

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 Nos.
LIABILITY LITIGATION	* 4:13-cv-335 (Davis)

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 Patricia Davis was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Mrs. Davis brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Mrs. Davis also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Her husband Patrick brought a loss of consortium claim. Mentor seeks summary judgment on all of Plaintiffs' claims. As discussed below, Mentor's summary judgment motion (ECF No. 40 in 4:13-cv-335) 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

Plaintiff Patricia Davis was diagnosed with stress urinary incontinence. On October 10, 2005, Dr. Michael Stever implanted Mrs. Davis with ObTape to treat her stress urinary incontinence. Before Dr. Stever implanted Mrs. Davis with ObTape, he reviewed the product insert data sheet for ObTape, which disclosed certain risks associated with the product. Stever Dep. 182:14-23, ECF No. 42-4 in 4:13-cv-335. Dr. Stever also testified that he probably spoke with a Mentor representative regarding the risks of ObTape. *Id.* at 155:10-19.

After Dr. Stever implanted Mrs. Davis with ObTape, he became aware of certain complications related to ObTape, including frequency of infections and other symptoms. *Id.* at 164:9-165:22. Dr. Stever testified that he would "like to know" such information and that it would have been a factor in his

decision to use ObTape in Mrs. Davis. *Id.* at 165:19-166:2. Had someone from Mentor told Dr. Stever about these issues with ObTape, he "possibly" would have considered using a different product for Mrs. Davis. *Id.* at 166:16-20. And, had someone from Mentor told Dr. Stever about these issues, he would have passed that information along to Mrs. Davis. *Id.* at 166:3-15. If Dr. Stever had told Mrs. Davis about these potential complications, she would not have gone forward with the ObTape implant. Davis Dep. 132:20-133:20, ECF No. 42-5.

After the ObTape implant, Mrs. Davis experienced chronic urinary tract infections, dysuria (pain while urinating), chronic genitourinary pain, and other symptoms; she sought treatment from a number of doctors for these symptoms. She also experienced incomplete emptying of her bladder and was told that her ObTape had not been tensioned properly. Mrs. Davis underwent several procedures to treat her symptoms, including partial excision of her ObTape in 2008. A pathologist analyzed the excised ObTape and diagnosed "foreign body giant cell reaction." Cook Decl. Ex. T, Surgical Pathology Report (Jan. 30, 2008), ECF No. 42-22 in 4:13-cv-335. After that procedure, Mrs. Davis underwent several other procedures to address her symptoms.

Dr. Andrew Siegel, a board certified urologist who is Mrs. Davis's general causation expert, opined that the physical

properties of ObTape can prevent tissue ingrowth and can cause chronic inflammation. Cook Decl. Ex. V, Siegel Report 4, ECF No. 42-24 in 4:13-cv-335. Dr. Siegel also opined that the physical properties of ObTape can cause pain and organ dysfunction. *Id.* Dr. Amanda White, a board certified urogynecologist who is Mrs. Davis's specific causation expert, also opined that ObTape's physical properties rendered it "prone to infection and extrusion." Cook Decl. Ex. A, White Report 4, ECF No. 42-3 in 4:13-cv-335.

Dr. White reviewed Mrs. Davis's medical records. She also relied on her extensive experience with urethral slings. Based on her review, Dr. White concluded that "Mentor ObTape is a substantial contributing cause of Ms. Davis's chronic bladder symptoms, including recurrent urinary tract infections, incomplete emptying, pelvic pain, vaginal pain, dyspareunia, and need for subsequent surgeries and treatments." White Report 7. She also opined that Mrs. Davis's "recurrent urinary tract infections were likely caused by the material properties of the ObTape device." *Id.* at 8. Finally, she opined that "[t]he material properties of the ObTape transobturator sling, namely unwoven, thermally bonded polypropylene microporous mesh are such that tissue in-growth with capillary penetration is prohibited. While bacteria are able to enter the graft, host defense mechanisms are unable to respond within the device

secondary to the size of leukocytes and macrophages. The result is an encapsulated graft with acute and chronic inflammation." *Id.*

In addition to Dr. White's opinion, Mrs. Davis relies on the expert opinion of Dr. Kimberly Allison, a board certified pathologist who is an Associate Professor of Pathology at Stanford University Medical Center. Dr. Allison reviewed the pathology slides and pathology report from Mrs. Davis's January 2008 ObTape partial excision. Dr. Allison observed "mild chronic inflammation in the mucosa and foreign body giant cell reaction to the mesh fibers." Cook Decl. Ex. W, Dr. Allison Report 8, ECF No. 42-25 in 4:13-cv-335. She also noted that "[d]ense scar was present around and in between the mesh fibers" and that "[t]here was evidence of mesh degradation (treebarking)." *Id.*

Mrs. Davis asserts claims for negligence, strict liability design defect, strict liability failure to warn, breach of warranties, unjust enrichment, fraud, and negligent misrepresentation. Mr. Davis asserts a loss of consortium claim. Mentor seeks summary judgment on all of these claims. Mrs. Davis does not challenge Mentor's summary judgment motion on her warranty and unjust enrichment claims, so the Court grants Mentor's summary judgment motion as to those claims.

DISCUSSION

Plaintiffs filed this action on July 9, 2013 in the United States District Court for the District of Minnesota. The case was 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 Mrs. Davis's claims. See *Cline v. Mentor Corp.*, 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).

I. Design Defect Claims

Mrs. Davis brings design defect claims under negligence and strict liability theories. She asserts that ObTape had a design defect that caused her injuries. Mentor argues that these claims fail for lack of causation. The Court disagrees.

First, Mentor contends that Mrs. Davis did not point to any evidence to establish general causation: that ObTape is capable of causing the types of injuries Mrs. Davis suffered. But Dr. Siegel testified that the physical properties of ObTape can prevent tissue ingrowth and can cause chronic inflammation. Siegel Report 4. He also opined that the physical properties of ObTape can cause pain and organ dysfunction. *Id.* And Dr. White opined that ObTape's physical properties rendered it "prone to infection and extrusion." White Report 4. Mrs. Davis asserts

that she suffered chronic infections and pain, along with other symptoms. Drs. Siegel and White opine that ObTape is capable of causing these types of injuries, so the Court is satisfied that the evidence from Drs. Siegel and White is sufficient to create a genuine fact dispute on general causation.

Second, Mentor asserts that Mrs. Davis did not point to sufficient evidence to establish specific causation: that ObTape actually caused Mrs. Davis's injuries. Again, Dr. White opined that based on her review of Mrs. Davis's medical records, ObTape more likely than not was a substantial contributing cause of Mrs. Davis's injuries, including her recurrent urinary tract infections and pelvic pain. Dr. White further opined that the material properties of ObTape inhibited tissue ingrowth and permitted bacteria to enter the graft while preventing defense mechanisms like leukocytes and macrophages from responding—leading to Mrs. Davis's injuries. Mentor contends that because Mrs. Davis's treating physicians did not diagnose her with poor tissue ingrowth, the Court should ignore Dr. White's opinion. But based on the present record, including Dr. Allison's pathology analysis finding inflammation and foreign body giant cell reaction in Mrs. Davis's excised ObTape, the Court finds that Mrs. Davis has submitted evidence sufficient to create a genuine fact dispute on specific causation. For these reasons, Mentor's summary judgment motion as to Mrs. Davis's design

defect claims is denied. Mentor's motion as to Mr. Davis's derivative loss of consortium claim is likewise denied.

II. Failure To Warn, Fraud, and Misrepresentation Claims

Mrs. Davis brings failure to warn claims under a strict liability theory, contending that Mentor did not adequately warn her physicians about the true risks of ObTape. Mrs. Davis also brings fraud and negligent misrepresentation claims, asserting that Mentor made fraudulent and negligent misrepresentations to her physicians about the risks of ObTape. Mentor argues that Mrs. Davis has not presented enough evidence to create a genuine fact dispute on causation for these claims.

Under Minnesota law, a plaintiff claiming a failure to warn must show that "the lack of an adequate warning caused the plaintiff's injuries." *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004) (applying Minnesota law). Thus, to establish causation on her failure to warn, fraud, and misrepresentation claims under Minnesota law, Cole must establish that a different warning or an accurate disclosure of the risks of ObTape would have made a difference in her treatment. There must be some evidence that the product user (or, in cases like this one where the learned intermediary doctrine applies, the product user's doctor) "would have acted differently had the manufacturers provided adequate warnings." *Id.*

Mrs. Davis pointed to evidence that Dr. Stever read the ObTape product data insert sheet before using ObTape. She also pointed to evidence suggesting that Dr. Stever relied on the representations of a Mentor representative when he began using ObTape. Mrs. Davis further pointed to evidence that if Dr. Stever had received information from Mentor regarding the true risks of ObTape—including information about complications related to ObTape—he possibly would have selected a different product for Mrs. Davis. And Mrs. Davis pointed to evidence that if Dr. Stever had received information regarding the true risks of ObTape, he would have passed that information to her and she would have declined to proceed with the ObTape implant. Based on this evidence, the Court is satisfied that there is a genuine fact dispute on causation for Mrs. Davis's failure to warn, fraud, and misrepresentation claims. Mentor is therefore not entitled to summary judgment on these claims.¹

CONCLUSION

As discussed above, Mentor's summary judgment motion (ECF No. 40 in 4:13-cv-335) is granted as to Mrs. Davis's warranty and unjust enrichment claims, as well any claims Mrs. Davis

¹ Mrs. Davis focuses on her argument that a different pre-implant warning would have made a difference. She did not respond to Mentor's summary judgment motion as to her continuing duty to warn claim or point to any evidence to support such a claim, such as evidence that her post-implant treatment would have been different had her doctors received different post-implant information from Mentor. Thus, if Mrs. Davis did assert a continuing duty to warn claim, Mentor is entitled to summary judgment on it.

asserted under a continuing duty to warn theory. Mentor's motion is denied as to Mrs. Davis's design defect claims and her failure to warn, fraud, and misrepresentation claims based on pre-implant warnings and representations. And Mentor's motion is denied as to Mr. Davis's loss of consortium claim.

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 28th day of November, 2016.

S/Clay D. Land

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