

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

<p>MARSHA FOSTER, and ALVIN A. JENSEN, Plaintiffs, vs. ETHICON, INC., and JOHNSON & JOHNSON, Defendants.</p>	<p>4:20-CV-04076-RAL OPINION AND ORDER GRANTING IN PART MOTION FOR SUMMARY JUDGMENT</p>
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This case began in the Southern District of West Virginia as part of the Ethicon multidistrict litigation (MDL). It is one of thousands of cases involving injuries patients allegedly suffered after being implanted with pelvic mesh products designed, manufactured, and sold by Ethicon, Inc., a wholly owned subsidiary of Johnson & Johnson. Plaintiffs Marsha Foster and Alvin Jensen sued Ethicon, Inc., and Johnson & Johnson (collectively “Ethicon”), claiming that an Ethicon product implanted in Ms. Foster was defectively designed and had inadequate warnings. Ethicon moved for partial summary judgment before the MDL judge, and that motion is now ripe for decision by this Court.

I. Facts¹

¹This Court takes the facts from the parties’ statements of material facts and the deposition transcript of Dr. Robert Ferrell. Because Dr. Ferrell’s testimony is critical to the failure-to-warn claim, this Court directed that his entire transcript be filed.

Ms. Foster, on a referral from her local physician, first saw Dr. Robert Ferrell on February 26, 2003, for stress urinary incontinence. Doc. 107 at 19.² One of the options Dr. Ferrell recommended to Ms. Foster was the TVT. Doc. 107 at 22–24; 29, 84–85. Because Dr. Ferrell was not yet trained on implanting the TVT, however, he asked Dr. Kevin Bray to perform the surgery. Doc. 107 at 33; 90–91. Dr. Ferrell met separately with Ms. Foster on March 19, 2003, to explain the risks and benefits of implanting the TVT. Doc. 107 at 24–26. Dr. Bray did not participate in any preoperative appointment or any informed consent conversations with Ms. Foster. Doc. 107 at 91; Doc. 27 p.2 at ¶ 4. On March 21, 2003, Dr. Bray implanted Ms. Foster with an Ethicon TVT to treat her stress urinary incontinence. Doc. 27 p.2 at ¶ 2; Doc. 26 p.2 at ¶¶ 1–2. Dr. Ferrell was present during and assisted Dr. Bray with the surgery. Doc. 27 p.2 at ¶¶ 3–4. After the surgery, Ms. Foster had postoperative appointments with Dr. Ferrell and seemed to have recovered from the surgery. Doc. 107 at 36–41.

More than seven years later, Ms. Foster returned to see Dr. Ferrell in December 2011 when she reported experiencing urinary problems. Doc. 27 p.2 at ¶ 5. She saw Dr. Ferrell again in March 2012, with the same problems. Doc. 27 p.2 at ¶ 6. Dr. Ferrell referred Ms. Foster to Dr. Matthew Barker. Doc. 27-3 at 7; Doc. 27 p.2 at ¶ 7. Ms. Foster saw Dr. Barker in September 2012, due to pelvic organ prolapse and voiding dysfunction. Doc. 27 p.2 at ¶ 7. In early December 2012, Dr. Barker performed pelvic reconstructive surgery on Ms. Foster. Doc. 27 p.3 at ¶ 8. Despite the surgery, Ms. Foster continued to experience and seek treatment for urinary problems, including urinary retention requiring self-catheterization, voiding difficulty, and infections. Doc. 27 p.3 at ¶ 9. Ms. Foster reports that she still suffers from life-changing complications, including

²When citing to Dr. Ferrell’s deposition transcript, this Court cites to the CM/ECF pagination rather than the transcript pagination.

vaginal pain, cramping, infections, urinary retention, and recurrent incontinence. Doc. 27 p.3 at ¶ 10; Doc. 26 p.2 at ¶ 4.

In February 2012, the Judicial Panel on Multidistrict Litigation opened an MDL to coordinate pretrial proceedings of all Ethicon pelvic mesh-related litigation (Ethicon MDL). In re: Am. Med. Sys., Inc. Pelvic Repair Sys. Prods. Liab. Litig., 844 F. Supp. 2d 1359, 1360–62 (J.P.M.L. 2012); In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 299 F.R.D. 502, 508 (S.D.W. Va. 2014). The Ethicon MDL was assigned to the Honorable Joseph R. Goodwin in the Southern District of West Virginia. Am. Med. Sys., 844 F. Supp. 2d at 1362.

In August 2015, Ms. Foster and Mr. Jensen filed this case in the Southern District of West Virginia as part of the Ethicon MDL. Doc. 1. Their short-form complaint pleaded the following claims: negligence (Count I); strict-liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); gross negligence (Count XIV); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). Doc. 1. Judge Goodwin assigned the cases in the Ethicon MDL to various “waves” to be prepared for trial. Doc. 6. Ms. Foster and Mr. Jensen’s case was assigned to Wave 8. Doc. 6.

While this case was pending in West Virginia, Ethicon moved for summary judgment on Counts II–IV, Counts VI–IX, Counts XI–XIII, and Counts XV and XVI. Doc. 25. Ms. Foster opposed the motion as to Counts III (strict liability – failure to warn) and IV (strict liability – defective product) but did not oppose summary judgment on the other counts addressed in

Ethicon's motion.³ Doc. 27. The parties recently stipulated that the following counts should be dismissed with prejudice: Counts II, VI–IX, XI–XIII, and XV.⁴ Doc. 106. In April 2020, Judge Goodwin transferred Ms. Foster's case to this Court. Doc. 36. Ethicon's motion for summary judgment on Counts III and IV remains pending and is ripe for decision.

II. Standard of Review

Under Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment is proper “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). Rule 56(a) places the burden initially on the moving party to establish the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986). Once the moving party has met that burden, the nonmoving party must establish that a material fact is genuinely disputed either by “citing to particular parts of materials in the record” or by “showing that the materials cited do not establish the absence . . . of a genuine dispute.” Fed. R. Civ. P. 56(c)(1)(A), (B); Gacek v. Owens & Minor Distrib., Inc., 666 F.3d 1142, 1145–46 (8th Cir. 2012); see also Mosley v. City of Northwoods, 415 F.3d 908, 910 (8th Cir. 2005) (stating that a nonmovant may not merely rely on allegations or denials). A party opposing a properly supported motion for summary judgment “may not merely point to unsupported self-

³Alvin A. Jensen is a plaintiff in the case solely for purposes of a loss of consortium claim. One of the claims Ethicon moved for summary judgment on was Count XVI, a claim for loss of consortium. Ethicon argued that this claim failed because Ms. Foster was Mr. Jensen's fiancée and the two weren't married when Ms. Foster underwent the TVT implant. Ms. Foster's response says she contests summary judgment on the claims for strict liability – failure to warn and strict liability – defective product, and these are the only two claims she addresses in her response. Doc. 27. However, the joint stipulation of dismissal the parties filed states that the loss of consortium claim remains pending. Doc. 106 at 2.

⁴Ethicon did not move for summary judgment on the gross negligence claim, but South Dakota law does not recognize a cause of action separate from a negligence claim for “gross negligence.” See Estate of Stengle, 3:20-CV-03001-RAL, 2021 WL 858836, at *4 (D.S.D. Mar. 8, 2021).

serving allegations, but must substantiate his allegations with sufficient probative evidence that would permit a finding in his favor, without resort to speculation, conjecture, or fantasy.” Reed v. City of St. Charles, 561 F.3d 788, 790–91 (8th Cir. 2009) (cleaned up and citations omitted). In ruling on a motion for summary judgment, the facts and inferences fairly drawn from those facts are “viewed in the light most favorable to the party opposing the motion.” Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587–88 (1986) (quoting United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) (per curiam)).

III. Analysis

Ethicon argues that Ms. Foster’s strict liability – failure-to-warn claim fails because she cannot show causation and that South Dakota does not recognize her claim for “strict liability – defective product.” This Court addresses these arguments in turn.

A. Law on causation for strict liability failure-to-warn claims

The parties agree that South Dakota law applies because South Dakota is where Ms. Foster lives and had the TVT implanted. Doc. 26 at 3; Doc. 27 at 4. Plaintiffs bringing a strict liability failure-to-warn claim in South Dakota must prove that the failure to warn was the legal cause of their injuries. Karst v. Shur-Co., 878 N.W.2d 604, 613 (S.D. 2016); Nationwide Mut. Ins. Co. v. Barton Solvents, Inc., 855 N.W.2d 145, 150–51 (S.D. 2014); Burley v. Kytac Innovative Sports Equip., Inc., 737 N.W.2d 397, 409–11 (S.D. 2007). “Legal cause means an immediate cause which, in the natural or probable sequence, produces the injury complained of. For legal cause to exist, the harm suffered must be a foreseeable consequence of the act complained of.” Berg v. Johnson & Johnson Consumer Cos., 983 F. Supp. 2d 1151, 1160 (D.S.D. 2013) (cleaned up and citation omitted). “[T]o prove causation in a failure-to-warn claim, a plaintiff must show that adequate warnings would have made a difference in the outcome, that is, that they would have

been followed.” Karst, 878 N.W.2d at 613 (cleaned up and citation omitted). “[T]he evidence must be such as to support a reasonable inference, rather than a guess, that the existence of an adequate warning may have prevented the accident before the issue of causation may be submitted to the jury.” Id. at 614 (citation omitted).

Two doctrines are relevant to the parties’ causation arguments. First, Ethicon relies on the learned intermediary doctrine. Under this doctrine, a manufacturer of medical devices or pharmaceuticals satisfies its duty to warn by providing the appropriate information to the treating physician. Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004); Dan B. Dobbs et al., Dobbs’ Law of Torts § 466 (2d ed. June 2020 update) (explaining that the learned intermediary doctrine applies “not only to drugs but also to medical devices and bodily implants that are usually accompanied by medical advice and supervision”). The treating physician then acts as a learned intermediary between the manufacturer and the patient, obviating the need for the manufacturer to warn the patient directly. Ehlis, 367 F.3d at 1016. In Schilf v. Eli Lilly & Co., this Court predicted that the Supreme Court of South Dakota would follow the learned intermediary doctrine. No. CIV 07-4015, 2010 WL 4024922, at *2 (D.S.D. Oct. 13, 2010), rev’d on other grounds, 687 F.3d 947 (8th Cir. 2012). The Eighth Circuit agreed with that prediction. Schilf, 687 F.3d at 949 (applying the learned intermediary doctrine); see also id. at 952 (Gruender, J., dissenting in part) (agreeing with the majority that South Dakota “likely would adopt the learned intermediary doctrine”). Although Schilf involved a drug manufacturer, this Court’s reasons for predicting that the Supreme Court of South Dakota would follow the learned intermediary doctrine apply with equal force here. Schilf, 2010 WL 4024922, at *2. Thus, this Court predicts that the Supreme Court of South Dakota would follow the learned intermediary doctrine in cases against a designer and manufacturer of medical devices.

Second, Ms. Foster argues that the “heeding presumption” applies under the Eighth Circuit’s decision in Schilf. The heeding presumption comes from the last paragraph of comment j of § 402A of the Restatement (Second) of Torts. See Schilf, 687 F.3d at 949 (citing comment j when explaining the heeding presumption); 2 David G. Owen & Mary J. Davis, Owen & Davis on Products Liability § 11:20 (4th ed. May 2020 update) (stating that the heeding presumption “has its roots” in comment j).⁵ The last paragraph of comment j reads: “Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.” Restatement (Second) of Torts § 402A cmt j (Am. Law Inst. 1965). Comment j creates a presumption that an adequate warning will be read and heeded. Pavlik v. Lane Ltd./Tobacco Exps. Int’l, 135 F.3d 879, 883 (3d Cir. 1998); Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1st Cir. 1992). When warnings are present, this presumption favors the manufacturer because it “receives the benefit of the doubt” that the warning will be effective. Tuttle v. Lorillard Tobacco Co., 377 F.3d 917, 925 n.5 (8th Cir. 2004). However, courts have interpreted comment j as also giving the plaintiff a rebuttable presumption that, had an adequate warning been given, the plaintiff would have read and heeded it. Schilf, 687 F.3d at 949; Pavlik, 135 F.3d at 883 (stating that it follows logically from comment j that “the law should also presume that, when no warning or an inadequate warning is provided, the end-user would have read and heeded an adequate warning had one been given by the manufacturer”); Garside, 976 F.2d at 81. This presumption thus helps plaintiffs prove causation when there is no warning, or the warning is inadequate. Tuttle, 377 F.3d at 925 n.5.

⁵Some jurisdictions base the heeding presumption on public policy rather than comment j. Benjamin J. Jones, Annotation, 38 A.L.R. 5th 683 § 2[a] (1996).

The Eighth Circuit in Schilf predicted that South Dakota would “likely” adopt the heeding presumption. 687 F.3d at 949. It cited McElhaney v. Eli Lilly & Co., 739 F.2d 340 (8th Cir. 1984) (per curiam), to support this prediction but did not analyze the issue further. Schilf, 687 F.3d at 949. McElhaney was a per curiam decision in which the Eighth Circuit upheld the district court’s prediction that South Dakota would apply comments k and j of § 402A of the Restatement (Second) of Torts. 739 F.2d at 340–41. The Eighth Circuit in McElhaney noted that the Supreme Court of South Dakota had adopted § 402A to govern strict liability cases and had applied comment k. 739 F.3d at 340. The McElhaney decision concerned the paragraph of comment j stating that manufacturers must warn of certain types of dangers, and thus did not mention the heeding presumption. 739 F.3d at 340 n.1.

This Court addressed the heeding presumption portion of comment j in Lindholm v. BMW of North America, LLC, 202 F. Supp. 3d 1082 (D.S.D. 2016). Lindholm involved a strict liability claim against a car manufacturer for supplying an allegedly defectively designed jack. The plaintiffs’ son had used the jack to lift his car to work beneath it when, tragically, the car fell off the jack and killed him. Id. at 1088. The son’s use of the jack contravened the manufacturer’s warnings that the jack should not be used to hold up the car while someone was underneath it. Id. at 1096. This Court predicted that the Supreme Court of South Dakota would apply comment j to a case like Lindholm given that court’s frequent reliance on § 402A and specific citation to comment h, which cross references comment j. Id. The car manufacturer was thus entitled to “reasonably assume” that the warnings accompanying the jack would be read and heeded. Id. (citation omitted). The Eighth Circuit agreed on appeal that the Supreme Court of South Dakota would apply comment j to the circumstances in Lindholm. Lindholm v. BMW of N. Am., LLC, 862 F.3d 648, 652 (8th Cir. 2017).

The Eighth Circuit's prediction in Schilf that South Dakota would apply the heeding presumption binds this Court absent an intervening decision by the Supreme Court of South Dakota indicating that the prediction in Schilf was wrong. See AIG Centennial Ins. Co. v. Fraley-Landers, 450 F.3d 761, 767–68 (8th Cir. 2006) (“Although our circuit has never specifically determined the binding effect of a state law determination by a prior panel, other circuits defer to prior panel decisions absent a subsequent state court decision or statutory amendment that makes the prior federal opinion clearly wrong. This provides us with an additional basis for our holding.” (cleaned up and citations omitted)); Arena Holdings Charitable, LLC v. Harman Pro., Inc., 785 F.3d 292, 295–96 (8th Cir. 2015) (following a prior Eighth Circuit prediction about North Dakota law where subsequent North Dakota cases raised “some doubt” about the prediction but did “not stand as decisive legal authority” that the prediction was wrong); RehabCare Grp. E., Inc. v. Stratford Health Care Props., No. 14-0886-CV-W-FJG, 2015 WL 5098303, at *4 (W.D. Mo. Aug. 31, 2015) (noting that an Eighth Circuit decision about state law binds district courts “absent a subsequent state court decision or statutory amendment making” the decision incorrect); Brown v. La.-Pac. Corp., No. 4:12-cv-00102-SMR-HCA, 2014 WL 11513168, at *10 n.10 (S.D. Iowa Sept. 18, 2014) (explaining that “absent any clear instruction from the Iowa courts,” the district court would need to defer to the Eighth Circuit’s prior determination of Iowa law).

There are no such decisions from the Supreme Court of South Dakota, although its decision in Karst deserves mention. The plaintiff in Karst suffered brain damage when he was knocked to the ground while attempting to fix an electric tarp system on his grain trailer. 878 N.W.2d at 608. He sued the manufacturer and seller of the tarp system for strict liability and negligence, alleging that the system did not come with adequate warnings. Id. at 607. The trial court granted the defendants’ motion for summary judgment on the failure-to-warn claims, concluding that the

plaintiff could not prove causation because he had not produced evidence that he read the warnings in the manual before the accident. Id. at 608. The plaintiff appealed, arguing that he was entitled to a presumption that he read the warnings. Id. at 615. Curiously, the plaintiff did not cite comment j or the heeding presumption to support this argument. Id. Instead, he relied on the presumption of due care afforded people injured or killed in moving-vehicle accidents. Id. For this presumption to apply, however, the injured person “must necessarily appreciate the danger inherent in the activity.” Id. The Supreme Court of South Dakota declined to extend the presumption of due care to create a presumption that the plaintiff had read the warnings in the manual. Id. It reasoned that the presumption of due care was inconsistent with the plaintiff’s concession of being unaware of the dangers associated with the electric tarp system and that testimony by the plaintiff’s experts—opining that most people do not read the owner’s manual for products they purchase—“negated” any basis for presuming that the plaintiff had read the manual for the tarp. Id.

Karst does not undermine Schilf to such a degree that this Court can refuse to apply the heeding presumption here. The Supreme Court of South Dakota did not mention comment j or the heeding presumption in Karst, let alone say that the presumption does not apply in South Dakota under any circumstances. Moreover, the circumstances in Schilf and this case are vastly different from those in Karst. Indeed, the plaintiff in Karst asked the Supreme Court of South Dakota to presume that he had read the instruction manual for his electric tarp system despite the plaintiff’s own expert witnesses testifying that most people do not read the manual for products they purchase. 878 N.W.2d at 615. The Supreme Court of South Dakota’s refusal to apply a presumption to those facts, when the heeding presumption was never raised, says little about whether that court would apply the heeding presumption to cases like Schilf and this one, where a doctor is functioning as a learned intermediary between the defendant and the plaintiff. In short,

Karst is not the sort of “decisive legal authority” courts have required before departing from prior federal predictions of state law. Arena Holdings, 785 F.3d at 295; see also AIG Centennial Ins. Co., 450 F.3d at 767–68 (explaining that other circuits defer to prior federal panel predictions about state law unless a later state court decision shows that the prediction was “clearly wrong” (quoting Broussard v. S. Pac. Tranp. Co., 665 F.2d 1387, 1389 (5th Cir. 1982) (en banc))); FDIC v. Abraham, 137 F.3d 264, 269 (5th Cir. 1998) (explaining that a state court must issue “a contrary ruling squarely on point” before a prior federal panel’s decision will be considered “clearly wrong”). Thus, this Court continues to predict, as has the Eighth Circuit twice, that South Dakota would apply the heeding presumption to a case like this. See Schilf, 687 F.3d at 949; Lindholm, 862 F.3d at 652.

The Eighth Circuit decisions in Schilf and Lindholm do not predict how the heeding presumption would operate in South Dakota, and states differ over the effect the presumption has on the defendant’s burden. Norwood v. Raytheon Co., 237 F.R.D. 581, 599 (W.D. Tex. 2006). Some states merely shift the burden of production to defendants, while other states shift both the burden of production and the burden of persuasion. Compare Kirkbride v. Terex USA, LLC, 798 F.3d 1343, (10th Cir. 2015) (stating that under Utah law, the heeding presumption requires the defendant to rebut the presumption by a preponderance of the evidence), and Butz v. Werner, 438 N.W.2d 509, 517–18 (N.D. 1989) (explaining that the heeding presumption in North Dakota shifts the burden of proof to the defendant), with Pavlik, 135 F.3d at 883–84 (applying Pennsylvania law and stating that the plaintiff still retains the burden of persuasion under the heeding presumption and that the presumption “drops from the case” once the defendant meets its burden of producing evidence to rebut the presumption (citation omitted)), and Durkin v. Wabash Nat’l, No. 10-2013, 2013 WL 2352612, at *12 (D.N.J. May 29, 2013) (applying New Jersey law and explaining that if

“the defendant satisfies its burden of production, that is, if defendant presents sufficient evidence to rebut the [heeding] presumption, . . . the presumption disappears and the plaintiff, consistent with his original burden of persuasion, must prove by a preponderance of the evidence that the failure to warn was a proximate cause of his injury”).

Federal courts naturally look to state law to determine the effects of the heeding presumption. Fed. R. Evid. 302 (“In a civil case, state law governs the effect of a presumption regarding a claim or defense for which state law supplies the rule of decision.”); Daniel v. Ben E. Keith Co., 97 F.3d 1329, 1332–33 (10th Cir. 1996) (looking to Oklahoma’s evidence code and case law to determine the effect of the heeding presumption). South Dakota’s rule on presumptions in civil cases says that a presumption shifts the burden of production but not the burden of persuasion:

In all civil actions and proceedings, unless otherwise provided for by statute or by this chapter, a presumption imposes on the party against whom it is directed the burden of going forward with evidence to rebut or meet the presumption, but does not shift to such party the burden of proof in the sense of the risk of nonpersuasion, which remains throughout the trial upon the party on whom it was originally cast. When substantial, credible evidence has been introduced to rebut the presumption, it shall disappear from the action or proceeding, and the jury shall not be instructed thereon.

SDCL § 19-19-301; see also In re Estate of Pringle, 751 N.W.2d 277, 289–90 (S.D. 2008) (stating that a presumption does not shift the burden of proof). The “substantial, credible evidence” requirement in § 19-19-301 means that a presumption may be rebutted by “evidence that if uncontradicted would be sufficient to sustain a finding of the nonexistence of the presumed fact.” In re Estate of Dimond, 759 N.W.2d 534, 538 (S.D. 2008). “[M]ere assertions, implausible contentions, and frivolous avowals will not avail to defeat a presumption.” Id.

Based on SDCL § 19-19-301, this Court predicts that the heeding presumption in South Dakota shifts the burden of production to the defendant but not the burden of persuasion. Thus, once the plaintiff shows the lack of an adequate warning, a presumption arises that the plaintiff (or the learned intermediary) would have read and heeded the warning. The defendant then has the burden of producing “substantial, credible evidence” to rebut this presumption. SDCL § 19-19-301. The court decides whether the defendant has rebutted the presumption and, if the defendant has, the presumption disappears, and the jury receives no instruction on any such presumption. See id. (“When substantial, credible evidence has been introduced to rebut the presumption, it shall disappear from the action or proceeding, and the jury shall not be instructed thereon.”); Bell v. E. River Elec. Power Coop, Inc., 535 N.W.2d 750, 754–55 (S.D. 1995) (concluding that substantial, credible evidence rebutted the presumption of due care, and that it was therefore not error for the trial court to refuse to instruct the jury on the presumption).

However, the mere rebuttal of the heeding presumption does not necessarily entitle the defendant to summary judgment. Instead, the defendant must show either that there is no genuine dispute of material fact on the adequacy of the warning or that an adequate warning would not have made a difference as a matter of law. See Pavlik, 135 F.3d at 884 (“While [defendant] need only produce evidence sufficient to support a finding contrary to the presumed fact to rebut the presumption at trial, to satisfy Rule 56 the record must show that a reasonable fact finder would be bound to find [contrary to the presumed fact.]” (internal citation omitted)); see also Bachtel v. TASER Int’l, Inc., 747 F.3d 965, 971 (8th Cir. 2014) (explaining that a defendant is entitled to have causation determined as a matter of law if it produces “rebuttal evidence so strong that it would necessarily persuade any reasonable trier of fact that an adequate warning would have been futile” (cleaned up and citation omitted)).

B. Ethicon is entitled to summary judgment on Ms. Foster's failure-to-warn claim

Ethicon does not move for summary judgment on the ground that they adequately warned Dr. Ferrell. Rather, it argues that Ms. Foster cannot show causation because Dr. Ferrell did not rely on the TVT's warnings and would have prescribed the TVT for Ms. Foster even if he had received an adequate warning. Since Ethicon does not argue that the warnings were adequate and Ms. Foster is the nonmoving party, this Court assumes without deciding that the TVT warnings were inadequate. Accordingly, Ms. Foster is entitled to a rebuttable presumption that Dr. Ferrell would have read and heeded an adequate warning. As explained below, however, Ethicon has rebutted the presumption and Ms. Foster has failed to show a material question of fact on causation.

Ethicon claims that Ms. Foster cannot show causation because Dr. Ferrell said that he did not rely on the TVT's instructions for use (IFU). "The majority of courts that have examined the issue have held that when a physician fails to read or rely on a drug manufacturer's warnings, such failure constitutes the intervening, independent and sole proximate cause of the plaintiff's injuries, *even where the drug manufacturer's warnings were inadequate.*" Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 856 (10th Cir. 2003) (cleaned up and citation omitted); see also Karst, 878 N.W. 2d at 613 ("[C]ourts generally hold that a plaintiff's failure to read a given warning precludes establishment of the causation element even if the warning is arguably inadequate.").

During direct examination by defense counsel, Dr. Ferrell testified that he didn't "believe" he read the TVT's IFU before Ms. Foster's surgery. Doc. 107 at 64. He also agreed that it was "fair to assume" that he couldn't have discussed anything in the IFU with Ms. Foster before her surgery and that he read the IFU after Ms. Foster's surgery when he was training on the TVT. Doc. 107 at 64–65. Dr. Ferrell's testimony about the IFU on direct examination constitutes substantial, credible evidence sufficient to rebut the heeding presumption. See Bayes v. Biomet,

Inc., No. 4:13-cv-00800-SRC, 2020 WL 5095346, at *13 (E.D. Mo. Aug. 28, 2020) (holding that surgeon's testimony that he did not read product's IFU rebutted the heeding presumption).

Ms. Foster argues, however, that Dr. Ferrell's testimony on cross examination is enough to create a question of fact on whether he relied on the TVT's IFU. That testimony went as follows:

Ms. Foster's counsel: All right. So would you have - - you testified that you didn't read the TVT before you recommended it to Ms. Foster?

Dr. Ferrell: Define TVT, what you're referring to with that.

Ms. Foster's counsel: The Gynecare TVT that - - which was the product that was implanted by Dr. Bray in Ms. Foster on March 21st, 2003.

Dr. Ferrell: Right.

Ms. Foster's counsel: So do I have that right?

Dr. Ferrell: Yes.

Ms. Foster's counsel: You recommended a device that you hadn't read the IFU on?

Dr. Ferrell: I don't think I read that IFU. I read about the procedure, talked to other physicians about it and then relied on Dr. Bray.

Ms. Foster's counsel: You just now said you don't think you did. Is it possible that you did considering that it was 15 years ago?

....

Dr. Ferrell: It is possible.

Doc. 107 at 82-83; see also Doc. 107 at 97 (agreeing again that it was "possible" that he had read the TVT's IFU before Dr. Bray implanted the device in Ms. Foster).

Ms. Foster has not produced enough evidence to create a genuine question of material fact on causation. Dr. Ferrell testified at two different points during his deposition that he did not read the IFU before Ms. Foster's surgery. Doc. 107 at 64-65, 82-83. Although Dr. Ferrell eventually agreed that it was "possible" that he read the IFU given that the surgery was fifteen years ago, a jury would still need to resort to guesswork and speculation to find that Dr. Ferrell read the IFU before Ms. Foster's surgery. See Pustejovsky v. Pliva, Inc., 623 F.3d 271, 277 (5th Cir. 2010) (holding that while doctor's testimony that she did "not recall" ever reading the package insert for a drug did not preclude the possibility that she did so, the testimony was not enough to create a

question of fact on causation); Karst, 878 N.W.2d at 614–15 (holding that a witness’s testimony that he saw the plaintiff read “something” shortly before the plaintiff’s accident with an electric tarp system was not enough to create a question of fact on whether the plaintiff read the system’s manual). Ethicon is therefore entitled to summary judgment on Ms. Foster’s failure-to-warn claim. Karst, 878 N.W.2d at 614 (“Where the theory of liability is failure to warn adequately, the evidence must be such as to support a reasonable inference, rather than a guess, that the existence of an adequate warning may have prevented the accident before the issue of causation may be submitted to the jury.” (citation omitted)).

C. Ethicon is not entitled to summary judgment on Count IV

Count IV of Ms. Foster’s complaint is entitled “Strict Liability – Defective Product.” Doc. 1 at 4. Ethicon argues that there is no such cause of action in South Dakota. See Rynders v. E.I. Du Pont De Nemours & Co., 21 F.3d 835, 842 (8th Cir. 1994) (explaining that three classes of defects are actionable under South Dakota strict liability law: “manufacturing defects where individual products within a product line are improperly constructed, design defects involving the entire product line, and defect by failure to properly warn or instruct users of a product where such failure renders the product hazardous” (citation omitted)). Ms. Foster replies that she is limiting her strict liability claim for defective product to design defect only. Doc. 27 at 12. She points out that Ethicon has not moved for summary judgment on Count V, which is entitled “Strict Liability-Design Defect.” Doc. 1 at 4. This Court denies Ethicon’s motion for summary judgment on Count IV with the understanding that Counts IV and V state a single claim for strict liability – design defect. This Court will consider those two counts as merged into a single strict liability claim for an alleged design defect of the TVT.

IV. Conclusion


For the reasons stated above, it is hereby

ORDERED that Defendants' Motion for Partial Summary Judgment, Doc. 25, is granted in part and denied in part. The motion is granted as to Count III but denied as to Count IV. It is further

ORDERED that the following counts are dismissed with prejudice: Counts II, VI-IX, XI-XIII, and XV.

DATED this 26th day of March, 2021.

BY THE COURT:



ROBERTO A. LANGE
CHIEF JUDGE