

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

U.S. DISTRICT COURT
DISTRICT OF VERMONT
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JACINTA LEAVITT and PAUL LEAVITT,)
)
Plaintiffs,)
)
v.)
)
ETHICON, INC. and)
JOHNSON & JOHNSON,)
)
Defendants.)

Case No. 2:20-cv-00176

**OPINION AND ORDER GRANTING IN PART AND DENYING IN PART
DEFENDANTS’ MOTION FOR PARTIAL SUMMARY JUDGMENT**
(Doc. 28)

This case arises out of alleged injuries suffered by Plaintiff Jacinta Leavitt (“Plaintiff J. Leavitt”) following the implantation of tension-free vaginal tape (“TVT”) for the treatment of her stress urinary incontinence. Plaintiff Paul Leavitt (“Plaintiff P. Leavitt”) is Plaintiff J. Leavitt’s husband.

Plaintiffs assert eighteen counts against Defendants Ethicon, Inc. (“Ethicon”) and Johnson & Johnson: (1) negligence (Count I); (2) strict liability for manufacturing defect (Count II); (3) strict liability for failure to warn (Count III); (4) strict liability for a defective product (Count IV); (5) strict liability for design defect (Count V); (6) common law fraud (Count VI); (7) fraudulent concealment (Count VII); (8) constructive fraud (Count VIII); (9) negligent misrepresentation (Count IX); (10) negligent infliction of emotional distress (Count X); (11) breach of express warranty (Count XI); (12) breach of implied warranty (Count XII); (13) violation of consumer protection laws (Count XIII); (14) gross negligence (Count XIV); (15) unjust enrichment (Count XV); (16) loss of consortium (Count XVI); (17) punitive damages (Count XVII); and (18) discovery rule and tolling (Count XVIII).

This case was originally filed on January 14, 2014 as part of a multi-district litigation in the United States District Court for the Southern District of West Virginia before the Honorable Joseph H. Goodwin. On November 3, 2020 the case was transferred to the United States District Court for the District of Vermont.

Pending before the court is Defendants' motion for partial summary judgment filed on October 29, 2019 requesting judgment as a matter of law on all claims with the exception of Plaintiffs' strict liability for design defect, loss of consortium, punitive damages, and discovery rule and tolling claims, as well as Plaintiffs' negligence and negligent infliction of emotional distress claims to the extent that they are based on a design defect. (Doc. 28.) Plaintiffs opposed Defendants' motion on November 15, 2019. Defendants did not file a reply. Oral argument was held on February 10, 2021, after which the court took the pending motion under advisement.

Plaintiffs are represented by D. Michael Noonan, Esq., Kenneth J. Brennan, Esq., Maxwell S. Kennerly, Esq., Steven D. Davis, Esq., and Tyler J. Schneider, Esq. Defendants are represented by James M. Campbell, Esq., and Kathleen M. Guilfoyle, Esq.

I. The Undisputed Facts.

At all relevant times, Plaintiffs were residents of Vermont. On August 28, 2009, Jane Lowell, MD, performed surgery on Plaintiff J. Leavitt in Vermont to implant TVT to treat Plaintiff J. Leavitt's stress urinary incontinence.

Plaintiff J. Leavitt testified that prior to the surgery she thinks she saw a TVT brochure but that she did not rely on that brochure in connection with her decision to undergo the surgery. When asked if she relied on the TVT brochure, she testified "[n]o. I relied on her[.]" (Doc. 29 at 2) referring to Dr. Lowell.

Dr. Lowell testified in deposition that she does not recall reading Defendant Ethicon's TVT Instructions for Use ("IFU") but that she might have looked at it "maybe once as a resident[.]" (Doc. 28-1 at 68.) She stated that "reading a really long thing that's put out by the manufacturer, you know, the reality is [it's] not super helpful." (Doc. 29 at 3) (alteration in original) (internal quotation marks omitted). She further testified:

Q. . . . Plaintiff's counsel was asking you some questions about the instructions for use and I believe you testified, you know, you may have read it, but you don't remember the last time you read the IFU; is that right?

A. That's true.

Q. So you didn't rely on the IFU to discuss risks of the mesh procedure with Miss Leavitt?

A. No definitely not.

Q. Did you rely on any statements made by Ethicon to discuss risks with Miss Leavitt?

A. No. It would have all been based on what I had seen in my training.

(Doc. 28-1 at 74.)

Dr. Lowell acknowledged that she would typically give her patients the TVT brochure:

Q. Do you normally give patients a brochure about TVT?

A. Yes.

...

Q. Would you go over – you know would you hand that brochure to a patient and then go through it with her?

A. Yes. Not maybe with me standing there by the picture, but I'm a pretty descriptive person.

...

Q. . . . Fair to say that any risk information that you get from any source is going to go into that pool of information that helps you as a physician to make an informed decision with your patient?

A. Yes.

Q. And that's true if you read the IFU about the risks in there?

A. Yes.

Q. And that's true about the risks that were in the brochures that you read when you handed them to your patients. Is that true?

A. Yes.

Id. at 58, 70, 75.

Sometime after implantation of the TVT, Plaintiff J. Leavitt underwent two surgeries to remove or revise the TVT, both of which were performed by Mary

Wakamatsu, MD, in Massachusetts.

II. Conclusions of Law and Analysis.

A. Standard of Review.

Summary judgment must be granted when “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). “A fact is ‘material’ . . . if it ‘might affect the outcome of the suit under the governing law.’” *Rodriguez v. Vill. Green Realty, Inc.*, 788 F.3d 31, 39 (2d Cir. 2015) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). “A dispute of fact is ‘genuine’ if ‘the evidence is such that a reasonable jury could return a verdict for the nonmoving party.’” *Id.* at 39-40 (quoting *Anderson*, 477 U.S. at 248). The court “constru[es] the evidence in the light most favorable to the nonmoving party and draw[s] all reasonable inferences in his favor.” *McElwee v. Cnty. of Orange*, 700 F.3d 635, 640 (2d Cir. 2012).

The moving party always “bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). When the moving party has carried its burden, its opponent must produce “sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party.” *Anderson*, 477 U.S. at 249. “A non-moving party cannot avoid summary judgment simply by asserting a ‘metaphysical doubt as to the material facts.’” *Woodman v. WWOR-TV, Inc.*, 411 F.3d 69, 75 (2d Cir. 2005) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). Moreover, not all disputes of fact are material, “[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Anderson*, 477 U.S. at 249-50 (citations omitted).

“The function of the district court in considering the motion for summary judgment is not to resolve disputed questions of fact but only to determine whether, as to any material issue, a genuine factual dispute exists.” *Kaytor v. Elec. Boat Corp.*, 609 F.3d

537, 545 (2d Cir. 2010). “Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.” *Proctor v. LeClaire*, 846 F.3d 597, 608 (2d Cir. 2017) (internal quotation marks omitted). The court may, however, grant judgment as a matter of law if the essential elements of a claim have not been established or if a rational fact finder could not find in a party’s favor. *See Celotex Corp.*, 477 U.S. at 323 (holding that “[t]he moving party is entitled to a judgment as a matter of law [if] the nonmoving party [fails] to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof”) (internal quotation marks omitted); *see also Matsushita Elec. Indus. Co.*, 475 U.S. at 587 (ruling that “[w]here 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”) (internal quotation marks omitted).

B. Vermont Law Applies.

“Under the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law.” *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427 (1996). To determine which state substantive law applies, “a federal court exercising diversity jurisdiction must apply the choice-of-law rules of the state in which that court sits to determine the rules of decision that would apply if the suit were brought in state court.” *Liberty Synergistics Inc. v. Microflo Ltd.*, 718 F.3d 138, 151 (2d Cir. 2013). Because this case was brought in the District of Vermont, Vermont’s choice of law jurisprudence applies.

The Vermont Supreme Court “has adopted the Restatement (Second) of Conflicts for choice-of-law questions in both tort and contract cases.” *McKinnon v. F.H. Morgan & Co.*, 750 A.2d 1026, 1028 (Vt. 2000). “The general choice-of-law principle for tort cases is that the rights and liabilities of the parties are determined by the law of the state that ‘has the most significant relationship to the occurrence and the parties[.]’” *Id.* (quoting Restatement (Second) of Conflict of Laws § 145(1)). When a plaintiff is domiciled in Vermont, the state has a “significant interest in assuring proper compensation to the

victim because the ‘social and economic repercussions of personal injury’ will occur in plaintiff’s domicile.” *Miller v. White*, 702 A.2d 392, 396 (Vt. 1997).

Plaintiffs are Vermont residents and assert claims that arise out of a personal injury from TVT purchased and implanted in Vermont by a Vermont physician. Vermont therefore has the most significant relationship to their claims, the parties, and the incident. As a result, Vermont law governs Plaintiffs’ substantive claims.

C. Whether Defendants are Entitled to Partial Summary Judgment Because Plaintiffs Have Abandoned Certain Claims.

In opposing summary judgment, Plaintiffs have affirmatively abandoned certain claims.¹

Under the Federal Rules of Civil Procedure, a court:

may not grant [a summary judgment] motion without first examining the moving party’s submission to determine if it has met its burden of demonstrating that no material issue of fact remains for trial. If the evidence submitted in support of the summary judgment motion does not meet the movant’s burden of production, then summary judgment must be denied *even if no opposing evidentiary matter is presented*.

D.H. Blair & Co. v. Gottdiener, 462 F.3d 95, 110 (2d Cir. 2006) (emphasis in original) (quoting *Vermont Teddy Bear Co. v. 1-800 Beargram Co.*, 373 F.3d 241, 244 (2d Cir. 2004)). “The burden is always on the movant to demonstrate why summary judgment is warranted. The nonmoving party’s failure to oppose summary judgment does not shift that burden.” *Grimes v. District of Columbia*, 794 F.3d 83, 97 (D.C. Cir. 2015). However, “a partial response arguing that summary judgment should be denied as to some claims while not mentioning others may be deemed an abandonment of the unmentioned claims.” *Jackson v. Fed. Exp.*, 766 F.3d 189, 195 (2d Cir. 2014); *see also Ostroski v. Town of Southold*, 443 F. Supp. 2d 325, 340 (E.D.N.Y. 2006) (holding that “[b]ecause

¹ At oral argument Plaintiffs conceded they are not pursuing the following claims to the extent based on manufacturing defect: negligence (Count I); strict liability for manufacturing defect (Count II); strict liability for defective product (Count IV); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); and unjust enrichment (Count XV).

plaintiff's opposition papers did not address defendants' motion for summary judgment on [a] claim, [that] claim is deemed abandoned and summary judgment could be granted on that basis alone").

The Second Circuit has observed that:

“[p]leadings often are designed to include all possible claims or defenses, and parties are always free to abandon some of them.” And insofar as summary judgment “is known as a highly useful method of narrowing the issues for trial,” it follows that “preparation of a response to a motion for summary judgment is a particularly appropriate time for a non-movant party to decide whether to pursue or abandon some claims or defenses.” Accordingly, “[g]enerally, but perhaps not always, a partial response reflects a decision by a party’s attorney to pursue some claims or defenses and to abandon others,” and “a court may, when appropriate, infer from a party’s partial opposition that relevant claims or defenses that are not defended have been abandoned.” If a district court so holds, it “should . . . include a finding of abandonment of undefended claims or defenses.”

Kovaco v. Rockbestos-Surprenant Cable Corp., 834 F.3d 128, 143 (2d Cir. 2016)

(quoting *Jackson*, 766 F.3d at 196, 198) (alterations in original) (internal footnotes and citations omitted).

In light of Plaintiffs’ unequivocal abandonment of certain claims, Defendants’ partial motion for summary judgment on Counts I, X, and XIV to the extent that they are based on manufacturing defect and on Counts II, IV, VI, VII, VIII, IX, XI, XII, XIII, and XV is GRANTED.

D. Whether Defendants are Entitled to Summary Judgment on Plaintiffs’ Failure to Warn Claims Under the Learned Intermediary Doctrine.

Defendants seek partial summary judgment to the extent Plaintiffs’ remaining claims² are based on a “failure to warn” theory because Plaintiff cannot establish causation. They argue that Vermont is likely to adopt the learned intermediary doctrine and, if it applies, Dr. Lowell testified she did not rely on any statements made by Defendant Ethicon in discussing the risks of TVT implantation with Plaintiff J. Leavitt.

² Negligence to the extent that claim is based on failure to warn (Count I); strict liability for failure to warn (Count III); negligent infliction of emotional distress based on failure to warn (Count X); and gross negligence based on failure to warn (Count XIV).

Under Vermont law, to establish a “failure to warn” claim, a “plaintiff must provide evidence from which a reasonable jury could find: (1) that defendant owed a duty to warn plaintiff; (2) lack of warning made the product unreasonably dangerous, hence defective; and (3) defendant’s failure to warn was the proximate cause of plaintiff’s injury.” *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995) (citing *Menard v. Newhall*, 373 A.2d 505, 506 (Vt. 1977)). Under the learned intermediary doctrine, a product or device manufacturer may provide warnings to a patient’s physician, and need not provide warnings directly to the patient:

The learned intermediary doctrine states that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as “learned intermediaries” between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient’s needs and assess risks and benefits of a particular course of treatment.

Vitanza v. Upjohn Co., 48 F. Supp. 2d 124, 127 (D. Conn. 1999), *aff’d*, 271 F.3d 89 (2d Cir. 2001).

Defendants acknowledge that the Vermont Supreme Court has not adopted the learned intermediary doctrine³ and urge this court to predict that it would do so if presented with an appropriate case. Plaintiffs argue it is unnecessary to determine whether the learned intermediary doctrine applies at this time because even if it applies, Defendant Ethicon failed to provide adequate warnings to Dr. Lowell and there are disputed issues of fact as to whether she relied on those warnings in advising Plaintiff J. Leavitt of the risks and benefits of TVT implantation.

“Where the substantive law of the forum state is uncertain or ambiguous, the job of the federal courts is carefully to predict how the highest court of the forum state would resolve the uncertainty or ambiguity.” *Travelers Ins. Co. v. 633 Third Assocs.*, 14 F.3d 114, 119 (2d Cir. 1994). This court predicts that the Vermont Supreme Court is likely to adopt the learned intermediary doctrine for three reasons.

³ “The learned intermediary doctrine has not been accepted or rejected by the Vermont Supreme Court.” *Drake v. Allergan, Inc.*, 63 F. Supp. 3d 382, 390 (D. Vt. 2014).

First, where Vermont law is undeveloped, the Vermont Supreme Court frequently looks to the Restatement for guidance. *See Birchwood Land Co. v. Krizan*, 2015 VT 37, ¶ 9, 198 Vt. 420, 425, 115 A.3d 1009, 1012 (“We frequently have adopted provisions of this Restatement where our law is undeveloped.”). The Restatement (Third) of Torts has adopted the learned intermediary doctrine as follows:

[a] medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: . . . prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings[.]

Restatement (Third) of Torts: Prods. Liab. § 6(d) (1998). Pursuant to this doctrine, “a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider[.]” *Id.* at § 6, cmt. e.

Second, forty-eight states have adopted, or a federal court has predicted the state’s highest court would adopt, the learned intermediary doctrine.⁴ Because the overwhelming

⁴ The United States District Court for the Southern District of West Virginia conducted a survey of all fifty state laws in 2014 and reported the following:

In 2012, the Texas Supreme Court counted thirty-five states, including the District of Columbia, in which the high court has “adopted some form of the learned intermediary doctrine within the prescription drug products-liability context” or that has at least “cited favorably to its application within this context.” *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 158 n.17 (Tex. 2012). I have confirmed this number. In addition, state intermediate courts or federal courts of thirteen other states have applied the learned intermediary doctrine or predicted that the highest state court would apply it. *See Piper v. Bear Med. Sys., Inc.*, 180 Ariz. 170, 883 P.2d 407, 415 (Ariz. Ct. App. 1993); *O’Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281-82 (Colo. App. 2010); *Ortho Pharm. Corp. v. Chapman*, 180 Ind. App. 33, 388 N.E.2d 541, 549 (1979); *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) (intimating that the doctrine is part of Iowa’s common law); *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79-80 (La. Ct. App. 1994); *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir.1995) (applying the doctrine under Maine law); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991); *Nelson v. Dalkon Shield Claimants Trust*, No. 84-276-sd, 1994 WL 255392, at *4 (D.N.H. June 8, 1994); *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 535-36 (E.D.N.C. 1987); *Harris v. McNeil Pharm.*, No. 3:98-cv-105, 2000 WL 33339657, at *4 n. 4 (D.N.D. Sept. 5, 2000); *In re Zyprexa Prods. Liab. Litig.*, 277 F.R.D. 243, 250 (E.D.N.Y. 2011) (predicting that the Rhode Island Supreme Court would adopt the “general and statutory law in this country”);

majority of the courts have embraced the learned intermediary doctrine, the Vermont Supreme Court is likely to do so as well. *See Dernier v. Mortg. Network, Inc.*, 2013 VT 96, ¶ 29, 195 Vt. 113, 123-24, 87 A.3d 465, 473 (relying on decisions by other states to decide an issue of first impression under Vermont contract law because “[w]hile we have never so held, courts in other states have qualified this strong proposition in the case of assignment of debts, [w]e agree with this reasoning.”); *Staruski v. Cont’l Tel. Co. of Vt.*, 581 A.2d 266, 268 (Vt. 1990) (observing that “invasion of privacy” as recognized by the Restatement (Second) of Torts was a cause of action “in virtually all jurisdictions[]” and noting that Vermont was joining “other states” in its recognition).

And third, the learned intermediary doctrine reflects the realities of patient consultations and identifies the best source of information regarding the risks and benefits of a particular device or procedure for a particular patient. As the Restatement observes:

The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider’s prescription traditionally has required warnings directed to health-care providers and not to patients. The rationale supporting this “learned intermediary” rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.

...

The traditional refusal by courts to impose tort liability for defective

McElhaney v. Eli Lilly & Co., 575 F.Supp. 228, 231 (D.S.D. 1983); *Lukaszewicz et al. v. Ortho Pharm. Corp.*, 510 F.Supp. 961, 963 (E.D. Wis. 1981).

This brings the total number of states employing some iteration of the learned intermediary doctrine to forty-eight (including D.C.), with the exceptions being Vermont, *see Kellogg v. Wyeth*, 762 F.Supp.2d 694, 700 (D. Vt. 2010) (asserting that Vermont has neither adopted nor rejected the learned intermediary doctrine), New Mexico, *see Rimbart v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1214-24 (D.N.M. 2008) (predicting that the Supreme Court of New Mexico would not adopt the learned intermediary doctrine), and, of course, West Virginia.

Tyree v. Bos. Sci. Corp., 56 F. Supp. 3d 826, 828 n.3 (S.D.W. Va. 2014).

designs of prescription drugs and medical devices is based on the fact that a prescription drug or medical device entails a unique set of risks and benefits. What may be harmful to one patient may be beneficial to another.

Restatement (Third) of Torts: Prods. Liab. § 6, cmt. b (1998). The “learned intermediary doctrine” does not apply “in certain limited therapeutic relationships [where] the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly.” *Id.* For example, “[w]hen a manufacturer supplies prescription drugs for distribution to patients in [an] unsupervised environment, if a direct warning to patients is feasible and can be effective, the law requires measures to that effect.” *Id.* at § 6, cmt. e. The court predicts that the Vermont Supreme Court would find the Restatement’s rationale persuasive especially where, as here, a plaintiff claims she relied exclusively on her physician’s warnings regarding the risks and benefits of TVT implantation.

Because the learned intermediary doctrine bars Plaintiffs’ negligence, strict liability, negligent infliction of emotional distress, and gross negligence failure to warn claims to the extent they are based on Defendants’ failure to directly warn Plaintiff J. Leavitt, Defendants’ motion for partial summary judgment with regard to those claims is GRANTED.

E. Whether Plaintiff J. Leavitt Fails to Establish Causation.

Defendants argue that they are entitled to summary judgment on Plaintiff J. Leavitt’s remaining failure to warn claims because even if she can establish the first two elements of failure to warn, that Defendants owed a duty to warn and that lack of warning rendered TVT unreasonably dangerous, she cannot establish causation because Dr. Lowell neither read nor relied upon Defendant Ethicon’s warnings. Plaintiffs counter that Dr. Lowell’s testimony was equivocal, creating a genuine issue of material fact.

Pursuant to Vermont law:

[p]roximate cause in [failure to warn] cases is typically shown by means of a presumption. If a plaintiff can demonstrate that the manufacturer had a duty to warn and failed to provide an adequate warning, a causal

presumption arises that had an adequate warning been provided, the user would have read and heeded the warning and the accident would have been avoided.

Town of Bridport v. Sterling Clark Lurton Corp., 693 A.2d 701, 704 (Vt. 1997); *see also Menard*, 373 A.2d at 506 (holding that after a plaintiff establishes a duty to warn and that inadequate warnings were provided, “a presumption is created that the [person to whom the warnings were directed] would have read the warning and heeded it”).

Correspondingly, if it is established that warnings would be futile because the person would have ignored them, “the presumption disappear[s] and there [is] no genuine issue of fact as to causation.” *Menard*, 373 A.2d at 507. “Thus, if the manufacturer can show that the user was warned of the risk and chose to ignore the warning, the presumption disappears, because ‘there is no reasonable basis to assume that the user would have heeded a warning from the manufacturer.’” *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 701 (D. Vt. 2010) (quoting *Town of Bridport*, 693 A.2d at 704).⁵

Defendants argue that under the learned intermediary doctrine, a physician’s

⁵ Although in *Town of Bridport*, the Vermont Supreme Court held that failure to read warnings did not negate causation, in that case it noted that “plaintiff squarely raised the conspicuousness of the warnings as an issue; . . . [and] argued that the warnings were inadequate in both form and content.” *Town of Bridport v. Sterling Clark Lurton Corp.*, 693 A.2d 701, 705 (Vt. 1997). It distinguished those facts from cases in which the challenge was solely to the content of the warning, not to its form:

[d]efendant points to several cases in which courts have held that a user’s failure to read a warning removed any causal connection between the inadequacy of the warning and the accident. In those cases, however, the conspicuousness of the warning was not at issue. *See, e.g., Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir.1981) (where physician testified that he already knew of risk associated with flu vaccine, and did not inform patients of warnings accompanying vaccines, manufacturer was not liable for failure to warn); *Bloxom v. Bloxom*, 512 So. 2d 839, 850-51 (La. 1987) (auto manufacturer had duty to warn of danger in manual, but as owner of car never looked at or read manual, manufacturer was insulated from liability for its failure to do so); *Felice v. Valleylab, Inc.*, 520 So. 2d 920, 926-27 (La.Ct.App.1987) (manufacturer of electrosurgical unit should have warned of danger of using machine on small appendages, but as doctor never read manual or warning on machine, adequate warning would have been futile).

Id. at 705. In this case, there is no claim that Defendants’ warnings were inconspicuous.

failure to read or rely on the device’s warning breaks the causal chain. *See Felan v. Bos. Sci. Corp.*, 2015 WL 2137180, at *4 (S.D.W. Va. May 7, 2015) (holding “a physician’s failure to rely on a product’s [IFU] may preclude a finding of causation”); *In re C.R. Bard, Inc.*, 2013 WL 2949033, at *3 (S.D.W. Va. June 14, 2013) (granting summary judgment on failure to warn claim where learned intermediary did not read the IFU, based on the “vast body of case law among many jurisdictions holding that there is no proximate cause where a warning—albeit ostensibly inadequate—was never read”); *Marie Renteria v. Ethicon, Inc.*, 2020 WL 7414744, at *7 (C.D. Cal. Nov. 18, 2020) (holding “[w]here a physician did not read the manufacturer’s product warnings, there is no causal connection on the failure to warn claim as a matter of law”); *Paseka v. Ethicon Inc.*, 2020 WL 8175427, at *5 (D. Ariz. Nov. 9, 2020) (concluding that after the defendants introduced evidence that the plaintiff’s treating physician never read the IFU, “it was [p]laintiff’s burden to produce evidence that [d]efendants’ failure to warn proximately caused Plaintiff’s injuries”); *Russell v. Ethicon, Inc.*, 2020 WL 5993774, at *6 (M.D. Pa. Oct. 9, 2020) (finding that a “[treating physician’s] admissions that he does not recall reading the IFU and that he does not use the IFU when consenting patients are fatal to this particular claim”).

Dr. Lowell testified that she looked at the IFU “maybe once as a resident” (Doc. 28-1 at 68) and that she “definitely[,]” *id.* at 74, did not rely on it in discussing TVT implantation with Plaintiff J. Leavitt because “[it’s] not super helpful” to “read[] a really long thing that’s put out by the manufacturer[.]” (Doc. 29 at 3) (first alteration in original). Because Dr. Lowell did not read or rely on the IFU, there is no “reasonable basis to assume” that she “would have heeded a [different] warning from the manufacturer” contained therein. *Town of Bridport*, 693 A.2d at 704; *see also Lewis v. Johnson & Johnson*, 601 F. App’x 205, 208 (4th Cir. 2015) (affirming a grant of summary judgment because the plaintiff “presented no evidence that [her physician] relied on the warning in Ethicon’s patient brochure in deciding to prescribe the TVT”). Plaintiffs’ argument that Dr. Lowell further testified that everything she read from “any source” would “go into [the] pool of information that helps [her] as a physician to make

an informed decision[.]” (Doc. 37 at 5), does not alter that conclusion because Dr. Lowell was not referring specifically to Defendants’ IFU and because no rational fact finder could conclude she relied on an IFU that she cannot confirm she even read. *See Matsushita Elec. Co.*, 475 U.S. at 587. Defendants’ motion for partial summary judgment on Plaintiffs’ failure to warn claims is therefore GRANTED to the extent that those claims rely on the IFU.

In contrast, Dr. Lowell acknowledged that she would have provided Defendant Ethicon’s TVT brochure to Plaintiff J. Leavitt and that she typically discussed the information in the brochure as well as the risks identified therein with her patients. When viewed in the light most favorable to Plaintiffs, this raises a genuine issue of material fact regarding the causal connection between an alleged failure to warn in the TVT brochure and Plaintiffs’ injuries. *See Fritzeen v. Trudell Consulting Eng’rs, Inc.*, 751 A.2d 293, 297 (Vt. 2000) (holding that “[p]roximate cause is ordinarily an issue to be resolved by the jury unless the proof is so clear that reasonable minds cannot draw different conclusions or where all reasonable minds would construe the facts and circumstances one way”) (quoting *Roberts v. State*, 514 A.2d 694, 696 (Vt. 1986)) (internal quotation marks omitted). Defendants’ motion for partial summary judgment on Plaintiffs’ failure to warn claims to the extent those claims rely on the TVT brochure is therefore DENIED.

CONCLUSION

For the foregoing reasons, Defendants’ motion for partial summary judgment is GRANTED as to Plaintiffs’ abandoned claims as set forth in Counts I, X, and XIV to the extent that they are based on manufacturing defect and Counts II, IV, VI, VII, VIII, IX, XI, XII, XIII, and XV; GRANTED as to Counts I, III, X, and XIV to the extent they are based on failure to directly warn Plaintiff J. Leavitt under the learned intermediary doctrine; GRANTED to the extent that Counts I, III, X, and XIV are based on failure to warn in the IFU; and DENIED to the extent they are based on failure to warn in the TVT brochure. (Doc. 28.)
SO ORDERED.

Dated at Burlington, in the District of Vermont, this ^{9th} day of March, 2021.



Christina Reiss, District Judge
United States District Court