

**IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF ARKANSAS  
CENTRAL DIVISION**

**DANA MEADE, *et al.***

**PLAINTIFF**

**v.**

**Case No. 4:20-cv-00694-KGB**

**ETHICON, INC., *et al.***

**DEFENDANTS**

**MEMORANDUM OPINION AND ORDER**

Before the Court is a supplemental motion for partial summary judgment filed by defendants Ethicon, Inc. and Johnson & Johnson (collectively “defendants”) (Dkt. No. 97). Defendants filed a supplemental statement of undisputed material facts and brief in support of their supplemental motion for partial summary judgment (Dkt. Nos. 98, 99). Plaintiffs Dana Meade and Glen Meade filed a response to defendants’ supplemental motion for partial summary judgment (Dkt. No. 100), and defendants filed a reply to the response (Dkt. No. 101). For the following reasons, the Court grants defendants’ supplemental motion for partial summary judgment and dismisses plaintiffs’ failure to warn claims in Count I and Count III of the complaint (Dkt. Nos. 1, 98).

**I. Background**

**A. Procedural History**

Plaintiffs filed suit in this case against defendants on September 27, 2013 (Dkt. No. 1). This case was originally filed in the United States District Court for the Southern District of West Virginia and was related to Multi-District Litigation 2327 (“Ethicon MDL”), 2:12-md-2327, one of seven MDLs assigned to United States District Judge Joseph R. Goodwin by the Judicial Panel on Multidistrict Litigation and totaling over 100,000 cases since inception (Dkt. Nos. 1; 48, at 1; 49-1). The Ethicon MDL includes as plaintiffs women who had one or more of defendants’ pelvic

mesh products inserted into their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence (Dkt. No. 49-1, ¶ 1). Plaintiffs to the Ethicon MDL also include the spouses and intimate partners of the aforesaid women, as well as others with standing to file claims arising from defendants' products (*Id.*, ¶ 2). Plaintiffs filed suit directly in the Ethicon MDL on September 27, 2013, but served Ethicon on June 7, 2013, pursuant to a delayed filing agreement (Dkt. Nos. 1; 2). On May 14, 2020, Judge Goodwin entered a transfer order transferring 35 cases from the Ethicon MDL to various appropriate jurisdictions (Dkt. No. 48). Judge Goodwin concluded that transferring these 35 cases to the venues from which they arose would better convenience the parties and promote the final resolution of these cases (*Id.*, at 1). As a result, Judge Goodwin transferred the Meades' case to this Court (*Id.*, at 4).

On November 2, 2020, the Court granted defendants' motion for partial summary judgment on the following claims: Count I – Negligence (to the extent based on negligent manufacturing defect); Count II – Strict Liability – Manufacturing Defect; Count IV – Strict Liability – Defective Product; Count VI – Common Law Fraud; Count VII – Fraudulent Concealment; Count VIII – Constructive Fraud; Count IX – Negligent Misrepresentation; Count X – Negligent Infliction of Emotional Distress; Count XI – Breach of Express Warranty; Count XII – Breach of Implied Warranty; Count XIII – Violation of Consumer Protection Laws; Count XIV – Gross Negligence; and Count XV – Unjust Enrichment (Dkt. No. 95, at 6-7). In the same Order, the Court granted defendants' motion for leave to file the supplemental motion for partial summary judgment currently before the Court (*Id.*, at 7).

The remaining claims in this case are plaintiffs' negligence claim based on design defect and failure to warn (Count I), plaintiffs' strict liability failure to warn claim (Count III), plaintiffs'

strict liability design defect claim (Count V), plaintiffs' punitive damages claim (Count XVII) and plaintiffs' "discovery rule and tolling" claim (Count XVIII) (Dkt. No. 1, ¶ 13).<sup>1</sup>

### **B. Factual Background**

Ms. Meade had a pelvic mesh product called a TVT-Obturator ("TVT-O") implanted on August 14, 2012, to treat stress urinary incontinence, cystocele, and rectocele by Charles McKnight, M.D., in Little Rock, Arkansas (Dkt. Nos. 1, ¶¶ 8-12; 35-1, at 4). Ms. Meade had the TVT-O partially removed on November 27, 2012, by Robert Summit, M.D., at Baptist Memorial Hospital for Women in Memphis, Tennessee, and Ms. Meade had an additional portion of the TVT-O removed on November 7, 2014, by Dionysios Veronikis, M.D., at Mercy Hospital St. Louis (Dkt. No. 35-1, at 5). Plaintiffs allege that Ms. Meade suffered a variety of bodily injuries resulting from the implantation of the TVT-O, including: exposed sling mesh; pelvic pain; vaginal mesh erosion; dyspareunia; bladder lesion; bladder mesh erosion; infection; urinary urgency/frequency; recurrent incontinence; bowel problems; organ perforation; fistulae; bleeding; neuromuscular problems; vaginal scarring; hematuria; bladder spasms; dysuria; urinary tract infection; and cystitis (*Id.*). Plaintiffs claim that Ms. Meade started experiencing symptoms attributable to the TVT-O in August 2012, but Ms. Meade did not associate those symptoms with the TVT-O until November 2012 (*Id.*, at 6).

Ms. Meade testified that she did not see any brochures related to the TVT-O prior to implantation (Dkt. No. 36, at 2). Ms. Meade also testified that she did not rely on any statements

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<sup>1</sup> Defendants mention in a footnote that the Court should dismiss plaintiffs' causes of action for punitive damages and discovery rule and tolling because they are not "recognized causes of action, but instead, legal theories." (Dkt. No. 99, n.1). Plaintiffs assert in their brief that defendants, while mentioning that the Court should dismiss the claims in a footnote, do not provide any argument or legal support for their assertion (Dkt. No. 100, at 9). Because defendants have not moved formally for summary judgment on these claims or briefed fully the issues, the Court will not rule on whether these claims should be dismissed at this stage.

or representations from Ethicon about the TVT-O before consenting to the implantation procedure (*Id.*, at 2-3). Ms. Meade testified that she consented to the procedure based on her trust in Dr. McKnight (*Id.*, at 3). Ms. Meade testified that she was unaware that Ethicon was the manufacturer of her TVT-O device prior to the implantation procedure (Dkt. No. 36, at 3). Ms. Meade did not depose Dr. McKnight prior to the close of discovery in the MDL, and Dr. McKnight died on June 6, 2018 (Dkt. No. 98, ¶ 2).

Plaintiffs were residents of Arkansas at the time of Ms. Meade's implantation surgery and remained residents through July 2013 (*Id.*). Plaintiffs subsequently moved to Punta Gorda, Florida, from July 2013 through August 2014 (*Id.*). In August 2014, plaintiffs moved to Heber Springs, Arkansas (*Id.*). Ms. Meade separated from Mr. Meade in March 2015, and the two subsequently divorced (*Id.*). Ms. Meade moved to Florence, Alabama, in March 2015, and Ms. Meade moved again to Highlands, California, in March 2016 (*Id.*).

## II. Legal Standard

Summary judgment is proper if there is no genuine issue of material fact for trial. *UnitedHealth Group Inc. v. Executive Risk Specialty Ins. Co.*, 870 F.3d 856, 861 (8th Cir. 2017) (citing Fed. R. Civ. P. 56). Summary judgment is proper if the evidence, when viewed in the light most favorable to the nonmoving party, shows that there is no genuine issue of material fact and that the defendant is entitled to entry of judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "In ruling on a motion for summary judgment '[t]he district court must base the determination regarding the presence or absence of a material issue of factual dispute on evidence that will be admissible at trial.'" *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 923 (8th Cir. 2004) (internal citations omitted). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Johnson Regional*

*Medical Ctr. v. Halterman*, 867 F.3d 1013, 1016 (8th Cir. 2017) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). A factual dispute is genuine if the evidence could cause a reasonable jury to return a verdict for either party. *Miner v. Local 373*, 513 F.3d 854, 860 (8th Cir. 2008). “The mere existence of a factual dispute is insufficient alone to bar summary judgment; rather, the dispute must be outcome determinative under the prevailing law.” *Holloway v. Pigman*, 884 F.2d 365, 366 (8th Cir. 1989).

However, parties opposing a summary judgment motion may not rest merely upon the allegations in their pleadings. *Buford v. Tremayne*, 747 F.2d 445, 447 (8th Cir. 1984). The initial burden is on the moving party to demonstrate the absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. The burden then shifts to the nonmoving party to establish that there is a genuine issue to be determined at trial. *Prudential Ins. Co. v. Hinkel*, 121 F.3d 364, 366 (8th Cir. 2008), *cert. denied*, 522 U.S. 1048 (1998). “The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

### **III. Motion For Partial Summary Judgment**

In their supplemental motion for partial summary judgment, defendants argue that plaintiffs’ failure to warn claims should be dismissed (Dkt. No. 97). Defendants contend that, as a matter of law, plaintiffs cannot establish their failure to warn claims, because Ms. Meade’s implanting surgeon, Dr. McKnight, is deceased and Ms. Meade did not procure testimony from him before he died (*Id.*, ¶ 4). Defendants maintain, therefore, that plaintiffs cannot show that any alleged deficiencies in their warnings proximately caused Ms. Meade to sustain any harm (*Id.*).

In order to succeed on a failure to warn claim under Arkansas law, Ms. Meade must show: (1) she has sustained damages; (2) defendants were engaged in the business of manufacturing or

assembling or selling or leasing or distributing the product; (3) the product was supplied by defendants in a defective condition which rendered it unreasonably dangerous; and (4) the defective condition was a proximate cause of her damages. *See* Ark. Code Ann. § 16-116-101(a); *West v. Searle & Co.*, 806 S.W.2d 608, 610 (Ark. 1991). In order to succeed on a failure to warn claim under the learned intermediary doctrine, which Arkansas has adopted, Ms. Meade must show:

(1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) *that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury*. Because the defective aspect of the product must cause the injury, the 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 not have used or prescribed the product.

*Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) (quoting *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098–99 (5th Cir. 1991)) (other citations omitted).

For purposes of deciding this motion, defendants ask the Court to assume that its warnings to Dr. McKnight were defective (Dkt. No. 101, at 1). Even assuming that defendants' warnings were defective, however, plaintiffs are still required to prove causation. To prove causation, plaintiffs must show that a proper warning would have changed the decision of Dr. McKnight, *i.e.*, that but for the inadequate warning, Dr. McKnight would not have prescribed the TVT-O. *See id.*; *see also Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)); *Higgins v. Ethicon, Inc.*, Case No. 2:12-cv-01365, 2017 WL 2813144, at \*2–3 (S.D. W. Va. Mar. 30, 2017). Here, plaintiffs are unable to meet their burden of proof regarding Dr. McKnight's reliance on any alleged inadequate warning and whether an alleged sufficient warning would have altered his decision to implant the device because plaintiffs did not depose Dr. McKnight prior to the close of discovery and because he is now deceased (Dkt. No. 98, ¶ 2). *See Mullins v. Ethicon, Inc.*, Case No. 2:12-cv-02952, 2017 WL

345865, at \*2 (S.D. W.Va. Jan. 20, 2017); *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 502–504 (D.S.C. 2012) (deciding that a plaintiff could not prove proximate causation because her treating physician—a learned intermediary—had died prior to giving any evidence in the case); *see also Sharp v. Ethicon, Inc.*, Case No. 2:20-cv-2028, 2020 WL 1434566, at \*4 (W.D. Ark. Mar. 24, 2020) (granting summary judgment for defendants on plaintiff’s failure to warn claim because implanting physician testified, without qualification, that different warnings would not have changed his decision to prescribe the TVT-O device and because, even after he was presented with plaintiff’s criticism of the product warnings, he still testified that he would have taken the same course of action as his good opinion of the device had not changed). Based on the record evidence and the operation of the learned intermediary doctrine, defendants are entitled to summary judgment on plaintiffs’ failure to warn claim.

Plaintiffs have produced the expert report and deposition testimony of Dr. Konstantin Walmsley in support of their response to the motion for summary judgment (Dkt. Nos. 100, at 7; 100-1; 100-2). Plaintiffs state that Dr. Walmsley has “opined to a reasonable degree of medical certainty that Mrs. Meade’s injuries were caused by the defective TVT-O sling.” (Dkt. No. 100, at 7). Even assuming this is true, however, plaintiffs’ reliance on Dr. Walmsley’s testimony to establish their failure to warn claim is misplaced. Dr. Walmsley cannot offer testimony as to whether Dr. McKnight relied on the inadequate warning defendants provided with the TVT-O device or whether Dr. McKnight would have acted differently had he been aware of the potential risks or had he been given an adequate warning. *See Heide v. Ethicon, Inc.*, Case No. 4:20-cv-160, 2020 WL 1322835, at \*5 (N.D. Ohio Mar. 20, 2020) (rejecting plaintiff’s reliance on expert report from physician who claimed that the implanted device was defective in several different respects because the expert did not establish that plaintiff’s physician was aware of the risks

associated with the product or that her physician would have acted differently if he had been aware of the potential risks or had been given an adequate warning).

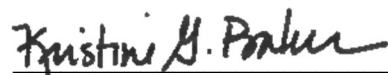
Without testimony from Ms. Meade's implanting physician, there is no triable issue of fact on causation as to plaintiffs' failure to warn claims that can withstand summary judgment. *See May v. Ethicon, Inc.*, Case No. 1:20-cv-322-TWT, 2020 WL 674357, at \*4 (N.D. Ga. Feb. 11, 2020) (granting summary judgment in favor of defendants on plaintiffs' failure to warn claim because plaintiffs could not proceed in the absence of any testimony from the implanting physician indicating how he responded to defendants' warning or how he might have responded to some different, more comprehensive warning); *Shahbaz v. Johnson & Johnson*, Case No. cv 13-07382-AB (SSX), 2020 WL 5894590, at \*17 (C.D. Cal. July 31, 2020) (granting summary judgment on plaintiffs' failure to warn claim after finding that, absent any admissible evidence from the implanting physician, plaintiff could not show that the allegedly inadequate warnings defendants provided with the TVT-O device were a substantial factor in the implanting physician's decision to recommend and implant the device) (citing *Contreras v. Boston Sci. Corp.*, Case No. 2:12-cv-03745, 2016 WL 1436682, at \*4 (S.D. W.Va. Apr. 11, 2016) (“[P]laintiffs have not provided any citations to the record showing that Dr. Barker, the implanting physician, would have taken a different course of action if she had been given an adequate warning. . . . Thus, the plaintiffs cannot establish proximate causation.”)). Accordingly, the Court grants defendants' motion for partial summary judgment as it relates to plaintiffs' failure to warn claims—Count I, in part, and Count III (Dkt. No. 97, at 2).



**IV. Conclusion**

For these reasons, the Court grants defendants' motion for partial summary judgment (Dkt. No. 97). The Court grants judgment in favor of defendants on the failure to warn claims in Count I and Count III of plaintiffs' complaint (Dkt. No. 1).

It is so ordered this 21st day of September, 2021.



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Kristine G. Baker  
United States District Judge