UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SHEILA MONGEON, **Plaintiff,** **v.** **ETHICON, INC., ETHICON, LLC, and JOHNSON & JOHNSON,** **Defendants.**	**CIVIL ACTION NO. 4:20-40024-TSH**

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT (Docket No. 21)

April 27, 2020

HILLMAN, D.J.

Sheila Mongeon ("Plaintiff") filed the instant action as part of an MDL against, *inter alia*, Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively, "Defendants"). She seeks to recover for complications associated with the implantation of Defendants' TVT-Secur mid-urethral sling. Defendants move for partial summary judgment. For the reasons set forth below, the Court ***grants in part*** and ***denies in part*** their motion (Docket No. 21).

Background[1]

Plaintiff suffers from stress urinary incontinence. In 2008, Dr. C. Scott Koenig ("Dr. Koenig") recommended that Plaintiff have a TVT-Secur mid-urethral sling (a "TVT-S") surgically implanted to treat the condition. He generally discussed the risks and complications of the

[1] The Court views "the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Scanlon v. Dep't of Army*, 277 F.3d 598, 600 (1st Cir. 2002) (citation and internal quotation marks omitted).

procedure with Plaintiff.[2] Plaintiff consented to it, and on February 9, 2009, Dr. Koenig performed surgery to implant a TVT-S in her urethra. Five years later, Dr. Christine Carey observed erosion in the TVT-S where it had penetrated Plaintiff's vaginal mucosal tissue. Plaintiff had the device removed, and her surgeon reported that the TVT-S had completely penetrated her vaginal mucosal tissue.

Plaintiff filed the instant action in the MDL on January 8, 2015. She raises 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); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII).

The parties deposed Dr. Koenig in September 2018. At the time, Dr. Koenig testified that, even accounting for everything he had since learned about the potential risks and benefits of TVT-S, he stood by his decision to recommend it to Plaintiff in 2009. (Docket Nos. 21-1 at 18, 26, 49; 23-5 at 12, 20, 43). He further stated that he believed he had adequately disclosed the risks and benefits to Plaintiff—including the risk of mesh erosion and dyspareunia. (Docket Nos. 21-1 at 22, 26; 23-5 at 16, 20). During cross-examination, however, Dr. Koenig admitted that, although

[2] The parties dispute whether he specifically identified the risk of chronic pain, dyspareunia (painful intercourse), or mesh erosion. (Docket Nos. 21-1 at 22; 23-4 at 42–43, 44; 23-5 at 16). But viewing the facts in the light most favorable to Plaintiff, the Court assumes he did not. *See Scanlon*, 277 F.3d at 600.

he was aware of these risks, he did not view them as significant. (Docket Nos. 21-1 at 41, 23-5 at 35). And he stated that, had the Instructions for Use for TVT-S identified mesh erosion or permanent dyspareunia as a significant risk, he would have disclosed that information to Plaintiff. (Docket Nos. 21-1 at 41, 23-5 at 35). Dr. Koenig also indicated that he would not have used a TVT-S in Plaintiff's case if he had known about the inferior patient reported outcomes and higher reoperation rates experienced by other doctors. (Docket Nos. 21-1 at 44, 23-5 at 38).

In her deposition, Plaintiff denied being informed of the risk of mesh erosion, chronic pain, or dyspareunia prior to her surgery. (Docket No. 23-4 at 42–43, 44). She testified that, if she had known that TVT-S could cause these conditions, she would not have agreed to the procedure.[3] (Docket No. 23-4 at 42–43).

On October 16, 2018, Defendants moved for summary judgment on Counts II, III, IV, V, VI, VII, VIII, IX, X, XII, XIII, and XV[4] and for partial summary judgment on Counts I and XIV. (Docket No. 21).

Legal Standard

Under Federal Rule of Civil Procedure 56, a court "shall grant summary judgment 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." An issue is "genuine" when a reasonable factfinder could resolve it in favor of the nonmoving party. *Morris v. Gov't Dev. Bank of P.R.*, 27 F.3d 746, 748 (1st Cir. 1994). A fact is "material" when it may affect the outcome of the suit. *Id*.

[3] Dr. Koenig confirmed that other options available to Plaintiff at the time would not have carried the risk of mesh erosion or dyspareunia. (Docket Nos. 21-1 at 45, 23-5 at 39).

[4] Because Plaintiff does not oppose summary judgment on Counts II, III, IV, V, VI, VII, VIII, IX, X, XIII, or XV (Docket No. 24 at 4), the Court ***grants*** Defendants' motion as to these claims.

Discussion

1. Negligence (Counts I and XIV)[5,6]

"In Massachusetts,[7] a manufacturer can be found liable to a user of the product if the user is injured due to the failure of the manufacturer to exercise reasonable care in warning potential users of hazards associated with use of the product." *Laaperi v. Sears, Roebuck & Co.*, 787 F.2d 726, 729 (1st Cir. 1986) (footnote omitted). "In the ordinary course, the manufacturer of a product that is dangerous in nature or is in a dangerous condition has a duty to warn consumers or others who will foreseeably come in contact with the product." *Tersigni v. Wyeth-Ayerst Pharm., Inc*., No. 11-10466, 2013 WL 6531118, at *5 (D. Mass. Dec. 13, 2013). The learned intermediary rule, however, carves out a middleman exception in context of medical products.[8] *See Tersigni*, 2013

---

5 In addition to challenging Plaintiff's negligence claim on failure to warn grounds, Defendants contend that Plaintiff has not demonstrated the existence of a manufacturing defect. Based on her responsive pleading, however, the Court gathers that Plaintiff does not intend to argue the existence of a manufacturing defect. (Docket No. 24 at 7).

6 Defendants do not move for summary judgment on the portion of Plaintiff's negligence claim premised on the existence of a design defect. The Court accordingly does not address the merits of this claim in its analysis.

7 The parties agree that Massachusetts law governs the substance of Plaintiff's claims. (Docket Nos. 22 at 3–4, 24 at 6).

8 Plaintiff argues that the learned intermediary rule should not apply in this case given the guidance of *MacDonald v. Ortho Pharmaceutical Corporation*, 394 Mass. 131 (1985). The Court disagrees. In *MacDonald*, the Supreme Judicial Court declined to apply the learned intermediary rule to a failure to warn claim in a case involving oral contraceptives. *Id.* at 138. The Supreme Judicial Court determined that manufacturers should instead be directly liable to consumers, reasoning that "[t]he oral contraceptive . . . stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of 'the pill'; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points when alternative methods may be considered." *Id.* Plaintiff has not shown that the same considerations favor direct liability here. Patients are not particularly involved in the choice of which surgical device to implant—much of the choice is governed by which procedures a physician is trained to do or a hospital is able to

WL 6531118, at *5; *see also Knowlton v. Deseret Med., Inc*., 930 F.2d 116, 120 n.12 (1st Cir. 1991). It relieves "manufacturers of the duty to warn a patient of the possible side effects of a [product] where it has adequately informed the prescribing physician of any associated risks." *Haughton v. Hill Labs., Inc*., No. 06-11217, 2007 WL 2484889, at *2 (D. Mass. Aug. 30, 2007) (citing *MacDonald*, 394 Mass. at 135).

Defendants suggest that Plaintiff cannot establish causation in this case given the applicability of the learned intermediary rule. To determine whether a plaintiff can make a prima facie case of negligence despite imposition of the learned intermediary rule, courts uses a burden-shifting framework. *See Liu v. Boehringer Ingelheim Pharm., Inc*., 230 F. Supp. 3d 3, 8 (D. Mass. 2017). Under this framework,

> (1) the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known; (2) assuming the plaintiff raises a triable issue on this question, a rebuttable presumption arises that the physician would have heeded an adequate warning; (3) defendant must then come forward with sufficient evidence to rebut that presumption; and (4) once the presumption is rebutted, plaintiff must produce sufficient evidence to create a triable issue on the question of causation.

Id. at 8–9 (citations and internal quotation marks omitted).

Here, Plaintiff has met her initial burden. Defendants indisputably did not include any information on the risk of dyspareunia or mesh erosion in the Instructions for Use for the TVT-S. (Docket Nos. 21-1 at 41, 23-5 at 35). Plaintiff is therefore entitled to a rebuttable presumption that Dr. Koenig would have heeded an adequate warning if Defendants had provided one.[9] *See Garside v. Osco Drug, Inc*., 976 F.2d 77, 82 (1st Cir. 1992).

---

accommodate—and it is not feasible to expect them to receive direct instructions or warnings from the manufacturer where such a small subset of the population will qualify to use the device.

[9] As noted above, *see supra* note 2, the Court assumes for the purposes of this motion that Dr. Koenig did not disclose these risks to Plaintiff prior to surgery.

Defendants offer enough evidence to rebut this presumption. Dr. Koenig testified that, even accounting for everything he had subsequently learned about TVT-S, he stood by his decision to recommend it to Plaintiff in 2009. (Docket Nos. 21-1 at 26, 49; 23-5 at 20, 43). A reasonable juror could determine from this statement that Dr. Koenig would not have heeded additional warnings.

Summary judgment is inappropriate, however, because Plaintiff has produced enough evidence "to create a triable issue on the question of causation." *See Liu*, 230 F. Supp. 3d at 9. Plaintiff offers evidence casting doubt on the credibility of Defendant's rebuttal evidence. Dr. Koenig admitted, for example, that he would not have used a TVT-S implant on Plaintiff if he had known about the inferior patient reported outcomes and higher reoperation rates associated with the implant. (Docket Nos. 21-1 at 44, 23-5 at 38). He also conceded that, while he was aware of the risk of mesh erosion and dyspareunia through other sources, he did not view them as significant. (Docket Nos. 21-1 at 41, 23-5 at 35). Under the circumstances, a reasonable juror could conclude that Dr. Koenig's testimony does not reflect how he would have acted if he had received an adequate warning from Defendant.

And in any event, even if Dr. Koenig would still have recommended TVT-S to Plaintiff, Plaintiff suggests that she would not have *accepted* that recommendation if she had known of the risk of mesh erosion, chronic pain, or dyspareunia. And because Dr. Koenig stated that he would have disclosed any risks identified in the Instructions for Use to Plaintiff (Docket Nos. 21-1 at 41, 23-5 at 35), a reasonable jury could find that Plaintiff would not have undergone the procedure if Defendants had provided an adequate warning to Dr. Koenig, i.e., that the failure to warn caused

her injuries.[10] The Court accordingly ***denies*** Defendants' partial motion for summary judgment as to Counts I and XIV.[11]

2. Breach of Implied Warranty (Count XII)[12]

A merchant who sells good implicitly warrants that his goods "are fit for the ordinary purposes for which such goods are used." Mass. Gen. Laws ch. 106, § 2-314(2)(c). This warranty is called the implied warranty of merchantability. In Massachusetts, liability for the implied warranty of merchantability has become "a remedy intended to be fully as comprehensive as the strict liability theory of recovery that has been adopted by a great many other jurisdictions." *Back v. Wickes Corp.*, 375 Mass. 633, 639 (1978). Thus, a manufacturer is liable for the foreseeable uses of its goods and "must design against the reasonably foreseeable risks attending the [good's] use in that setting." *Id.* at 641.

Warranty liability may be premised on a design defect or the failure to warn. *See Haglund v. Philip Morris, Inc.*, 446 Mass. 741, 747 (2006). Here, Defendants move for summary judgment on Plaintiff's failure to warn theory of liability.[13] Defendants contend that they are entitled to judgment as a matter of law because Plaintiff has not established any causal connection between her injury and the failure to warn. For the reasons discussed above, the Court disagrees. A genuine

---

[10] Plaintiff, after all, had other, non-surgical options available to her at the time. (Docket Nos. 21-1 at 45, 23-5 at 39).

[11] Defendants do not separately argue the merits of Count XIV. Instead, Defendants appear to move for summary judgment on this count solely because its success depends on the success of Count I.

[12] In addition to challenging Plaintiff's breach of the implied warranty of merchantability claim, Defendants contend that Plaintiff has not demonstrated any breach of the implied warranty of fitness for a particular purpose claim. Plaintiff, however, indicates that she "will not pursue an implied warranty of fitness for a particular purpose claim" under Count XII. (Docket No. 24 at 10).

[13] Defendants do not move for summary judgment on the portion of Plaintiff's warranty claim premised on the existence of a design defect. The Court accordingly does not address the merits of this claim.

dispute of material fact exists as to whether Defendants' failure to warn of the risk of mesh erosion and dyspareunia caused Plaintiff's injuries, so the Court must ***deny*** the motion for partial summary judgment as to Count XII.

Conclusion

For the reasons stated above, Defendants' motion for summary judgment (Docket No. 21) is ***granted in part*** and ***denied in part***. Defendants are entitled to judgment as a matter of law on Counts II, III, IV, V, VI, VII, VIII, IX, X, XIII, and XV. Counts I, XII, and XIV survive this motion.

SO ORDERED

/s/ Timothy S. Hillman
TIMOTHY S. HILLMAN
DISTRICT JUDGE