

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 Nos. 4:12-cv-115 (Hale)

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 Betty Hale was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Hale brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Hale also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor seeks summary judgment on several of Hale's claims. For the reasons set forth below, Mentor's partial summary judgment motion (ECF No. 64 in 4:12-cv-115) is granted in part and denied in part.

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

In 2005, Plaintiff Betty Hale visited Dr. Paul Marsidi for treatment of stress urinary incontinence. Dr. Marsidi recommended ObTape, and he implanted Hale with ObTape on March 21, 2005. If Dr. Marsidi had known that ObTape had a higher rate of complications than other sling products, he would not have implanted it in Hale. Marsidi Dep. 168:1-169:10, ECF No. 65-3 in 4:12-cv-115.

The ObTape helped with Hale's incontinence for a while. Two or three years ago, Hale began experiencing pelvic pain. In 2014, Hale went to Dr. Brent Zamzow and asked him to remove her ObTape. Dr. Zamzow removed Hale's ObTape on August 7, 2014. Hale continues to experience pelvic pain.

Hale is a Tennessee resident whose ObTape-related treatment took place in Tennessee. She filed her action in this Court

pursuant to the Court's direct filing order on June 1, 2012, asserting claims for strict liability, negligence, strict liability - failure to warn, breach of implied warranty, breach of express warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

DISCUSSION

Hale filed her action in this Court 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. Hale is a Tennessee resident whose ObTape-related treatment took place in Tennessee, and the parties agree that Tennessee law applies to her claims.

Mentor seeks summary judgment on Hale's claims for breach of warranty, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and breach of the continuing duty to warn. Hale does not contest Mentor's summary judgment motion as to her warranty claims and her negligent misrepresentation claim. Summary judgment is therefore granted as to those claims. The Court will evaluate Mentor's remaining summary judgment arguments in turn.

I. Fraudulent Concealment

Mentor argues that Hale cannot establish her fraudulent concealment claim because Tennessee law does not recognize a tort claim for fraudulent concealment under the circumstances of this case. "The tort of fraudulent concealment is committed when a party who has a duty to disclose a known fact or condition fails to do so, and another party reasonably relies upon the resulting misrepresentation, thereby suffering injury." *Chrisman v. Hill Home Dev., Inc.*, 978 S.W.2d 535, 538-39 (Tenn. 1998) (evaluating fraudulent concealment in the context of homeowners' claim against the developer who constructed their home). Citing *Shah v. Racetrac Petroleum Co.*, 338 F.3d 557, 571 (6th Cir. 2003), a case involving a gas station lease agreement gone awry, Mentor argues that it had no duty to disclose the risks of ObTape because there was no fiduciary relationship between Mentor and Hale.

One line of Tennessee cases states that a duty to disclose only arises between parties to a contract if there is a fiduciary relationship (or similar relationship of trust) between the parties. See, e.g., *Domestic Sewing Mach. Co. v. Jackson*, 83 Tenn. 418, 425 (1885). Another line of Tennessee cases has a broader view on the duty to disclose: "each party to a contract is bound to disclose to the other all he may know respecting the subject matter materially affecting a correct

view of it, unless common observation would have furnished the information." *Simmons v. Evans*, 206 S.W.2d 295, 296 (Tenn. 1947). For example, a home seller has a duty to disclose to a buyer "'a fact of controlling importance in determining the desirability and value of that residence' that would not be apparent to the buyer through the exercise of ordinary diligence.'" *Patel v. Bayliff*, 121 S.W.3d 347, 353 (Tenn. Ct. App. 2003) (quoting *Simmons*, 206 S.W.2d at 296). Likewise, a car dealer must disclose material facts about the car it sells to a buyer. *Garrett v. Mazda Motors of Am.*, 844 S.W.2d 178, 181 (Tenn. Ct. App. 1992); accord *Bradley v. All Am. Classics Of Tennessee, Inc.*, No. M200801738COAR3CV, 2009 WL 1034797, at *4 (Tenn. Ct. App. Apr. 16, 2009) (noting that this concept goes back to the Tennessee Supreme Court's 1813 decision in *Perkins v. McGavock*, 3 Tenn. 415, 417 (1813) ("Not disclosing facts within the knowledge of one and not the other, would in equity be deemed a concealment which is both immoral and unjust."). In *Shah*, the Sixth Circuit acknowledged the *Simmons* line of cases but "decline[d] to anticipate that the Tennessee Supreme Court would" find a duty to disclose in "the context of a franchise dispute." *Shah*, 338 F.3d at 572 n.9.

This case is not like *Shah*, where there was no established duty to disclose. As the Tennessee Supreme Court observed, "[m]anufacturers of prescription drugs, like the manufacturers

of any other unavoidably dangerous product, have a duty to market and distribute their products in a way that minimizes the risk or danger." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428 (Tenn. 1994). Manufacturers "may discharge their duty by distributing the drugs with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products." *Id.* While Mentor may "reasonably rely on intermediaries to transmit [its] warnings and instructions," Mentor still must provide those sufficient warnings to the learned intermediary. *Id.* The Court thus rejects Mentor's argument that Mentor had no duty to disclose the risks of ObTape to Hale's physician.

As far as the Court can tell, the Tennessee courts have not yet decided whether a patient may pursue a fraudulent concealment claim based on a prescription medical device manufacturer's fraudulent concealment of material facts from the patient's physician. A U.S. District Court applying Tennessee law has recognized such a claim given the well-settled obligation of a pharmaceutical company "to advise the prescribing physician of any potential dangers that may result from" use of the company's drug. *Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735, 753 (M.D. Tenn. 2010) (quoting *Laws v. Johnson*, 799 S.W.2d 249, 253 (Tenn. Ct. App. 1990)). The Court agrees with the rationale of *Smith*. Since Hale presented evidence that

Dr. Marsidi would not have implanted her with ObTape had he known its true risks, which Hale contends Mentor intentionally concealed from him, the Court denies Mentor's summary judgment motion as to Hale's fraudulent concealment claim.

II. Fraudulent Misrepresentation

Mentor contends that Hale cannot make out her fraudulent misrepresentation claim because Mentor did not make any misrepresentations regarding ObTape directly to her and because she did not rely on any misrepresentations from Mentor regarding ObTape. In other words, Mentor argues that Hale has not presented sufficient evidence of reliance and causation. *See, e.g., Hodge v. Craig*, 382 S.W.3d 325, 343 (Tenn. 2012) (noting that "intentional misrepresentation" claim requires an intentional false representation about a material fact, justifiable reliance, and damages as a result of the reliance on the false representation).

As discussed above, Mentor had a duty to distribute ObTape "with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products." *Pittman*, 890 S.W.2d at 428. And, if Mentor wanted to rely on learned intermediaries like Dr. Marsidi to transmit its warnings to patients like Hale, then Mentor was required to provide sufficient warnings to the learned intermediary. *Id.*

Mentor appears to argue that Tennessee does not recognize a fraudulent misrepresentation claim based on a prescription medical device manufacturer's misrepresentation to a patient's physician, even if the patient relies on the misrepresentation that is communicated through the physician. In support of this argument, Mentor cites *Carter v. Danek Medical, Inc.*, No. CIV. 96-3243-G, 1999 WL 33537317 (W.D. Tenn. June 3, 1999) and *Zobrist v. Sofamor, S.N.C.*, No. 95-2542, 1999 WL 33537316 (W.D. Tenn. May 12, 1999), both of which stand for the proposition that Tennessee does not recognize a fraudulent misrepresentation claim based on a medical device manufacturer's misrepresentations to the FDA. Here, Hale contends that Mentor, intending to defraud her and induce her to undergo the ObTape procedure, made misrepresentations to her physician that induced him to recommend ObTape to her. Hale presented evidence that she relied on Dr. Marsidi in deciding to proceed with the ObTape procedure. And she pointed to evidence that Dr. Marsidi would not have implanted her with ObTape had he known its true risks. Thus, the Court is satisfied that a genuine fact dispute exists on the justifiable reliance and causation elements of Hale's fraudulent misrepresentation claims, and Mentor is not entitled to summary judgment on that claim.

III. Continuing Duty to Warn

Mentor also seeks summary judgment on Hale's continuing duty to warn claim. As Hale acknowledges, Tennessee law requires "evidence that a warning would have altered the doctor's actions and that the change in the doctor's actions would have averted the patient's injury." *Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 531-32 (6th Cir. 2014). There is a genuine fact dispute on Hale's pre-implant failure to warn claim because Hale presented evidence that Dr. Marsidi would not have implanted her with ObTape had he known its true risks. But Hale did not point to any evidence that her post-implant medical care would have changed or that her injuries would have been different if Mentor had provided additional post-sale warnings. Hale did not point to any evidence that she sought medical care for complications that might have been diagnosed as ObTape complications. Rather, the only evidence the parties pointed to regarding Hale's post-implant medical care is that Hale asked Dr. Zamzow to remove the ObTape after she filed this action. Without any evidence to create a genuine fact dispute on causation, Hale's continuing duty to warn claim fails.

CONCLUSION

Mentor's motion for partial summary judgment (ECF No. 64 in 4:12-cv-115) is granted as to Hale's breach of warranty, negligent misrepresentation, and continuing duty to warn claims.

Mentor's summary judgment motion is denied as to Hale's claims for fraudulent concealment and fraudulent misrepresentation. Those claims, along with her claims for strict liability, negligence, and strict liability - failure to warn, remain pending for trial.

Within seven days of the date of this Order, the parties shall notify the Court whether the parties agree to a Lexecon waiver.

IT IS SO ORDERED, this 25th day of February, 2016.

s/Clay D. Land

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