UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ELAINE LANGLOIS and MARK LANGLOIS, **Plaintiffs,** **v.** **AMERICAN MEDICAL SYSTEMS, INC.,** **Defendant.**	**CIVIL ACTION NO. 4:20-40021-TSH**

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT (Docket No. 34)

May 22, 2020

HILLMAN, D.J.

Elaine Langlois ("Mrs. Langlois") and Mark Langlois ("Mr. Langlois") (collectively, "Plaintiffs") filed the instant action as part of an MDL against, *inter alia*, American Medical Systems, Inc. ("Defendant"). They seek to recover for complications associated with the implantation of two of Defendant's medical products. Defendant moves for partial summary judgment. For the reasons set forth below, the Court ***grants in part*** and ***denies in part*** their motion (Docket No. 34).

Background[1]

Mrs. Langlois suffers from cystocele, rectocele, and prolapse. To treat these conditions, Dr. Samuel Zylstra ("Dr. Zylstra") recommended that Mrs. Langlois have one of Defendant's polypropylene mesh devices implanted. Mrs. Langlois consented, and on February 17, 2006, Dr.

[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).

Zylstra surgically implanted Mrs. Langlois with an AMS Perigee System with IntePro ("Perigee"). (Docket No. 39-1 at 2). Two years later, on September 28, 2009, Dr. Zylstra surgically implanted Mrs. Langlois with an AMS Elevate Anterior and Apical System with IntePro Lite ("Elevate"). (Docket No. 39-2 at 2).

Over time, the mesh eroded, and in 2013, Mrs. Langois underwent a procedure to have the device excised. (Docket No. 39-4 at 2). Surgeons could only partially remove it. Mrs. Langlois alleges that, due to the erosion and the remaining mesh in her body, she continues to experience lingering pain, scarring, difficulty walking, vaginal infections, recurrence, and dyspareunia. (Docket Nos. 34-1 at 8; 34-2 at 3–5).

Plaintiffs filed the instant action in the MDL in December 2015.[2] (Docket No. 1). Mrs. Langlois raises the following claims against Defendant: negligence (Count I); strict liability – design defect (Count II); strict liability – manufacturing defect (Count III); strict liability – failure to warn (Count IV); strict liability – defective product (Count V); breach of express warranty (Count VI); breach of implied warranty (Count VII); fraudulent concealment (Count VIII); constructive fraud (Count IX); discovery rule, tolling and fraudulent concealment (Count X); negligent misrepresentation (Count XI); negligent infliction of emotional distress (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); and punitive damages (Count XVII). Mr. Langlois brings a claim for loss of consortium (Count XVI).

[2] Plaintiffs initially premised their claims solely on use of the Elevate device (Docket No. 1), but they later amended their complaint to include Perigee (Docket No. 17).

On August 14, 2019, Defendant moved for summary judgment on Counts I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XIII, and XV.[3,4] (Docket No. 34).

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*.

Discussion

1. Negligence (Count I)[5]

"In Massachusetts,[6] 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*.,

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3 Because Plaintiffs do not oppose summary judgment on Counts II, III, IV, V, VI, XI, XIII, or XV (Docket No. 39 at 13–14), the Court ***grants*** Defendant's motion as to these claims.

4 During a hearing before this Court on May 11, 2020, Defendant suggested that the Court should convert the motion for partial summary judgment into a motion for complete summary judgment and enter judgment in Defendant's favor on Plaintiffs' remaining claims. The Court declines to do so. It would not appropriate to address the merits of arguments raised for the first time during oral argument.

5 In addition to challenging Plaintiffs' negligence claim on failure to warn grounds, Defendant contends that Plaintiffs have not demonstrated the existence of a manufacturing defect. (Docket No. 35 at 7). Plaintiffs, however, do not intend to pursue a separate claim for manufacturing defect. (Docket No. 39 at 12–13).

6 Defendant asserts, and Plaintiffs do not appear to dispute, that Massachusetts law governs the substance of Plaintiffs' claims. (Docket Nos. 35 at 2–3; 39 at 1).

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. *See Tersigni*, 2013 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 v. Ortho Pharm. Corp*., 394 Mass. 131, 135 (1985)).

Defendant suggests that Plaintiffs cannot establish causation in this case. 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.

Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1st Cir. 1992) (citations omitted).

Plaintiffs submit the expert reports of Bruce Rosenzweig, M.D. ("Dr. Rosenzweig") to establish that Defendant failed to warn physicians of a non-obvious risk about which it knew or should have known.[7] In his reports, Dr. Rosenzweig identifies a number of risk factors associated with use of Perigee and Elevate that Defendant allegedly knew of prior to Mrs. Langlois' surgeries

[7] Plaintiffs also submit the expert reports of Ralph Zipper, M.D. ("Dr. Zipper"). As Defendant challenges the admissibility of Dr. Zipper's report (Docket No. 36), however, the Court opts, out of an abundance of caution, to rely on Dr. Rosenzweig's reports to establish the existence of a genuine dispute of material fact.

but failed to adequately disclose. (Docket Nos. 39-6 at 64–66; 39-7 at 58–60). For example, he testifies that, despite knowing that polypropylene degrades *in vivo* and that there is no safe way to remove either device from a patient if the mesh begins to erode (Docket Nos. 39-6 at 17–26, 27, 53–54; 39-7 at 18–26, 29, 52–53), Defendant did not include any warning in the Instructions for Use that Perigee or Elevate can cause "permanent debilitating pain that may be exacerbated by multiple revision surgeries" or "a lifelong risk of erosion and that erosions can be severe and incurable." (Docket Nos. 39-6 at 64; 39-7 at 58–59). He also asserts that Defendant intentionally hid its use of a certain resin from physicians because that resin had not been approved for permanent use in humans by the manufacturer. (Docket Nos. 39-6 at 67 n.215; 39-7 at 60 n.183).

Read in the light most favorable to Plaintiffs, this testimony plausibly suggests that Defendant failed to disclose certain risks about which it had knowledge. Plaintiffs therefore have met their initial burden of production. *See Garside*, 976 F.2d at 81 (finding that the plaintiffs had met their initial burden where they produced the affidavit of an expert suggesting that "a physician should have been warned about the risks of acquiring TEN from the combined ingestion of phenobarbital and amoxicillin" given twenty-three articles "making it 'clear' that 'barbiturates and penicillins are implicated in TEN'"); *Liu*, 230 F. Supp. 3d at 8, 9 (finding that the plaintiffs had met their initial burden where they produced the affidavit of experts suggesting "that the Defendants knew of an increased risk of major bleeding for patients over age 80 taking Pradaxa" and chose not to "include this risk in the product's warning label").

Defendant argues that the Court should disregard Dr. Rosenzweig's reports because, "[a]lthough Dr. Rosenzweig speculates that information 'readily available' to AMS was omitted from its Instructions for Use, he provides no support for that assertion." (Docket No. 42 at 3). The Court disagrees. Contrary to Defendant's allegations otherwise, Dr. Rosenzweig does provide

factual support for his opinions. At the beginning of each report, he notes that he has "reviewed scientific literature, corporate documents from [Defendant], sample products and depositions of [Defendant's] employees and witnesses" in forming his opinions. (Docket Nos. 39-6 at 3–4; 39-7 at 3–4). He then spends dozens of pages elaborating on that review, referencing specific portions of the scientific literature discussing risk factors (e.g., that polypropylene mesh degrades *in vivo*) and Defendant's internal documents acknowledging those studies. (Docket Nos. 39-6 at 17–26, 27, 53–54; 39-7 at 18–26, 29, 52–53). And in the section of his reports addressing the adequacy of each device's warnings, in particular, Dr. Rosenzweig cites to internal risk studies conducted by Defendant (Docket Nos. 39-6 at 65 n.214; 39-7 at 59 n.182), emails between Defendant's employees acknowledging that the manufacturer of a resin used in the devices had not approved it for permanent use in humans (Docket Nos. 39-6 at 67 n.215; 39-7 at 60 n.183), and emails between employees regarding whether to include certain risks in the Instructions for Use (Docket No. 39-7 at 61 n.184). Under the circumstances, the Court cannot say that Dr. Rosenzweig's opinion that Defendant knew of certain undisclosed risks lacks support.[8]

Defendant alternatively contends that it is entitled to judgment as a matter of law because, even if Plaintiffs have met their initial burden of proof, they have not submitted any evidence that an adequate warning would have changed Dr. Zylstra's prescribing decision. But Defendant misconstrues Massachusetts law. Under the burden-shifting framework set forth in *Garside*, if a plaintiff produces sufficient evidence to establish that the defendant failed to warn of a non-obvious risk about which it knew or should have known, he or she is entitled to the rebuttable

[8] To the extent Defendant challenges Dr. Rosenzweig's reliance on this evidence as weak, the issue of credibility is a question for the factfinder. *Iconics, Inc. v. Massaro*, 266 F. Supp. 3d 461, 470 (D. Mass. 2017) ("[I]t is the factfinder's role to evaluate the credibility of an expert's testimony, which may include a consideration of the data underlying the testimony.").

presumption that his or her physicians "would have heeded an adequate warning." *See Garside*, 976 F.2d at 81. Thus, where—as here—a plaintiff has met his or her initial burden of production, the absence of any evidence that an adequate warning would have changed the physician's prescribing decision is not, by itself, dispositive. Defendant must offer evidence to rebut the presumption before the absence becomes relevant. As Defendant has not done so in this case, Defendant has not shown that it is entitled to judgment as a matter of law on this issue. The Court accordingly ***denies*** the motion as to Count I.

2. Breach of Implied Warranty and Fraud Claims (Counts VII, VIII, IX, and X)

Defendant contends that Plaintiffs' warranty and fraud claims are repackaged failure to warn claims and should fail for the same reasons. But as noted above, the Court disagrees that Defendant is entitled to judgment as a matter of law on Plaintiffs' failure to warn claims. The Court accordingly declines to grant summary judgment as to Count VII, VIII, IX, and X.

Conclusion

For the reasons stated above, Defendant's motion for summary judgment (Docket No. 34) is ***granted in part*** and ***denied in part***. Defendant is entitled to judgment as a matter of law on Counts II, III, IV, V, VI, XI, XIII, and XV. Counts I, VII, VIII, IX, and X survive this motion.

SO ORDERED

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