UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

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BIANCA COSTA and JOHN COSTA,

Plaintiffs,

v.

C.A. No. 17-452 WES

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

MEMORANDUM AND ORDER

WILLIAM E. SMITH, District Judge.

Before the Court is Defendants Johnson & Johnson's and Ethicon, Inc.'s Motion for Summary Judgment ("Defs.' MSJ"), ECF No. 38. For the reasons that follow, Defendants' Motion is GRANTED as to Counts II, IV and V of the Complaint, ECF No. 1, and DENIED as to Counts I, III, VI, and VII.

I. Background

A. Facts

The following facts are either undisputed or viewed in the light most favorable to Plaintiffs. <u>See Cadle Co. v. Hayes</u>, 116 F.3d 957, 959 (1st Cir. 1997).

On October 10, 2014, Plaintiff Bianca Costa underwent surgery at Women and Infants Hospital Division of Gynecology in Providence, Rhode Island, performed by Dr. Kyle Wohlrab. Defs.' Statement Undisp. Facts ("Defs.' SUF") ¶¶ 1, 2 , ECF No. 39; Pls.' Statement Undisp. Facts ("Pls.' SUF") ¶ 7, ECF No. 43. The surgery was to correct stress urinary incontinence and uterovaginal prolapse and involved implantation of TVT-Exact, a pelvic mesh manufactured by Defendants. Defs.' SUF ¶ 1; Pls.' SUF ¶ 7. Dr. Wohlrab was aware of Ms. Costa's comorbidities at the time of the surgery, which included a stroke in 2005, histories of deep vein thrombosis and hypertension, systemic lupus erythematosus, and chronic immunosuppression due to the use of Prednisone and Imuran to treat He concluded that there were no absolute the lupus. contraindications for Ms. Costa to have the TVT-Exact implanted. Defs.' SUF ¶ 4; Pls.' SUF ¶¶ 2, 3.

Dr. Wohlrab had knowledge of the risks associated with the TVT-Exact from the Instructions for Use ("IFU") that Defendants provided with the product. Defs.' SUF ¶ 5; Pls.' SUF ¶ 4. The IFU listed the following risks: retropubic bleeding; dysuria; detrusor instability; punctures or lacerations of vessels, nerves, bladder, or bowel that may require surgical repair; local irritation at the wound site; extrusion; erosion; fistula formation; inflammation; potentiation of existing infection; and temporary or permanent lower urinary tract infection ("UTI"). Pls.' SUF ¶ 4. Dr. Wohlrab was also aware of additional risks, not listed in the IFU, from his own training and research,

including: acute or chronic pain with intercourse; acute or chronic pain; vaginal scarring; infection; urinary problems such as urinary frequency, urgency, dyspareunia, retention, obstruction, or incontinence; organ or nerve damage; wound complications; neuromuscular problems in the pelvic floor muscles, lower extremities, or abdominal area; the need for additional surgeries to treat an adverse event; recurrent failure of the TVT or mesh; foreign body response; and contraction or shrinkage of the tissues. Defs.' SUF ¶¶ 5, 7.

In 2015, Defendants revised the IFU to add additional risks that were not included in the previous version. Pls.' SUF ¶ 23. These added risks are: foreign body response; acute and/or chronic pain; voiding dysfunction; pain with intercourse which, in some patients, may not resolve; neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area; recurrence of incontinence; bleeding, including hemorrhage or hematoma; need for one or more revision surgeries; seroma; urge incontinence; urinary frequency; urinary retention; adhesion formation; atypical vaginal discharge; pain or discomfort to patient's partner during intercourse from exposed mesh; and death. See Pls.' SUF ¶ 24.

Following her surgery in 2014, Ms. Costa experienced recurrent UTIs, pelvic pain, painful voiding, dyspareunia, and incomplete sensation of bladder emptying. Defs.' SUF ¶ 12; see

Pls.' SUF ¶ 11. Cystoscopies performed in 2016 revealed foreign material that eroded into the urethra and narrowing of the lumen. Pls.' SUF ¶ 12. On June 13, 2016, Ms. Costa underwent surgery to remove the TVT-Exact and repair the urethra. Defs.' SUF ¶ 11; Pls.' SUF ¶ 15. Following this surgery, Ms. Costa continued to experience urinary incontinence with urethral erosion and a urethrovaginal fistula. Defs.' SUF ¶ 12; Pls.' SUF ¶ 16. Ms. Costa underwent a third surgery on May 30, 2017, after a small fistula was discovered mid-urethra. Pls.' SUF ¶ 20.

On October 19, 2018, Ms. Costa underwent an additional procedure to have an autologous rectus fascial sling placed at the bladder neck to address recurrent urinary stress incontinence. Pls.' SUF ¶ 22. According to the doctor's notes in January 2019, the sling worked well for forty-five days before Ms. Costa's original stress incontinence returned. Pls.' SUF ¶ 21.

As a result of the implantation of the TVT-Exact and its ensuing complications, Ms. Costa continues to suffer from incontinence, UTIs, pain in the pelvis and abdomen, and permanent damage to the urethra. Defs.' SUF ¶ 12; Pls.' SUF ¶ 25.

B. Procedural History

Plaintiffs filed this lawsuit on September 29, 2017. Compl. 1. On October 23, 2017, the action was conditionally transferred to the Southern District of West Virginia pursuant to 28 U.S.C. § 1407 to be consolidated with other actions involving common

questions of fact as part of a multi-district litigation ("MDL") against Defendants. Conditional Transfer Order (CTO-235), ECF No. 5. On June 5, 2020, the action was conditionally remanded to this Court pursuant to 28 U.S.C. § 1407(a) following the completion of coordinated or consolidated pretrial proceedings in the Southern District of West Virginia. Conditional Remand Order, ECF No. 9. Following discovery, Defendants filed this Motion for Summary Judgment. Defs.' MSJ 1.

II. Legal Standard

Summary judgment is appropriate 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). In deciding a motion for summary judgment, the Court views the record in the light most favorable to the non-moving party and draws all inferences in that party's favor. <u>Cadle Co.</u>, 116 F.3d at 959. It is the Court's function "to determine whether there is a genuine issue for trial," not to weigh evidence or assess credibility. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986).

The burden is on the movant to demonstrate an "absence of any genuine issue of material fact." <u>Borges ex rel. S.M.B.W. v.</u> <u>Seranno-Isern</u>, 605 F.3d 1, 5 (1st Cir. 2010) (citing <u>Celotex Corp.</u> <u>v. Catrett</u>, 477 U.S. 317, 323 (1986)). If the movant satisfies this burden, the nonmovant must produce "significant[ly] probative" evidence "demonstrat[ing] that a trier of fact could

reasonably resolve that issue in her favor." <u>Id.</u> If the nonmovant fails to do so, summary judgment is appropriate. <u>Id.</u>

The parties agree that Rhode Island law applies to Plaintiffs' substantive claims under the most significant relationship test. <u>See Harodite Indus., Inc. v. Warren Elec. Corp.</u>, 24 A.3d 514, 526 (R.I. 2011); Defs.' Mem. Supp. Mot. Summ. J. ("Defs.' Mem.") 3, ECF No. 38-1; Pls.' Mem. Supp. Opp'n Defs.' Mot. Summ. J. ("Pls.' Opp'n") 3 n.1, ECF No. 40-1.

III. Discussion

A. Strict Liability

Under Rhode Island law, a plaintiff may pursue a strict product liability claim under three theories: failure to warn, design defect, and manufacturing defect. <u>Castrignano v. E.R.</u> <u>Squibb & Sons, Inc.</u>, 546 A.2d 775, 779 (R.I. 1988); <u>see Guilbeault</u> <u>v. R.J. Reynolds Tobacco Co.</u>, 84 F. Supp. 2d 263 (D.R.I. 2000) (summarizing Rhode Island law of strict product liability). "If one of these three types of defects appears in the product and that defect renders the product unreasonably dangerous in spite of all reasonable care exercised by the manufacturer, then the manufacturer is liable for that defect." <u>Castrignano</u>, 546 A.2d at 779 (citing Ritter v. Narragansett Elec. Co., 283 A.2d 255, 262

(R.I. 1997)). Here, Plaintiffs pursue claims on the theories of failure to warn and design defect.¹

1. Failure to Warn (Count II)

Under a failure-to-warn theory of strict product liability, a plaintiff must prove that the failure to warn of the product's dangers "that are reasonably foreseeable and knowable at the time of marketing" "render[ed] the product unreasonably dangerous in spite of all reasonable care exercised by the manufacturer." <u>Castrignano</u>, 546 A.2d at 779, 782.² "The plaintiff has the burden of proving a defect in the product and that his or her injury was proximately caused by this defect." <u>Austin v. Lincoln Equip.</u> <u>Assocs., Inc.</u>, 888 F.2d 934, 936 (1st Cir. 1989). The Rhode Island Supreme Court has described the standard as "equivalent to the standard for negligence." <u>Castrignano</u>, 546 A.2d at 782; <u>accord</u> DiPalma v. Westinghouse Elec. Corp., 938 F.2d 1463, 1466 (1st Cir.

¹ Plaintiffs initially asserted a manufacturing defect claim in their Complaint. <u>See</u> Compl. Count IV, $\P\P$ 58-63. They have since opted not to pursue this claim. <u>See</u> Pls.' Mem. Supp. Opp'n Defs.' Mot. Summ. J. ("Pls.' Opp'n") 5 n.2, ECF No. 40-1. In addition, they have opted to abandon their claim of breach of express warranty that they initially asserted. <u>See</u> Compl. Count V, $\P\P$ 64-69; Pls.' Opp'n 20 n.4. Accordingly, Defendants' Motion for Summary Judgment is GRANTED as to Counts IV and V of the Complaint.

² In addition, a manufacturer has no duty "to warn of dangers that, given the present state of scientific knowledge, are unknowable." <u>Castrignano</u>, 546 A.2d at 779, 782. Here, Defendants do not contend that the risk complained of by Plaintiffs was unknowable at the time of the surgery.

1991) ("It is clear under Rhode Island law that the duty to warn . . . is measured, in all respects material to this case, by the same standard as the duty to warn that is enforceable in a negligence cause of action."). Plaintiffs must establish the standard of care with expert testimony. <u>See Mills v. State Sales,</u> <u>Inc.</u>, 824 A.2d 461, 468 (R.I. 2003); <u>Raimbeault v. Takeuchi Mfg.</u> (U.S.), Ltd., 772 A.2d 1056, 1063 (R.I. 2001).

Defendants argue that the learned intermediary doctrine applies to absolve them of liability. Defs.' MSJ 4-5. Under the doctrine, a manufacturer of a medical device can discharge its liability by providing an adequate warning of the risks of the device 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," even if the manufacturer did not provide an adequate warning to the patient directly. Restatement (Third) of Torts: Products Liability § 6(d) (1). "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 . . . 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." Id. cmt. b. In addition, if the specific risk was known to the physician, a manufacturer's alleged failure

to warn of that risk cannot be considered a defect. <u>See In re</u> <u>Zyprexa Products Liab. Litig.</u>, 277 F.R.D. 243, 250 (E.D.N.Y. 2011) <u>aff'd sub nom Greaves v. Eli Lilly & Co.</u>, 503 F. App'x 70, 71 (2d Cir. 2012).

The Rhode Island Supreme Court has not expressly adopted the learned intermediary doctrine, and Plaintiffs urge the Court to certify the question to the Rhode Island Supreme Court. Pls.' Opp'n 6. The Court declines this invitation. "Even in the absence of controlling precedent, certification would be inappropriate where state law is sufficiently clear to allow us to predict its course." In re Engage, Inc., 544 F.3d 50, 53 (1st Cir. 2008); see Hugel v. Milberg, Weiss, Bershad, Hynes & Lerach, LLP, 175 F.3d 14, 18 (1st Cir. 1999) ("[W]hen state law is sufficiently clear to allow [a federal court] to predict its course, certification is both inappropriate and an unwarranted burden on the state court."). Here, a number of factors counsel in favor of predicting that the Rhode Island Supreme Court would adopt the learned intermediary doctrine. First, the Rhode Island Supreme Court has implicitly referenced the doctrine when describing the proximate cause element of a failure to warn claim. See Hodges v. Brannon, 707 A.2d 1225, 1227-28 (R.I. 1998). In addition, the Rhode Island Supreme Court frequently relies on the Second and Third Restatements of Torts as a basis for the state's product liability law. The learned intermediary doctrine is defined in § 388 of the

Second Restatement, which the Rhode Island Supreme Court has cited with approval in other contexts. See Maggi v. De Fusco, 267 A.2d 424, 427 (R.I. 1970) (citing § 388(b)). The doctrine is also defined in § 6 of the Third Restatement of Torts: Products Liability, other provisions of which the Rhode Island Supreme Court has cited with approval. See, e.g., Calise v. Hidden Valley Condo Ass'n, 773 A.2d 834, 846 n.13 (R.I. 2001) (citing Restatement (Third) Torts). Thus, the Rhode Island Supreme Court's treatment of the Second and Third Restatements leaves this Court with "no reason to expect Rhode Island, if it were to adopt the learned intermediary doctrine, to offer an unusual interpretation of it, thereby rejecting the current edition of the Restatement." Hogan v. Novartis Pharms. Corp., No. 06 Civ. 0260(BMC)(RER), 2011 WL 1533467, at *10 (E.D.N.Y. Apr. 24, 2011). Finally, the Court follows the lead of other federal courts that have predicted that "the Rhode Island Supreme Court would likely adopt the learned intermediary doctrine." Greaves v. Eli Lilly & Co., 503 F. App'x 70, 71 (2d Cir. 2012); see Hogan, 2011 WL 1533467, at *10.

Turning to the merits of the claim, Plaintiffs argue that the warning provided in the TVT-Exact IFU by Defendants was inadequate because it (1) failed to contraindicate the use of the device in patients, like Ms. Costa, with preexisting medical conditions, specifically a compromised immune system from chronic steroid use to treat lupus, (2) failed to warn of certain adverse reactions

that were later added to the IFU,³ and (3) failed to warn of the risk of erosion and degradation of the polypropylene mesh of which the TVT Exact is constructed. Pls.' Opp. 11-12. Plaintiffs point to the expert report of Dr. Robert Gutman, Defendants' expert witness, to support the suggestion that the complications Ms. Costa experienced were due to problems with her immune response caused by immunosuppressant use. <u>Id.</u> at 10. Dr. Gutman states in his report that Ms. Costa's recurrent UTIs, retention issues, and urethral erosion following the initial surgery were "unlikely to be a problem with the sling material/construction or the alleged defects, and more likely than not to be a problem with her immune response and poor wound healing with chronic immunosuppressant use." Ex. 7, Case Specific Expert Rep. of Robert E. Gutman, MD, Mar. 28, 2019, ECF No. 40-7.

As to the first alleged inadequacy -- failure to warn of the risk of poor wound healing associated with immunosuppression from chronic steroid use -- Defendants have presented evidence that Dr. Wohlrab was aware of the specific risk that Plaintiffs complain of. In his deposition, Dr. Wohlrab stated generally that Ms.

³ These risks are acute and/or chronic pain, voiding dysfunction, pain with intercourse which in some patients may not resolve, neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area, recurrence of incontinence, bleeding including hemorrhage or hematoma, one or more revision surgeries to treat adverse reactions, and significant dissection to remove the mesh in part or in whole. Pls.' Opp'n 11-12.

Costa's preexisting medical conditions "did raise the risk of her procedure, which we had discussed," and specifically that he was aware at the time of the surgery that "[w]ith chronic steroid use, there is a decrease in overall healing." Ex. 5, Wohlrab Dep. at 90:11-22 ("Wohlrab Dep."), ECF No. 40-6. Because the risk was known to the Plaintiff's physician, the alleged failure to warn of that risk cannot be considered a defect. <u>See In re Zyprexa</u> Products Liab. Litig., 277 F.R.D. at 250.

As to the alleged failure to warn of certain adverse reactions that were later added to the IFU, Dr. Wohlrab also testified to his knowledge of these risks. Wohlrab Dep. at 47:3-51:20. And, he specifically testified that he was aware of the risk of erosion of the mesh, the third inadequacy that Plaintiffs allege. <u>Id.</u> at 51:15-17.

Finally, Plaintiffs make much of Dr. Wohlrab's testimony that, had he been aware of any "absolute contraindications for Ms. Costa" based on her medical history, he "wouldn't have done" the procedure. Wohlrab Dep. at 90:5-21. Plaintiffs have not, however, demonstrated that an absolute contraindication was present here. Dr. Wohlrab testified specifically that Ms. Costa's medical history did <u>not</u> make her an inappropriate candidate for the TVT Exact, <u>see id.</u>, and Plaintiffs have not identified any facts or expert testimony to the contrary. <u>See Mills</u>, 824 A.2d at 468 (plaintiffs must establish the standard of care with expert

testimony). Therefore, Defendants' Motion for Summary Judgment is GRANTED as to Count II of the Complaint.

2. Design Defect (Count III)

A claim for design defect consists of five elements:

(1) that there was a defect in the design or construction of the product in question; (2) that the defect existed at the time the product left the hands of * * * defendant; (3) that the defect rendered the product unreasonably dangerous, and by unreasonably dangerous it is meant that there was a strong likelihood of injury to a user who was unaware of the danger in utilizing the product in a normal manner; (4) that the product was being used in a way in which it was intended at the time of the accident; and (5) that the defect was the proximate cause of the accident and plaintiff's injuries.

Raimbeault, 772 A.2d at 1063 (quoting <u>Crawford v. Cooper/T. Smith</u> Stevedoring Co., 14 F. Supp. 2d 202, 211 (D.R.I. 1998)).

Here, Defendants identify the fifth factor as where Plaintiffs' claim falls short. <u>See</u> Defs.' Mot. 12-13. A plaintiff must show not only that the use of the product resulted in injury, but must also show "the necessary proximate relationship between . . . the defect and the injury." <u>Thomas v. Amway Corp.</u>, 488 A.2d 716, 722 (R.I. 1985); <u>see DiPalma</u>, 938 F.2d at 1466 ("absence of any evidence to support a finding that there was a . . . defect in the [product], is the exact sort of conjecture and speculation that the Rhode Island Supreme Court has specifically forbidden juries to consider in strict liability cases"); <u>Salk v. Alpine Ski</u> Shop, Inc., 342 A.2d 622, 625 (R.I. 1975) ("mere happening of an

accident" does not establish proximate cause). Plaintiffs' expert, Dr. Steven Berliner, identified a causal connection between the TVT-Exact and Ms. Costa's injuries in his report. <u>See</u> Ex. 5, Berliner Apr. 15, 2019 Rep. 9, ECF No. 39-5 ("Plaintiff's injuries would not have occurred but for the TVT Exact mesh sling."). However, Dr. Berliner did not opine as to any <u>defect</u> in the mesh that caused Ms. Costa's injuries.

However, Plaintiffs point to the statements of two other experts to establish this missing causal link. First, the affidavit of Scott Guelcher, Ph.D., identifies the defect in the mesh. Dr. Guelcher attested that the material that the mesh is made out of, polypropylene, reacts upon implantation in the human body to cause an inflammatory response resulting in oxidation, chain scission, mesh embrittlement degradation, flaking, pitting, and cracking. Ex. 3, Guelcher Aff. $\P\P$ 8(b)-(c), ECF No. 40-4. The defect, therefore, is the material from which the mesh is constructed.⁴

⁴ The MDL court and others have concluded that, because he is a chemical engineer and not a medical doctor, "Dr. Guelcher is simply not qualified to offer opinions on medical complications that may be caused by polymer degradation." <u>In re Ethicon, Inc.</u> <u>Pelvic Repair Sys. Prod. Liab. Litig.</u>, MDL No. 2327, 2016 WL 4547055, at *3 (S.D. W. Va. Aug. 31, 2016); <u>see also Salinero v.</u> <u>Johnson & Johnson</u>, No. 1:18-cv-23643-UU, 2019 WL 7753453, at *15 (S.D. Fla. Sept. 5, 2019) ("Dr. Guelcher is not qualified to opine about clinical manifestations of the body's response to implanted polypropylene mesh."); <u>Enborg v. Ethicon, Inc.</u>, No. 2:20-cv-02477-AWI-BAK, 2022 WL 800879, at *5 (E.D. Cal. Mar. 16, 2022) ("[T]he Court agrees with the finding in Salinero that since Dr. Guelcher

Second, Plaintiffs cite the affidavit and report of Dr. Vladimir Iakovlev, a licensed pathologist. <u>See</u> Pls.' Opp'n 17-18. Dr. Iakovlev opined that "polypropylene of the mesh device degraded while in the body of Ms. Costa and that this process contributed to the development of the mesh related complications," causing "urethral damage and the associated de-novo urinary symptoms for Ms. Costa." Ex. 6, Iakovlev Aff. ¶¶ 11(a), (d), ECF No. 41.

Taken together, these affidavits establish the defect of the mesh - the material from which it was constructed - and the causal connection between that defect and Ms. Costa's injuries - the degradation caused urethral damage and urinary symptoms. Thus, Plaintiffs have put sufficient facts in dispute as to the proximate relationship between the defect and the injury to survive summary judgment on this claim. Accordingly, Defendants' Motion for Summary Judgment is DENIED as to Count III of the Complaint.⁵

is not a physician, he is not in a position to observe and assess patient outcomes and that, consequently, his opinions as to patient complications are not reliable."). Here, however, Plaintiffs rely on Dr. Guelcher's affidavit only for the proposition that polypropylene reacts upon implantation in the human body and degrades, not to establish any medical consequences that may arise from such degradation.

 $^{^{\}rm 5}$ Defendants do not challenge the other four requirements of a design defect claim.

B. Negligence (Count I)

Under Rhode Island law, product liability claims based on theories of strict liability and negligence are subject to overlapping standards of proof. <u>See DiPalma</u>, 938 F.2d at 1466 ("It is clear under Rhode Island law that the duty to warn, the violation of which is actionable by means of the so-called strict liability cause of action, is measured, in all respects material to this case, by the same standard as the duty to warn that is enforceable in a negligence cause of action."); <u>Raimbeault</u>, 772 A.2d at 1063 (equating standards for negligence and design defect). Here, because Plaintiffs' strict liability claim on the theory of design defect survives summary judgment, as discussed <u>supra</u>, so too does their negligence claim, and Defendants' Motion for Summary Judgment is DENIED as to Count I of the Complaint.

C. Breach of Implied Warranty of Merchantability (Count VI)

Rhode Island recognizes a cause of action for personal injuries based on breach of the implied warrantv of merchantability. Castrignano, 546 A.2d at 783. A claim for breach of the implied warranty of merchantability requires a plaintiff to demonstrate that the product is defective, that it was in defective condition at the time it left the hands of the manufacturer, and that the defect was a proximate cause of the injury. Dent v. PRRC, Inc., 184 A.3d 649, 656 (R.I. 2018) (quoting Lariviere v. Dayton Safety Ladder Co., 525 A.2d 892, 896 (R.I. 1987)).

1. Notice

Defendants first argue that Plaintiffs' claim fails because they did not provide the requisite notice to Defendants of any alleged breach of the warranty. Defs.' Mem. 16. Under R.I. Gen. Laws § 6A-2-607(3)(a), a "buyer must within a reasonable time after he or she discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." The purpose of the notice requirement is threefold: to "provide[] the seller a chance to correct any defect," to "afford[] the seller an opportunity to prepare for negotiation and litigation," and to "provide[] the seller a safeguard against stale claims being asserted after it is too late for the manufacturer or seller to investigate them." DiPetrillo v. Dow Chemical Co., 729 A.2d 677, 682 (R.I. 1999) (quoting Prutch v. Ford Motor Co., 618 P.2d 657, 661 (Colo. 1980)). "The question of what constitutes a reasonable time in which to give notice of breach is ordinarily a question of fact; when the facts are undisputed and only one inference can be drawn from those facts, the question becomes one for the courts." Parrillo v. Giroux Co., Inc., 426 A.2d 1313, 1317 (R.I. 1981).

Plaintiffs' first notice of breach to Defendants in this case was in the Complaint. <u>See Pls.' Opp'n 21</u>. In some instances, filing a complaint "constitute[s] sufficient notice of the breach of the implied warranty." <u>DiPetrillo</u>, 729 A.2d at 683. In DiPetrillo, the Rhode Island Supreme Court concluded that although

the product that the plaintiff alleged was defective was manufactured and sold only between 1968 and 1972, the plaintiff "could not reasonably have discovered any putative effect" until 1990, when he was diagnosed with cancer. <u>Id.</u> "By that time, there was nothing that defendant could have done to reverse the effects of [plaintiff's] exposure to the allegedly defective product between 1968 and 1972." On those facts, the court concluded, "the filing of the complaint," which occurred in 1993, "constituted sufficient notice of the breach of implied warranty." <u>Id.</u>

Here, Ms. Costa testified that she was not aware that her symptoms were caused by the TVT-Exact until 2016. Pls.' Opp'n 21; Ex. 3, Bianca Costa Depo. Tr. 36:17-38:17, ECF No. 39-3. Defendants have not identified any evidence demonstrating that she could have become aware sooner, and as in <u>DePetrillo</u>, there was nothing Defendants could have done at that time to "reverse the effects of [Plaintiff's] exposure to the allegedly defective product." <u>DePetrillo</u>, 729 A.2d at 683. Plaintiffs filed their complaint on September 29, 2017. <u>See</u> Compl. 1. This is in line with the timing approved by the Rhode Island Supreme Court in <u>DePetrillo</u>, in which the complaint, filed three years after the plaintiff could reasonably have known about the breach, constituted sufficient notice. <u>See DePetrillo</u>, 729 A.2d at 683. Therefore, lack of compliance with the statutory notice

requirement is not a basis on which to grant summary judgment for this claim.

2. Causation

Defendants also argue that Plaintiffs cannot demonstrate that the defect was the proximate cause of Ms. Costa's injury. Under Rhode Island law, "strict liability and implied warranty of merchantability are parallel theories of recovery, one in contract and the other in tort." <u>Castrignano</u>, 546 A.2d at 783. Thus, for the reasons discussed <u>supra</u> in regard to Plaintiffs' design defect claim, Defendant' request for summary judgment as to Count VI of the Complaint is DENIED.

D. Loss of Consortium (Count VII)

Loss of consortium "is not an independent action but a derivative one that is attached to the claim of the injured spouse." <u>Fiorenzano v. Lima</u>, 982 A.2d 585, 591 (R.I. 2009) (quoting Sama v. Cardi Corp., 569 A.2d 432, 433 (R.I. 1990)). Defendants argue that because Ms. Costa's substantive claims cannot survive summary judgment, her husband's loss of consortium claim must also fail. However, as the Court has determined that Plaintiffs' claims of design defect, negligence, and breach of implied warranty of merchantability survive summary judgment, discussed <u>supra</u>, so too must Mr. Costa's loss of consortium claim. Accordingly, Defendants' request for summary judgment as to Count VII of the Complaint is DENIED.

IV. Conclusion

For the foregoing reasons, Defendants' Motion for Summary Judgment, ECF No. 38, is GRANTED as to Counts II, IV and V of the Complaint and DENIED as to Counts I, III, VI, and VII of the Complaint.

IT IS SO ORDERED.

William E. Smith District Judge Date: March 28, 2023