UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

KATHRYN M. NELSON,

Plaintiffs,

v. Case No. 12-C-472

JOHNSON & JOHNSON and
ETHICON INC.,

Defendants.

DECISION AND ORDER

Plaintiff Kathryn Nelson alleges that she was injured as a result of the implantation of a Prolift device that is made by Defendants Johnson & Johnson, a New Jersey corporation, and Ethicon Inc., a New Jersey corporation and subsidiary of Johnson & Johnson. Nelson initiated this lawsuit in the Eastern District of Wisconsin on May 11, 2012. On June 15, 2012, the case was conditionally transferred to the Southern District of West Virginia under 28 U.S.C. § 1407 for coordination and consolidation of pretrial proceedings. Dkt. No. 5. After the case was conditionally remanded back to the Eastern District of Wisconsin on April 26, 2019, the court held a telephonic status conference on June 18, 2019, where the parties agreed that two fully-briefed motions were ready for resolution by this court: 1) Ethicon's motion for partial summary judgment; and 2) Nelson's motion to file a sur-reply or alternatively strike portions of Ethicon's reply brief. The court has jurisdiction over the case pursuant to 28 U.S.C. § 1332. For the reasons that follow, Ethicon's motion will be granted-in-part and denied-in-part and Nelson's motion will be denied.

BACKGROUND

In April of 2009, Nelson consulted with an OBGYN, Dr. Thomas Reinardy, regarding symptoms of pelvic organ prolapse—including cystocele and rectocele—and stress urinary incontinence. On May 14, 2009, Dr. Reinardy performed a total vaginal hysterectomy on Nelson, implanted a Prolift device to treat the prolapse, and a TVT-O-Obturator device to treat the urinary incontinence. Prior to the devices' implantation, Dr. Reinardy attended two training sessions by Ethicon regarding both Prolift and TVT-O that demonstrated proper surgical technique and addressed possible complications. Dr. Reinardy was provided information on the risks and benefits associated with the use of the Prolift in pelvic organ prolapse repair surgery. In addition, Dr. Reinardy had received training during his residency program and was aware that the use of mesh products could result in complications such as pain, erosion, and dyspareunia. Based on his general practice experience, Dr. Reinardy knew that any pelvic floor surgery involves the risks of dyspareunia, vaginal scarring, infection, urinary problems, bleeding, inflammation, neuoromuscular problems, recurrence, failure, or acute and chronic pain. Dr. Reinardy was familiar with the potential adverse reactions to Prolift and risks associated with implantation stated in Prolift's instructions for use (IFU) prior to implanting it in Nelson. Nelson subsequently underwent multiple surgeries for partial mesh excision of the Prolift on July 22, 2010; January 31, 2011; April 13, 2011; and October 3, 2011.

LEGAL STANDARD

Summary judgment should be granted when the moving party shows that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In other words, the time and expense of the parties and the court should not

be wasted on a trial when there are no material facts in dispute, one party is entitled to judgment on those facts, and thus there is nothing to try. In deciding a motion for summary judgment, all reasonable inferences are construed in favor of the nonmoving party. *Foley v. City of Lafayette*, 359 F.3d 925, 928 (7th Cir. 2004). The party opposing the motion for summary judgment must "submit evidentiary materials that set forth specific facts showing that there is a genuine issue for trial." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 937 (7th Cir. 2010) (quoted source and internal quotation marks omitted). "The nonmoving party must do more than simply show that there is some metaphysical doubt as to the material facts." *Id.* Summary judgment is properly entered against a party "who fails to make a showing sufficient to establish the existence of an element essential to the party's case, and on which that party will bear the burden of proof at trial." *Parent v. Home Depot U.S.A., Inc.*, 694 F.3d 919, 922 (7th Cir. 2012) (internal quotation marks omitted) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

ANALYSIS

In its motion for partial summary judgment, Ethicon moves to dismiss the following claims of Nelson's Amended Short Form Complaint:

> Count I - Negligence; Count II - Strict Liability - Manufacturing Defect; Count III - Strict Liability - Failure to Warn; 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; and Count XV - Unjust Enrichment.

In her response, Nelson states that she does not oppose dismissal of claims associated with the implantation of the TVT-O-Obturator product, and Counts II, IV, VII, VIII, X, XI, XII, XIII, and XV as they relate to the Prolift product. Pl.'s Resp., Dkt No. 12 at 1–2. Consequently, Ethicon's

motion will be granted as it relates to those claims. This leaves for determination Ethicon's motion for summary judgment on Nelson's claims for strict liability and negligent failure to warn, fraud and negligent misrepresentation.

A. Choice-Of-Law

As jurisdiction in this district is based on diversity, the court looks to Wisconsins' choice-of-law rules to determine which State's law applies to Nelson's claims. *GATX Leasing Corp. v. Nat'l Union Fire Ins. Co.*, 64 F.3d 1112, 1114 (7th Cir. 1995) ("A federal court sitting in diversity looks to the conflict-of-laws rules in the state jurisdiction in which it sits in order to choose the substantive law applicable to the case.") Under Wisconsin law, "'the law of the forum should presumptively apply unless it becomes clear that nonforum contacts are of greater significance.'" *Drinkwater v. Am. Family Mut. Ins. Co.*, 2006 WI 56, ¶ 40, 290 Wis. 2d 642, 714 N.W.2d 568 (quoting *State Farm Mut. Auto Ins. Co. v. Gillette*, 2002 WI 31, ¶ 51, 251 Wis. 2d 561, 641 N.W.2d 662).

Here, Wisconsin's contacts predominate. Nelson lived in Wisconsin when she received the implant and did not leave the state until after filing her case in Wisconsin. In addition, the surgery was performed in Wisconsin by a Wisconsin surgeon and nearly all of her follow-up treatment occurred in Wisconsin. Consequently, the court will apply Wisconsin law to Nelson's claims.

B. Count I - Negligence and Count III - Strict Liability - Failure to Warn

As an initial matter, the parties dispute whether the learned intermediary doctrine applies to Nelson's claims. "The doctrine holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018).

Although "neither the Wisconsin Supreme Court nor the state's intermediate appellate courts have addressed the doctrine," *id.*, "there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases," *id.* at 752, and the Seventh Circuit has predicted that Wisconsin's Supreme Court would do so. *Id.* Definitive resolution of this question, however, is not necessary at this time to resolve Ethicon's motion for partial summary judgment.

Ethicon asserts that Nelson's negligent failure to warn claim and strict liability failure to warn claim should be dismissed because she cannot prove the failure to warn contributed to her injury. In addition, Ethicon contends that it had no duty to warn Dr. Reinardy about dangers generally known to pelvic floor surgeons.

1. Strict Liability Failure to Warn Claim

Regarding Nelson's strict liability failure to warn claim, under Wisconsin's strict liability statute, Wis. Stat. § 895.047, a product is defective because of inadequate instructions or warnings if the plaintiff can show that:

> a) The foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omissions of the instructions or warnings renders the product not reasonably safe;
>
> b) The defective condition rendered the product unreasonably dangerous to persons or property;
>
> c) The defective condition existed at the time the product left the control of the manufacturer;
>
> d) The product reached the user or consumer without substantial change in the condition in which it was sold; and

e) The defective condition was a cause of the claimant's damages.

Wis. Stat. § 895.047(1)(a)–(e). A manufacturer, however, "does not have a duty to warn about dangers that are obvious to or readily known by potential users, or so commonly known that it can reasonably be assumed that users will be familiar with them." *Burton v. Am. Cyanamid*, 334 F. Supp. 3d 949, 958 (E.D. Wis. 2018) (citing *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 2009 WI 78, ¶ 32, 319 Wis. 2d 91, 768 N.W.2d 674).

Nelson disputes that Wis. Stat. § 895.047 applies to her claim. "The treatment of section[] . . . 895.047 . . . first appl[ies] to actions or special proceedings that are commenced on the effective date of this subsection." 2011 Wis. Act 2, § 45(5). Section 895.047 became effective as of February 1, 2011, and Nelson did not initiate this lawsuit until May 11, 2012—after it went into effect. Nelson contends that the retroactive application of § 895.047 would be unconstitutional. Wisconsin tests "the due-process constitutionality of the retroactive application of state statutes by asking, first, whether the statute is taking away a 'vested right' of the challenger." *Gibson v. Am. Cyanamid Co.*, 760 F.3d 600, 609 (7th Cir. 2014) (citing *Matthies v. Positive Safety Mfg. Co.*, 2001 WI 82, ¶¶ 21–23, 244 Wis. 2d 720, 628 N.W.2d 842). "If the answer is that no vested right is at stake, then the statute satisfies due process and the inquiry ends." *Id.*

Here, it does not appear that § 895.047 takes away a vested right, but it is unnecessary to decide that issue now in any event. This is because even if § 895.047 applies, Ethicon is not entitled to summary judgment because there is a dispute of fact regarding what Ethicon knew about the hazards of the Prolift device, whether it warned users about those hazards, and whether it caused Nelson's injuries. Regarding the adequacy of Ethicon's warnings, Nelson produced proposed

warning language drafted by Ehticon's Medical Affairs Director Axel Arnaud to be added to a new version of Prolift's IFU that was ultimately not added. The proposed language stated:

> Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in sexually active women.

Dkt. No. 12-1 at 46. In addition, Dr. Daniel Elliott opined in his expert report that "Ethicon . . . knowingly failed to completely disclose the known risks of prolapse surgery using Prolift to physicians and patients," *id.* at 148, and listed all of the risks that he believes Ethicon knew about but failed to disclose. *Id.* at 143–46.

Ethicon contends that Nelson "is required to present case-specific expert testimony to prove Ehitcon's warnings were inadequate," Def.'s Reply, Dkt. No. 13 at 7, and that Dr. Elliott's expert opinion is only a general opinion about the alleged inadequacies in Ethicon's warnings and has no specific connections or relevance to Nelson's case. Ethicon, however, cites no case in support of its contention. "[E]stablishing the existence of a product defect based on failure to warn in the strict liability context requires analysis of what the manufacturer knew and what potential consumers or users knew about the hazards of the product at the time that the product left the manufacturer's control." *Burton*, 334 F. Supp. 3d at 958. Dr. Elliott's expert testimony does just that: analyzes and identifies hazards known by Ethicon that were not included in its warnings and were not known by doctor's such as Dr. Reinardy. While the general nature of Dr. Elliott's expert testimony may mean on its own it is not sufficient to establish causation for purposes of Nelson's injuries, it is sufficient to identify hazards that Ethicon failed to warn potential users of Prolift.

Regarding causation, Dr. Reinardy testified in his deposition that had he known about information contained in the proposed language to be added to Prolift's IFU or some of the risks identified in Dr. Elliott's expert report that were not included in Prolift's IFU, such as the risk that the inflammatory reaction caused by implanting Prolift could be severe and chronic causing permanent pain to the patient, he would not have recommended Prolift to Nelson and would have treated her conditions through other means. Reinardy Dep. at 44:1–22, 51:7–53:25, Dkt. No. 12-1 at 11, 13–14.

Ethicon argues that Dr. Reinardy's testimony is not sufficient to create a material dispute of fact for two reasons: 1) Dr. Reinardy testified that Prolift's IFU informed him and warned of each complication that Nelson alleges she suffered as a result of having a Prolift implanted; and 2) Dr. Reinardy's responses to hypothetical questions during his deposition are not admissible evidence. When asked, "Were there any complications that Ms. Nelson experienced that are not listed in the [IFU] that you're aware of," Dr. Reinardy responded, "None that I'm aware of." *Id.* at 111:4–7, Dkt. No. 12-1 at 28. But Dr. Reindary also testified in response to hypothetical questions that if he had known about the risks identified in those hypotheticals or the proposed Prolift IFU language, he would not have recommended that Nelson have a Prolift implanted nor would he have recommended it to anybody:

> Q: Had you known in May of 2009, before Ms. Nelson's surgery, what you know today about all of the potential risks associated with the Prolift, would you have recommended the use of the Prolift mesh to Kay Nelson?
>
> [Objection by opposing counsel as to form]
>
> A: The answer is no. What I know today, I wouldn't recommend it in anybody.

Id. at 41:22–42:4, Dkt. No. 12-1 at 11. And Nelson testified that she made her decision to have the Prolift implanted based on the recommendation of Dr. Reinardy. Nelson Depo. at 45:3–7, Dkt. No. 12-1 at 155.

> The standard for causation in strict products liability cases is: whether the defect was a substantial factor in producing the injury . . . . "It need not be the sole factor or the primary factor, only a 'substantial factor.' The phrase 'substantial factor' denotes that the defendants conduct has such an effect in producing the harm as to lead the trier of fact, as a reasonable person, to regard it as a cause, using that word in the popular sense. There may be several substantial factors contributing to the same result."

Tanner v. Shoupe, 228 Wis. 2d 357, 368–69, 596 N.W.2d 805 (Ct. App. 1999) (quoting *Sumnicht v. Toyota Motor Sales, U.S.A., Inc.*, 121 Wis. 2d 338, 358, 360 N.W.2d 2 (1984)). Evidence that the inclusion of language warning of known risks or hazards would alert a doctor's prescribing decisions can establish cause in a failure to warn claim. *See Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968–69 (E.D. Wis. 2009). There is also a question of the significance of the risks Ethicon noted in the IFU. Ethicon seems to assume that the mere mention of a possible side effect is sufficient to insulate it from liability for failure to warn. But if the frequency of the risk is greater than disclosed, the failure to so state can also give rise to liability. Consequently, based on Dr. Reinardy's testimony that the inclusion of this information would have affected his decision, and consequently Nelson's decision, regarding the use of Prolift, a reasonable jury viewing the evidence in a light most favorable towards the plaintiff could conclude that Nelson would not have sustained her injuries but for Ethicon's failure to warn about known side effects and hazards.

Ethicon's arguments that Dr. Reinardy's responses to hypothetical questions are not admissible evidence are unsubstantiated. Regarding the lack of foundation for the hypothetical question, a hypothetical question "must be based on assumptions that have some support in the

evidence," though it is not necessary that those assumptions be "uncontroverted." *Schulz v. St. Mary's Hospital*, 81 Wis. 2d 638, 652, 260 N.W.2d 783 (1978). Here, the hypothetical questions are supported by the expert testimony of Dr. Elliott regarding particular known risks and hazards that Ethicon knew about. Regarding relevance, Dr. Reinardy's responses are relevant as they go to causation and whether he would have still used or recommended Prolift to Nelson had he known about these particular side effects.

2. Negligent Failure to Warn Claim

For the same reasons, there is also a dispute of fact regarding Ethicon's failure to warn as it relates to Nelson's negligence claim. "In order to grant summary judgment on a negligence claim, a court must be able to say 'that no properly instructed, reasonable jury could find based on the facts presented that the defendant failed to exercise ordinary care.'" *Michaels v. Mr. Heater, Inc.*, 411 F. Supp. 2d 992, 1007 (W.D. Wis. 2006) (quoting *Lambrecht v. Estate of Kaczmarczyk*, 2001 WI 25, ¶ 2, 241 Wis. 2d 804, 623 N.W.2d 751). "Such scenarios are uncommon, though not nonexistent." *Id.* To the extent Nelson argues the negligence claim is duplicative of the strict liability claim, "negligence and strict liability are separate avenues of recovery." *Morden v. Cont'l AG*, 2000 WI 51, ¶ 42, 235 Wis. 2d 325, 611 N.W.2d 659. Consequently, as there is a material dispute of fact as to whether Ehticon's failure to warn caused Nelson's injuries, Ethicon's motion is denied with respect to Nelson's failure-to-warn claims.

C. Count VI - Common Law Fraud

Ethicon asserts, that because it warned of the side effects Nelson alleges to have suffered and Dr. Reinardy was independently aware of those side effects, Nelson cannot prove that it made a false misrepresentation. "To prove fraud under Wisconsin law, a plaintiff must demonstrate: 1)

a misrepresentation; 2) intent to defraud; 3) reliance upon the false representations; and 4) damages." *Forst*, 602 F. Supp. 2d at 971 (E.D. Wis. 2009) (citing *Mackenzie v. Miller Brewing Co.*, 2001 WI 23, ¶ 18, 241 Wis. 2d 700, 623 N.W.2d 739). Nondisclosure is actionable as a misrepresentation when there is a duty to disclose. *Tietsworth v. Harley-Davidson, Inc.*, 2004 WI 32, ¶ 12, 270 Wis. 2d 146, 677 N.W.2d 233 (citing *Ollerman v. O'Rourke Co., Inc.*, 94 Wis. 2d 17, 26, 288 N.W.2d 95 (1980)). "Civil liability for misrepresentation exists when it is 'foreseeable and intended that a fraudulent misrepresentation will be repeated to third parties and acted upon by them.'" *Forst*, 602 F. Supp. 2d at 971 (quoting *State v. Timblin*, 2002 WI App 304, ¶ 31, 259 Wis. 2d 299, 657 N.W.2d 89).

As discussed earlier, there is a genuine issue of material fact as to whether Nelson and Dr. Reinardy relied on Ethicon's alleged misrepresentations and had they known about side effects that were not disclosed they would have altered their decision regarding the Prolift device. It is reasonable for physicians and their patients to rely on information provided by the manufacturer of a medical device. *See id. at* 971–72 ("It is wholly foreseeable to a drug manufacturer that its prescribing and side effect information will be communicated to and relied upon by patients, even when the drug company only interacts directly with prescribing physicians and not patients. Though [the drug manufacturer] made no direct representations to the plaintiffs, the plaintiffs based their decision regarding [the medication] on the information and advice of [the prescribing physician] . . . . This information in turn, was based upon [the drug manufacturer's] representations."). And Ethicon has "an obligation to warn consumers about the hidden dangers of their products." *Burton*, 334 F. Supp. 3d at 962 (quoting *Godoy*, 2009 WI 78, ¶ 36 n.5); RESTATEMENT (SECOND) OF TORTS & 402A, cmt. h ("Where . . . [a manufacturer] has reason to

anticipate that a danger may result from a particular use, . . . he may be required to give adequate warning of the danger, and a product sold without such warning is in defective conditions."). Accordingly, Ethicon's motion will be denied as it relates to Nelson's fraud claim.

D. Count IX - Negligent Misrepresentation

Ethicon contends that Nelson's negligent misrepresentation claim should be dismissed because it is duplicative of the failure to warn claim and Nelson cannot establish that Ethicon made an untrue representation of fact. "[U]nder Wisconsin law, negligent misrepresentation has four elements: (1) a representation of fact made by the defendant, (2) the representation of fact is untrue, (3) the defendant was negligent in making the representation of fact, and (4) plaintiff's belief that the representation was true and reliance thereupon to plaintiff's damage." *Chevron Chem. Co. v. Deloitte & Touche*, 168 Wis. 2d 323, 331–32, 483 N.W.2d 314 (Ct. App. 1992), *aff'd and remanded*, 176 Wis. 2d 935, 501 N.W.2d 15 (1993). As discussed earlier, the nondisclosure here is actionable as a misrepresentation. Additionally, the claim is not duplicative of Nelson's failure to warn claim as Nelson, relying on Dr. Elliott's expert report, alleges Ethicon made affirmative misrepresentations about the Prolift product—such as that the Prolift mesh system will restore normal function—and not just that Ethicon omitted information, as is the case with Nelson's failure-to-warn claims. Consequently, Ethicon's motion will be denied with respect to Nelson's negligent misrepresentation claim.

E. Nelson's Motion for Leave to File Sur-Reply Brief or Alternatively Strike Ethicon's New Arguments and Authority and Ethicon's Motion To Strike Nelson's Notice of Supplemental Authority and Proposed Sur-Reply Brief

Nelson filed a motion to file a sur-reply to Ethicon's reply brief or in the alternative strike portions of Ethicon's reply because Ethicon raised new arguments and authority in support of its

motion. Nelson also filed a notice of supplemental authority. Ethicon subsequently filed a motion to strike's Nelson's motion and notice of supplemental authority. In order to avoid further delay and costs, and because the court is able to resolve Ethicon's motion based on the briefs, the motions will be denied.

CONCLUSION

For the foregoing reasons, Ethicon's Motion for Partial Summary Judgment (Dkt. No. 10) is **GRANTED-IN-PART** and **DENIED-IN-PART**. The motion is **GRANTED** with respect to all claims associated with the implantation of the TVT-O-Obturator product and Counts II, IV, VII, VIII, X, XI, XII, XIII, and XV as they relate to the Prolift product and **DENIED** in all other respects. Nelson's Motion For Leave to File a Sur-Reply or Alternatively Strike Ethicon's New Arguments and Authority (Dkt. No. 21) and Ethicon's Motion to Strike Plaintiff's Notice of Supplemental Authority and Plaintiff's "Response" to Motion for Partial Summary Judgment (Dkt. No. 32) are **DENIED**. The Clerk is directed to schedule a telephone conference to discuss the status of the remaining pending motions, Dkt. Nos. 14, 18, and 25.

SO ORDERED this 15th day of July, 2019.

s/ William C. Griesbach
William C. Griesbach, Chief Judge
United States District Court