke contends that she suffered adverse symptoms related to her ObTape, including chronic vaginal pain. Her ObTape has never been removed, although Dr. E. Stanton Shoemaker did diagnose her with a small mesh extrusion in 2012. Burke is a Texas resident, and her ObTape related medical treatment occurred in Texas.

In her Complaint, Burke asserted the following Counts: I - negligence; II - strict liability – design defect; III - strict liability – manufacturing defect; IV - strict liability – failure to warn; V - strict liability – defective product; VI -

breach of express warranty; VII - breach of implied warranty; VIII - fraudulent concealment; IX - constructive fraud; X - discovery rule, tolling and fraudulent concealment; XI - negligent misrepresentation; XII - negligent infliction of emotional distress; XIII - violation of consumer protection laws; XIV - gross negligence; XV - unjust enrichment; and XVII - punitive damages. Mentor seeks summary judgment on all Counts except for counts I, II, III, XIV, and XVII. Burke does not oppose summary judgment as to Counts V, VI, VII, VIII, IX, X, XI, XII, XIII, and XV. Mentor is therefore entitled to summary judgment on those claims. The only issue remaining is whether Burke presented enough evidence to create a genuine fact dispute on Count IV, Burke's strict liability – failure to warn claim.

DISCUSSION

Burke filed this action on June 4, 2013 by filing a short form complaint in *In Re: Coloplast Corp. Pelvic Support System Products Liability Litigation*, MDL No. 2387. In that Complaint, Burke stated that the proper venue for her action is the U.S. District Court for the Southern District of Texas. Compl. ¶ 5, ECF No. 1 in 4:13-cv-229. The Judicial Panel on Multidistrict Litigation transferred the action to this Court for pretrial proceedings. The parties agree that Texas law applies to Burke's claims because Burke is a Texas resident and all of her ObTape-related medical treatment took place in Texas.

Burke asserts that Mentor did not provide Dr. Rothschild accurate information regarding ObTape's risks, including the true risks of complications like erosion, infection, and inadequate tissue ingrowth. Under Texas law, the learned intermediary doctrine requires a prescription medical device manufacturer to provide an adequate warning about the device's risks to the prescribing physician and not to the patient directly. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012) (holding "that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly").

To establish her failure to warn claim, Burke must show that Mentor did not adequately warn Dr. Rothschild about the true risks of ObTape and that the inadequate warning caused Burke's injuries. *See id.* at 170 (explaining causation requirements). In other words, Burke must show that her prescribing physician "would have acted differently had [Mentor] provided a different warning" about ObTape. *Id.* at 171; *accord Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) ("[T]he plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have

not used or prescribed the product." (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)); *McNeil v. Wyeth*, 462 F.3d 364, 372 (5th Cir. 2006) ("Under Texas law, a plaintiff who complains 'that a prescription drug warning is inadequate must also show that the alleged inadequacy caused her doctor to prescribe the drug for her.'" (quoting *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999)).

Burke's implanting physician, Dr. Rothschild, died before he could testify in this action, and there is no direct evidence that different warnings would have changed how Dr. Rothschild treated Burke. Burke tries to establish causation in two other ways. First, Burke argues that if Dr. Rothschild had been provided with additional information about ObTape's risks, then Dr. Rothschild likely would have told Burke about those risks. In support of this assertion, Burke argues that a "read and heed" presumption applies here; under this presumption, causation may be established "by the rebuttable presumption that the user would have read and heeded the warnings had they been given." *Guzman v. Synthes (USA)*, 20 S.W.3d 717, 720 (Tex. App. 1999). The Fifth Circuit Court of Appeals has expressed doubt that Texas courts would hold that this presumption applies in cases involving prescription drugs or devices. *Ackermann*, 526 F.3d at 212 (noting that "neither Texas nor federal courts applying Texas law have applied the read-and-heed presumption to

pharmaceutical cases involving learned intermediaries"). In *Guzman*, the Court of Appeals of Texas did address the "read and heed" presumption in the context of a medical device case where there was undisputed evidence that the doctor would not have changed his treatment if he had been given a different warning; the court concluded that the "read and heed" presumption could not establish causation in such a case. *Guzman*, 20 S.W.3d at 720. The *Guzman* court did not *hold* that the "read and heed" presumption can establish causation in medical device cases.

Even if the "read and heed" presumption does apply in the medical device context, it would simply permit the Court to presume that Dr. Rothschild would have considered ObTape's tissue ingrowth risks and the infection and erosion rates—among other considerations—in determining which product to select for Burke. The presumption does not, however, permit the Court to speculate about how Dr. Rothschild would have weighed the additional warnings. To fill the gap, Burke points to the expert report of Dr. Bruce Rosenzweig, who opines that: (1) Dr. Rothschild likely did not know that ObTape had certain risks that were not disclosed in the product insert data sheet and (2) a reasonable physician in Dr. Rothschild's position would have told his patients about all of these additional risks had he known of them.

Burke did not point to any Texas authority to establish that she can rely on Dr. Rosenzweig's opinion to establish that Dr. Rothschild would have given her different warnings. The cases Burke cited in support of her contention that Dr. Rosenzweig's affidavit establishes causation do not explicitly state that a plaintiff may rely on evidence of what *other* doctors might have done to establish that a different warning to the *plaintiff's* doctor would have made a difference. In *McNeil*, for example, there was a fact question on causation because the *plaintiff's own doctor* testified that he would have alerted the plaintiff to the significant risks associated with a drug had he known of them. 462 F.3d at 372. The Court is aware that in *Centocor*, the Supreme Court of Texas noted in dicta that the plaintiffs had not only failed to point to "subjective evidence, but they presented no objective evidence that a different warning would have affected the decision of a reasonable doctor to prescribe [the drug] for [the plaintiff's] condition." *Centocor,* 372 S.W.3d at 171. But the *Centocor* court's *holding* was based on the plaintiff's failure to present evidence that a different warning would have caused the *plaintiff's own doctors* to stop prescribing the drug. *Id.* at 172-73.

Even if Burke could rely on Dr. Rosenzweig's opinion to establish that Dr. Rothschild would have given her different warnings had he known of them, she did not point to any evidence

of what she would have done differently if she had been given a different warning. In her response brief, Burke stated that she would have declined ObTape if Dr. Rothschild had given her accurate complication rates for ObTape. Pl.'s Br. in Resp. to Def.'s Mot. for Summ. J. 9, ECF No. 49 in 4:13-cv-229. In support of this statement, Burke cites Dr. Rosenzweig's opinion that a reasonable physician in Dr. Rothschild's position would have passed all warnings to his patients. But the cited material does not establish what *Burke* would have done differently had she received a different warning from Dr. Rothschild, and Burke did not point to any evidence of how she would have weighed an additional warning. Thus, Burke failed to establish that a different warning from Dr. Rothschild would have resulted in a different outcome.

Burke asserts that even if she cannot establish that a different warning from Dr. Rothschild would have changed her outcome, she can establish causation based on Dr. Rosenzweig's opinion that Dr. Rothschild "[m]ore likely than not . . . would have altered his clinical practice in treating [stress urinary incontinence]" if he had received additional warnings about ObTape "in that he would have not offered [ObTape] as option to Ms. Burke, would have offered additional options to Ms. Burke and/or would have relayed additional safety information from Mentor to Ms. Burke." Rosenzweig Aff. ¶ 8, ECF No. 49-6 in

4:13-cv-229. Burke did not point to any Texas authority suggesting that she may establish causation by having an expert opine about what her doctor might have done with different warnings. Even if she had, Dr. Rosenzweig's affidavit does not explain how he reached this conclusion. Dr. Rosenzweig cannot offer an expert opinion unless it is based on "sufficient facts or data," Fed. R. Evid. 702(b), and Burke did not point to anything in the present record to suggest that Dr. Rosenzweig's opinion on this point is supported by any facts or data about Dr. Rothschild's practices, including how Dr. Rothschild evaluated the risks and benefits of the products he implanted in his patients. For all of these reasons, the Court finds that Dr. Rosenzweig's affidavit does not establish causation on Burke's failure to warn claim. Burke did not point to any other evidence of causation, so Mentor is entitled to summary judgment on this claim.

CONCLUSION

For the reasons set forth above, Mentor's Motion for Partial Summary Judgment (ECF No. 47 in 4:13-cv-229) is granted. Mentor is entitled to judgment as a matter of law on the following counts: IV - strict liability – failure to warn; V - strict liability – defective product; VI - breach of express warranty; VII - breach of implied warranty; VIII - fraudulent concealment; IX - constructive fraud; X - discovery rule,

tolling and fraudulent concealment; XI - negligent misrepresentation; XII - negligent infliction of emotional distress; XIII - violation of consumer protection laws; and XV - unjust enrichment. The following counts remain pending: I - negligence; II - strict liability – design defect; III - strict liability – manufacturing defect; XIV - gross negligence; and XVII - punitive damages.

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
CLAY D. LAND
CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA