STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

PROVIDENCE, SC. **SUPERIOR COURT**

(FILED: November 28, 2016)

WAYNE SMITH and REBECCA SMITH *Plaintiffs,*	:	
v.	:	**C.A. No. PC-08-8307**
DAVOL INC. and C. R. BARD INC. *Defendants.*	:	

DECISION

GIBNEY, P.J. The Defendants, Davol Inc. (Davol) and C. R. Bard Inc. (Bard) (collectively, Defendants), bring this Super. R. Civ. P. 12(b)(6) (Rule 12(b)(6)) motion to dismiss against Plaintiffs Wayne and Rebecca Smith (Plaintiffs) in the above-titled negligence and product liability action. Defendants assert that Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted because Plaintiffs do not establish a product "defect" as required under Rhode Island strict product liability law. Additionally, Defendants contend that Plaintiffs' claims lack proximate cause essential to establish product liability and negligence. Plaintiffs assert that Davol's Composix Kugel Hernia Patch (patch) meets definitions of "defective" under Rhode Island strict product liability law, and that there is sufficient proximate cause alleged in their Amended Complaint in order to survive a Rule 12(b)(6) motion to dismiss. This Court exercises jurisdiction pursuant to G.L. 1956 § 8-2-14.

I

Facts and Travel

On February 7, 2005, Mr. Wayne Smith (Mr. Smith) underwent surgery to repair a ventral hernia. Doctors implanted a 7.7" x 9.7" patch to repair the hernia. Davol designed,

manufactured, and distributed the mesh patch that doctors implanted into Mr. Smith. Bard is the corporate parent and stockholder of Davol, and it participates in the manufacture and distribution of the patch, in addition to supplying Davol with material that forms part of the patch. After implantation surgery, Mr. Smith suffered severe abdominal pain and tenderness at the site of implantation. On December 22, 2005, Davol issued the first of several recalls, which included a recall for the type of patch implanted into Mr. Smith. Additional recalls were again issued in January and March of 2006. The patch was recalled due to a faulty "memory recoil ring" that could potentially break under pressure. This recall was issued after there were reports of incidents of ring migration within the body, intestinal fistulae, bowel perforation, and even death.

After reporting his pain and symptoms to his physician, Mr. Smith's doctor advised him that his hernia repair patch was subject to a recall due to defects in the product. Specifically, the product recall included information on possible symptomology that would suggest necessary removal of the patch. The recall advised doctors to remain alert for patients reporting "symptoms that could be associated with ring breakage such as unexplained or persistent abdominal pain, fever, tenderness at the implant site or other unusual symptoms." Defs.' Mem., Ex. A. As a result of this information—and with notice of Mr. Smith's reported abdominal pain and tenderness at the site of implantation—Mr. Smith's physician recommended explantation surgery to remove the patch.

As a result of such explantation procedures, Mr. Smith alleges he suffered severe and continuing physical pain and mental anguish. Plaintiffs bring this action and assert eight claims, including: 1) Negligence; 2) Violation of the Rhode Island Deceptive Trade Practices Act (DTPA); 3) Strict Product Liability; 4) Negligent Infliction of Emotional Distress; 5) Intentional Infliction of Emotional Distress; 6) Breach of Implied Warranty; 7) Failure to Warn; and 8) Loss

of Consortium. Defendants now bring this motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6).

II

Parties' Arguments

Davol and Bard maintain that Plaintiffs' claims contained in the Amended Complaint rely on a nonexistent theory of "product recall liability" that is unfounded in Rhode Island law. They assert that because Mr. Smith was injured by the explantation surgery and not the implanted patch itself, Plaintiffs' claims for personal injury and product liability cannot survive a Rule 12(b)(6) motion. Further, Defendants contend that "[m]anufacturers have no post-sale duty to ensure that physicians [have] 'sufficient information to inform and assist [] in diagnosing a ring breakage.'" Defs.' Mem. 5. Additionally, Defendants argue that there is no claim in negligence under Rhode Island law for a product that merely has a propensity to produce injury, rather than an actual malfunction in the product itself. Defendants assert that under negligence, the Plaintiffs lack proximate cause and thus their claims cannot survive. Finally, Defendants argue that all other claims included in the Plaintiffs' Amended Complaint will also necessarily fail under Rhode Island law if the Plaintiffs fail to establish a defect and proximate cause.

Alternatively, Plaintiffs contend that their Amended Complaint survives a Rule 12(b)(6) motion to dismiss because it asserts sufficient legally cognizable claims. Plaintiffs argue that Rhode Island product liability law merely requires a defect in the product at the time it leaves a defendant's control—rather than an actual malfunction or failure of the product itself—especially when dealing with recalls for products that are intended for health purposes and inserted into the body. Further, Plaintiffs claim that the defect rendered the product very likely to fail, that, therefore, the product was unreasonably dangerous, and that the defect was the proximate cause of Mr. Smith's pain symptoms and resulting injuries from the explantation

surgery. Finally, Plaintiffs contend that Defendants had a duty to warn patients and to provide proper information to doctors who may be monitoring patients for product issues. Plaintiffs maintain that their Amended Complaint asserts legally cognizable claims sufficient to provide notice to Davol and Bard and to move past Defendants' Rule 12(b)(6) motion to dismiss.

III

Standard of Review

"The sole function of a motion to dismiss is to test the sufficiency of the complaint." Palazzo v. Alves, 944 A.2d 144, 149 (R.I. 2008) (citations omitted). Looking at the four corners of a complaint, this Court examines the allegations in a plaintiff's complaint, assumes them to be true, and views them in a light most favorable to the plaintiff. Barrette v. Takavonis, 966 A.2d 1231, 1234 (R.I. 2009). This Court is mindful of the policy to interpret the pleading rules liberally so that cases are not "disposed of summarily on arcane or technical grounds." Haley v. Town of Lincoln, 611 A.2d 845, 848 (R.I. 1992). The complaint need not include the precise legal theory upon which the claims are based or even the ultimate facts to be proven; all that is required is fair and adequate notice to the opposing party of the claims being asserted. Gardner v. Baird, 871 A.2d 949, 953 (R.I. 2005) (citations omitted); see also Berard v. Ryder Student Transp. Servs., Inc., 767 A.2d 81, 83-84 (R.I. 2001). Consequently, '"[a] motion to dismiss is properly granted when it is clear beyond a reasonable doubt that the plaintiff would not be entitled to relief from the defendant under any set of facts that could be proven in support of the plaintiff's claim."' Goddard v. APG Sec.-RI, LLC, 134 A.3d 173, 175 (R.I. 2016); Woonsocket Sch. Comm. v. Chafee, 89 A.3d 778, 787 (R.I. 2014) (quoting Mendes v. Factor, 41 A.3d 994, 1000 (R.I. 2012)).

IV

Analysis

A

Product Defect

Defendants allege that the Plaintiffs' Amended Complaint, specifically Count III for Strict Product Liability, must be dismissed under Rule 12(b)(6) because Plaintiffs cannot establish a "defect" under Rhode Island product liability law. Defendants maintain that under strict liability law, Plaintiffs must show that the specific product malfunctioned or failed in order to proceed with a claim. Davol and Bard contend that they cannot be held liable for "product recall liability," suggesting that the only injuries here occurred during removal surgery and not from a defect in Mr. Smith's actual patch. Defs.' Mem. 5. Alternatively, Plaintiffs contend that Rhode Island law does not require a specific product to malfunction or fail before liability can attach; rather, that a defect existing in the product when it left a defendant's control is sufficient for strict product liability. Plaintiffs maintain that their Amended Complaint contains adequate information to put the Defendants on notice and that their claims are legally cognizable.

In strict product liability actions, the Rhode Island Supreme Court has held that plaintiffs must prove that 1) the product contained a defect when it left the hands of the defendant supplier, and 2) that the defect was the proximate cause of the injury for which plaintiffs are suing. Romano v. Westinghouse Elec. Co., 114 R.I. 451, 462, 336 A.2d 555, 561 (1975); see Ritter v. Narragansett Elec. Co., 109 R.I. 176, 191, 283 A.2d 255, 263 (1971). Further, a defendant will be liable under this doctrine when the defendant "[sold the] product in a 'defective condition unreasonably dangerous' . . . [to the] user or consumer[,] . . . the [defendant] is engaged in the business of selling such a product,' and . . . the product 'is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.'" Olshansky v. Rehrig

Int'l, 872 A.2d 282, 287 (R.I. 2005) (quoting Ritter, 109 R.I. at 188, 283 A.2d at 261); see Gray v. Derderian, 472 F. Supp. 2d 172, 181-82 (D.R.I. 2007).

In Ritter, the Rhode Island Supreme Court formally adopted the product liability doctrine as described in Restatement (Second) Torts § 402A at 347-48 (1965). 109 R.I. at 191, 283 A.2d at 263. In its analysis, the Court contemplates first, that there must be a defect in the design or manufacture which makes the product unsafe for its intended use, and second, that liability does not attach unless the plaintiff was using the product in a way for which it was intended to be used when he was injured. Id. at 190, 283 A.2d at 262; see Parrillo v. Giroux Co., 426 A.2d 1313, 1316 (R.I. 1981). Under the doctrine of strict liability in tort for defective design, it is immaterial whether the manufacturer was negligent in creating the design or exercised all reasonable care in the creation of the design. Ritter, 109 R.I. at 190, 283 A.2d at 262. Further, the Court has stated that "[i]f a defect appears in the product in spite of all reasonable care exercised by the manufacturer, he is liable just the same." Parrillo, 426 A.2d at 1316.

Under Rhode Island product liability law, there is no requirement that a defective product actually fail or malfunction; rather, Rhode Island law states that "[a]s a threshold element of tort liability for personal injuries under each theory a plaintiff must prove that the defendant sold a defective product which posed a threat of injury to potential consumers." Scittarelli v. Providence Gas Co., 415 A.2d 1040, 1046 (R.I. 1980) (emphasis added); see Geremia v. Benny's, Inc., 119 R.I. 868, 872-73, 383 A.2d 1332, 1334 (1978). In Simmons v. Lincoln Elec. Co., the Supreme Court stated that a plaintiff must show that a defect existed at the time the product left the defendant's control, not that the product failed or malfunctioned. 696 A.2d 273, 275 (R.I. 1997) (finding that Court should analyze whether a defect existed in the product when it left defendant's control and whether that defect caused the injuries in question). In Geremia, the Court noted the distinction between "defect" and "failure" when it held that a showing of a

mere failure or malfunction of a product is insufficient to establish that a defect existed at the time of sale, as required under strict product liability law. 119 R.I. at 872, 383 A.2d at 1334 ("The mere occurrence of a tire explosion does not establish that the tire was defective.").

In the present matter, Defendants contend that the claims contained in Plaintiffs' Amended Complaint do not allege a sufficient "defect" under Rhode Island strict product liability law because Mr. Smith's patch was not actually defective and did not fail after implantation. However, our Supreme Court has held that plaintiffs need only allege that the patch was defective when it left the defendant's control and that a party was later injured by that defect. See Simmons, 696 A.2d at 275. In their Amended Complaint, the Plaintiffs allege that the patches that were subject to the Class I recall "were defective because they failed to perform safely and effectively for the purpose [for which] they were originally designed." Pls.' Am. Compl. ¶ 47. Further, the patch was a defective product that, "based on [Mr. Smith's] severe abdominal pain[,] required subsequent painful and unnecessary removal surgery." Id. Plaintiffs allege that the patches were inherently dangerous for their intended use, and that the patch implanted into Mr. Smith was "substantially in the same condition as when it left the possession of Davol." Id. at ¶¶ 48, 50. This Court finds that Plaintiffs have sufficiently alleged a product defect in their Amended Complaint because they assert that the patches, as a whole, were defective when they left Defendants' control, and that the patches posed a serious threat to consumers, necessitating removal surgery. See Scittarelli, 415 A.2d at 1046; Romano, 114 R.I. at 462, 336 A.2d at 561.

Plaintiffs contend that they could not wait for the patch to actually break or malfunction before removing the product from Mr. Smith's body—considering that a recall was issued for the product and the recall included symptomology that would suggest necessary removal. While the Rhode Island Supreme Court has not squarely addressed a fact pattern similar to that of the case

at hand, the Supreme Court of Hawaii has addressed the issue of "defect" under strict product liability in cases that involve the recall of surgically-implanted medical devices. Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1286 (Haw. 1992). The Hawaii court noted that when dealing with surgically-implanted devices, policy ideals underlying strict product liability law suggest that removal of a defective device prior to actual malfunction or failure is appropriate and actionable. Id. at 1287 (finding that defect existed where injury was allegedly caused by the propensity of a product to malfunction and where product was designed to be implanted in the body). In the present matter, Plaintiffs similarly contend that the patches produced by Defendants were defective when they left Defendants' control and that the potential of the product's failure required removal before actual malfunction. Therefore, this Court finds that Plaintiffs have alleged legally cognizable claims of a product defect under Rhode Island strict product liability law and policy. See Scittarelli, 415 A.2d at 1046; Romano, 114 R.I. at 462, 336 A.2d at 561 (exploring the policy rationales underlying strict product liability law, as opposed to more stringent requirements of a tort or contract claim).

B

Proximate Cause

Defendants contend that Plaintiffs have failed to allege legally sufficient claims of proximate cause under either Rhode Island strict product liability or negligence law. Defendants maintain that Plaintiffs' claims in strict product liability should be dismissed under Rule 12(b)(6) because Plaintiffs cannot establish that any product defect caused Mr. Smith's injuries. Further, Defendants maintain that Plaintiffs' claims lack proximate cause under Rhode Island negligence law because Plaintiffs do not allege that Defendants' breach of duty was the but for and proximate cause of Mr. Smith's injuries. Defendants allege that Plaintiffs' reliance on a purported "product recall liability" cannot establish proximate cause under strict product liability

or negligence law. Plaintiffs contend that their Amended Complaint does allege sufficient claims of proximate cause under strict product liability—as required to defeat a Rule 12(b)(6) motion to dismiss—because they allege that a defect in the Defendants' patches was the proximate cause of Mr. Smith's pain and injuries. Plaintiffs also maintain that their Amended Complaint provides sufficient proximate cause under negligence law since it alleges that Defendants had a duty to Mr. Smith, that they breached that duty, and that those breaches were the but for and proximate cause of Mr. Smith's injuries. Finally, Plaintiffs aver that they have alleged sufficient legally cognizable claims regarding proximate cause under both strict product liability and negligence in order to provide proper notice to Defendants.

In a strict product liability claim, "the plaintiff has the burden of proving a defect in the design or manufacture that makes the product unsafe for its intended use, and also that the plaintiff's injury was proximately caused by this defect." Thomas v. Amway Corp., 488 A.2d 716, 722 (R.I. 1985). In the present case, Defendants in their memorandum assert that the Plaintiffs' Amended Complaint does not allege how a product defect led to an injury. Defs.' Mem. 6. However, Plaintiffs allege that the patches were defective because they "failed to perform safely and effectively for the purpose [for which] they were originally designed." Pls.' Am. Compl. ¶ 47. Further, Plaintiffs allege that this defect caused Mr. Smith's injuries when, based on his reported "severe abdominal pain," "subsequent painful and unnecessary removal surgery" was required. Id. Plaintiffs allege that after the painful explantation surgery, Mr. Smith has "suffered and will continue to suffer severe physical pain." Id. at ¶ 18. This Court is satisfied that Plaintiffs have alleged a sufficient defect and proximate cause under Rhode Island strict product liability law. See Thomas, 488 A.2d at 722; Bougopoulos v. Altria Grp., Inc., 954 F. Supp. 2d 54, 61 (D.N.H. 2013) (finding that plaintiffs alleged sufficient causal connection between defective design and injury at the motion to dismiss stage, which requires only minimal

assertion of a causal connection at that stage in order to survive) (citing Szulik v. State St. Bank and Trust Co., 935 F. Supp. 2d 240 (D.Mass. 2013)).

Defendants next assert that Plaintiffs have failed to allege sufficient claims of proximate cause under Count I for Negligence. Under Rhode Island law, cognizable negligence claims must set forth four essential elements: duty, breach, causation, and damages. See Santana v. Rainbow Cleaners, 969 A.2d 653, 658 (R.I. 2009). With regard to causation, "[a] plaintiff must not only prove that a defendant is the cause-in-fact of an injury, but also must prove that a defendant proximately caused the injury." Almonte v. Kurl, 46 A.3d 1, 18 (R.I. 2012); State v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 451 (R.I. 2008). A defendant is the cause-in-fact of a plaintiff's injury when there is "a causal relation between the act or omission of the defendant and the injury to the plaintiff." Almonte, 46 A.3d at 18.

To show that a defendant is the proximate cause of the alleged harm, a plaintiff must present proof "that the harm would not have occurred but for the [defendant's] act and that the harm was a natural and probable consequence of the act." Id.; see Skaling v. Aetna Ins. Co., 742 A.2d 282, 288 (R.I. 1999) (finding that "proximate cause is established by showing that but for the negligence of the tortfeasor, injury to the plaintiff would not have occurred"). In other words, "'[proximate] cause' is that [the defendant's conduct] shall have been a substantial factor in bringing about the harm." Wells v. Uvex Winter Optical, Inc., 635 A.2d 1188, 1191 (R.I. 1994) (quoting Krauss v. Greenbarg, 137 F.2d 569, 572 (3rd Cir. 1943)) (quotation marks omitted) (emphasis in original).

Under their claim for Negligence, the Plaintiffs allege that as a direct and proximate result of the duties breached, Mr. Smith suffered severe pain both before and after explantation surgery. Pls.' Am. Compl. ¶ 32. Plaintiffs allege that, "[u]pon information and belief, Davol and Bard were aware of the high degree of complication and failure rate associated with their Kugel

Patch before it was recalled." Id. at ¶ 22. Additionally, Plaintiffs allege that "[a]s a direct and proximate result of Davol's and Bard's negligence, including product recall liability, Mr. Smith has suffered injuries and damages." Id. at ¶ 33 (emphasis added). While it is true that there is no "product recall liability" claim per se under Rhode Island law, Plaintiffs do not invent a new claim for liability; rather, they allege that proximate cause exists in Mr. Smith's case and that their claim of proximate cause is recognized under Rhode Island negligence laws. Id.

Generally, this Court looks to federal jurisprudence for guidance or interpretation of Rule 12(b)(6). See Hall v. Kuzenka, 843 A.2d 474, 476 (R.I. 2004) ('"[W]here the Federal rule and our state rule are substantially similar, we will look to the Federal courts for guidance or interpretation of our own rule."') (quoting Heal v. Heal, 762 A.2d 463, 466-67 (R.I. 2000)). In Gray, the District Court of Rhode Island stated that "the rules of notice pleading do not require each element of a legal theory to be supported by factual allegations." 472 F. Supp. 2d at 179. In the present matter, the Plaintiffs have sufficiently alleged in their Amended Complaint that the Defendants had a duty to carefully and properly manufacture, test, inspect, and distribute safe patches to consumers. See Gray, 472 F. Supp. 2d at 179. The Plaintiffs have sufficiently alleged that Defendants breached that duty when they produced a defective product and that this breach caused Mr. Smith's pain and injuries. Id.

On March 24, 2006, Defendants issued a Class I recall notice recommending that doctors identify patients who were implanted with a recalled device and that they "direct [patients] to seek attention immediately if they experience symptoms that could be associated with ring breakage such as unexplained or persistent abdominal pain, fever, tenderness at the implant site or other unusual symptoms." Pls.' Mem. 8. In fact, Mr. Smith had earlier reported to his doctor both abdominal pain and tenderness at the site of implantation. Plaintiffs contend that Defendants breached their duty to Mr. Smith when they negligently designed and marketed defective patches

to consumers, and that Mr. Smith's abdominal pain and explantation surgery—which led to his alleged suffering and injuries—would not have occurred but for the Defendants' acts. See Skaling, 742 A.2d at 288. This Court finds that Plaintiffs have sufficiently alleged proximate cause as they assert that the Defendants' actions were a substantial factor in causing Mr. Smith's injuries. See Wells, 635 A.2d at 1191; Pls.' Am. Compl. ¶ 47. Therefore, this Court finds that Plaintiffs' allegations of proximate cause offer sufficient legally cognizable claims—with respect to both strict product liability and negligence—in order to survive a Rule 12(b)(6) motion to dismiss. See Goddard, 134 A.3d at 175; Almonte, 46 A.3d at 18.

C

Remaining Causes of Action

Defendants assert that without proper allegations of a defect or proximate cause in Mr. Smith's patch, Plaintiffs cannot go forward with their six remaining causes of action. These claims include: Count II – Violation of the Rhode Island Deceptive Trade Practices Act; Count IV – Negligent Infliction of Emotional Distress; Count V – Intentional Infliction of Emotional Distress; Count VI – Breach of Implied Warranty; Count VII – Failure to Warn; and Count VIII – Loss of Consortium. Plaintiffs assert that after presenting legally cognizable claims for defect and proximate cause under both Strict Product Liability and Negligence claims, they have alleged sufficient claims under each Count in order to survive a Rule 12(b)(6) motion. Each of Plaintiffs' remaining claims will be addressed individually below.

1

Rhode Island Deceptive Trade Practices Act

Rhode Island's DTPA states that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful." G.L 1956 § 6-13.1-2. The Rhode Island Supreme Court has stated that "'a plaintiff must establish that

he or she is a consumer, and that defendant is committing or has committed an unfair or deceptive act while engaged in a business of trade or commerce.'" Long v. Dell, Inc., 93 A.3d 988, 1000 (R.I. 2014) (quoting Kelley v. Cowesett Hills Assocs., 768 A.2d 425, 431 (R.I. 2001)). To prove that a trade practice is "deceptive" under the DTPA, a plaintiff must set forth three elements: (1) a representation, omission, or practice, that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3) the representation, omission, or practice is material. Id. at 1003. The deception supporting a claim for violation of DTPA need not be made with intent to deceive; it is enough that the representations or practices were likely to mislead consumers acting reasonably. Id.

The Plaintiffs in this action have alleged that "Defendants . . . knowingly committed unfair and deceptive practices in their study, test, design . . . distribution sale and recall of the [] [p]atch . . ." Pls.' Am. Compl. ¶ 37. Further, the Plaintiffs state that Defendants committed these practices while engaged in trade and commerce during the course of their business. Id. ¶ 43. Plaintiffs further allege that Defendants' practices—through their design and manufacturing of the patch—were unreasonably dangerous to Mr. Smith, and that the patch did not perform safely as an ordinary consumer or patient like Mr. Smith would expect. Id. at ¶¶ 50(iii) and (iv).

Our Rhode Island Supreme Court has recently clarified the standard of review for motions to dismiss under Rule 12(b)(6). Such a motion should only be granted "when it is clear beyond a reasonable doubt that the plaintiff would not be entitled to relief from the defendant under any set of facts that could be proven in support of the plaintiff's claim." Chhun v. Mortg. Elec. Registration Sys., Inc., 84 A.3d 419, 422 (R.I. 2014) (internal quotation omitted). The Court notes that a newer federal standard of review has been adopted by federal courts, but

that—despite Rhode Island's long adherence to federal law for guidance—the state has not yet adopted that newer test.[1] Id. at 422-23.

Regardless of whether the Rhode Island Supreme Court adheres to the traditional standard or turns to the newer plausibility standard, this Court is satisfied that Plaintiffs have sufficiently alleged legally viable claims under the DTPA under both the traditional and federal standards. See Long, 93 A.3d at 1000; Chhun, 84 A.3d at 422. Rhode Island law states that it is the "[Court's] function to examine the complaint to determine if plaintiffs are entitled to relief under any conceivable set of facts." McKenna v. Williams, 874 A.2d 217, 225 (R.I. 2005). Further, determining whether a complaint states a plausible claim for relief is a context-specific task that requires this reviewing Court to draw on its judicial experience and common sense. Chhun, 84 A.3d at 422.

Plaintiffs have alleged that Mr. Smith was a consumer of Defendants' product and that Defendants committed an unfair or deceptive act while in the course of business. Pls.' Am. Compl. ¶¶ 37, 43; See Kelley, 768 A.2d at 431. Plaintiffs have alleged that Mr. Smith acted reasonably when he relied on Defendants' representations regarding the safety of the patch, considering that the patch was authorized as a Class II medical device. Pls.' Am. Compl. ¶ 7. Plaintiffs allege that Defendants' practices were likely to mislead reasonable consumers, since Defendants represented the patch to be an appropriate, cost-effective and suitable product for hernia repair surgery. Id. at ¶ 9. Regarding the third element, the Rhode Island Supreme Court has stated that a representation is material if it "involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product." F.T.C. v.

[1] Federal standards now state that '"[f]actual allegations must be enough to raise a right to relief above the speculative level,' and a plaintiff must 'nudge[] their claims across the line from conceivable to plausible.'" Chhun, 84 A.3d at 422 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

Patriot Alcohol Testers, Inc., 798 F. Supp. 851, 855 (D.Mass. 1992) (quoting In re Cliffdale Assocs., Inc., 103 F.T.C. 110, 165 (1984)).

Plaintiffs allege that Defendants' actions constitute a material misrepresentation because the patch was later recalled due to reported incidents of ring migration, intestinal fistulae, bowel perforation, and even death. Pls.' Am. Compl. at ¶ 12. All of these reported incidents are very serious in nature and would likely affect a consumer's decision to implant Defendants' patch. See In re Cliffdale, 103 F.T.C. at 165. Therefore, this Court is satisfied that Plaintiffs have alleged sufficient facts and cognizable legal claims with respect to the DTPA, and therefore, Defendants' challenge to Count II is denied. See Long, 93 A.3d at 1000; Chhun, 84 A.3d at 422.

2

Negligent and Intentional Infliction of Emotional Distress

Defendants contend that Plaintiffs' Count IV – Negligent Infliction of Emotional Distress (NIED) and Count V – Intentional Infliction of Emotional Distress (IIED) should both be dismissed because Count IV is based on a nonexistent theory of "negligent recall liability," while Count V fails to allege that Defendants acted intentionally. Plaintiffs respond that they have alleged sufficient claims under both counts to establish a legally viable claim.

Under Rhode Island law, only two groups of plaintiffs are able to seek recovery under a theory of negligent infliction of emotional distress: "those within the 'zone-of-danger' who are physically endangered by the acts of a negligent defendant, and bystanders related to a victim whom they witness being injured." Jalowy v. Friendly Home, Inc., 818 A.2d 698, 710 (R.I. 2003) (citing Marchetti v. Parsons, 638 A.2d 1047, 1049, 1051 (R.I. 1994)); see Perrotti v. Gonicberg, 877 A.2d 631, 636 (R.I. 2005). Additionally, to prevail on a claim for IIED, a party must prove: "(1) the conduct [was] intentional or in reckless disregard of the probability of causing emotional distress, (2) the conduct [was] extreme and outrageous, (3) there [was] a

causal connection between the wrongful conduct and the emotional distress, and (4) the emotional distress in question [was] severe." Swerdlick v. Koch, 721 A.2d 849, 862 (R.I. 1998) (citations omitted).

Rhode Island courts have noted that "at least some proof of medically established physical symptomatology" is required for a successful NIED or IIED action. Id. at 863; see also DiBattista v. State, 808 A.2d 1081, 1089 (R.I. 2002) (affirming that a party asserting a claim involving negligent or intentional infliction of emotional distress may not rely upon unsupported conclusory assertions of physical ills, but rather, must produce evidence of the requisite physical manifestations of their alleged emotional distress); Vallinoto v. DiSandro, 688 A.2d 830, 839 (R.I. 1997) (requiring claims of psychic and physical injury to be supported by competent expert medical opinion regarding origin, existence, and causation).

Plaintiffs in the present action have alleged legally cognizable claims for both NIED and IIED in their Amended Complaint. See Jalowy, 818 A.2d at 710; Swerdlick, 721 A.2d at 862. Plaintiffs allege that in respect to their NIED claims, Defendants have negligently produced and distributed a defective product which has directly caused physical and medically documented harm to Mr. Smith. Pls.' Am. Compl. ¶ 58. Plaintiffs assert that Mr. Smith has suffered severe emotional distress, as well as physical injury, as a result of Defendants' negligence—including abdominal pain, tenderness at the site of implantation, and continuing pain and injury after explantation surgery was required. With respect to Count V – IIED, Plaintiffs have sufficiently alleged that Defendants intentionally designed, produced, advertised, and sold a defective product; that Defendants' conduct was extreme and outrageous since they continued to sell the product after "obtaining knowledge that [the patches] were failing" evidencing a "conscious disregard for the safety of others"; and that there is a causal connection between Defendants' conduct and Mr. Smith's severe emotional distress. Pls.' Am. Compl. ¶¶ 57, 58, 60; see

Swerdlick, 721 A.2d at 862. This Court finds that Plaintiffs have alleged sufficient legally cognizable claims under both Negligent and Intentional Infliction of Emotional Distress and therefore denies Defendants' motion to dismiss with respect to Counts IV (NIED) and V (IIED). See Jalowy, 818 A.2d at 710; Swerdlick, 721 A.2d at 862.

3

Breach of Implied Warranty

Defendants contend that Plaintiffs' Count VI for Breach of Implied Warranty should be dismissed because Plaintiffs "do not allege any defect in the product, relevant injury or proximate cause, which are necessary requirements of such a claim based in tort." Defs.' Mem. 9. Rhode Island law provides that "a warranty that [] goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." G.L. 1956 § 6A-2-314. This implied warranty of merchantability is breached "when a product of fair average quality does not pass in the trade and is unfit for the ordinary purpose for which it is used [.]" Thomas, 488 A.2d at 719.

As a threshold element of tort liability for personal injuries under breach of implied warranty, a plaintiff must prove that the defendant sold a defective product which posed a threat of injury to potential consumers. Geremia, 119 R.I. at 872-73, 383 A.2d at 1334; Plouffe v. Goodyear Tire & Rubber Co., 118 R.I. 288, 295, 373 A.2d 492, 496 (1977). This Court is satisfied that Plaintiffs have, in fact, alleged sufficient legally cognizable claims relating to a product defect, physical injuries, and proximate cause in order to survive a Rule 12(b)(6) motion to dismiss (as discussed above). See Goddard, 134 A.3d at 175; Almonte, 46 A.3d at 18; Scittarelli, 415 A.2d at 1046. Therefore, Defendants' motion to dismiss is denied with respect to Count VI for Breach of Implied Warranty.

4

Failure to Warn

Defendants contend that Plaintiffs' Count VII for Failure to Warn should be dismissed because Plaintiffs have failed to allege that Defendants neglected to warn against the product's potential hazard. Further, Defendants assert that Plaintiffs have not alleged a proximate cause resulting from failure to warn because Mr. Smith has not suffered any injury from a hazard of the product, and any theoretical additional warnings would have no impact. Plaintiffs maintain that that they have alleged all necessary elements of the claim in order to preclude dismissal.

In Rhode Island, "[t]he elements of a [strict products liability] claim and a negligence claim based on a product defect overlap significantly, with the negligence claim having the additional requirement that the defendant 'knew or had reason to know . . . that [the product] was defective in any manner.'" Guilbeault v. R.J. Reynolds Tobacco Co., 84 F. Supp. 2d 263, 268 (D.R.I. 2000) (quoting Ritter, 283 A.2d at 259). With regard to a negligent failure-to-warn claim, a product manufacturer, designer, or seller "only has a duty to warn if he had reason to know about the product's dangerous propensities which caused plaintiff's injuries." Thomas, 488 A.2d at 722. The defendant need only warn of "reasonably foreseeable" dangers. Id. Such knowledge may be actual or constructive. Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 782 (R.I. 1988). When the defendant fails to warn of "reasonably foreseeable" and knowable dangers, the defendant has breached the duty of care and "the product is rendered defective." Raimbeault v. Takeuchi Mfg. (U.S.), Ltd., 772 A.2d 1056, 1064 (R.I. 2001).

In the present matter, this Court is satisfied that Plaintiffs have alleged legally cognizable claims under Rhode Island Failure to Warn law. See Guilbeault, 84 F. Supp. 2d at 268. Plaintiffs allege that the patches, including the patch implanted into Mr. Smith, were "defective and unreasonably dangerous when put to their intended and reasonably anticipated use." Pls.' Am.

Compl. ¶ 69. Further, Plaintiffs contend that the patches "were not accompanied by proper warnings regarding significant adverse consequences associated with the [] [p]atch, all of which resulted in the recall notice." Id. Finally, Plaintiffs allege that Defendants "failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution." Id. at ¶ 70. Therefore, this Court is satisfied that Plaintiffs have alleged sufficient claims under Rhode Island Failure to Warn law as required by the Supreme Court. See Guilbeault, 84 F. Supp. 2d at 268; Castrignano, 546 A.2d at 782.

5

Loss of Consortium

Finally, Defendants assert that Plaintiffs have failed to allege legally valid claims under Count VIII for Loss of Consortium because Plaintiffs' Negligence claim, Strict Product Liability claim, and other claims all fail under Rhode Island law. Plaintiffs cite to Rhode Island case law to maintain that their Loss of Consortium claim should survive a Rule 12(b)(6) motion to dismiss because all of their other claims based in negligence and product liability are viable.

In evaluating whether the Plaintiffs' claim for loss of consortium is sufficient to withstand the Defendants' Rule 12(b)(6) motion to dismiss for failure to state a claim, this Court looks to the standards articulated by the Rhode Island Supreme Court in Bragg v. Warwick Shoppers World, Inc. and its progeny. 102 R.I. 8, 227 A.2d 582 (1967) (holding that plaintiffs' complaints should meet and satisfy proper notice requirements, and that Courts should not consider vagueness in complaints as fatal defects). Rhode Island's Loss of Consortium statute provides in pertinent part that "[a] married person is entitled to recover damages for loss of consortium caused by tortious injury to his or her spouse." G.L. 1956 § 9-1-41. In Desjarlais v. USAA Ins. Co., the Supreme Court held that a plaintiff's Loss of Consortium claim is ultimately

dependent on a plaintiff's success in alleging the underlying tort or personal injury claim. 824 A.2d 1272, 1277 (R.I. 2003).

In the present matter, Plaintiffs contend that Mrs. Smith has suffered great pain and mental anguish by virtue of her loss of consortium with her husband, Mr. Smith, and the loss or impairment of her husband's services. Pls.' Am. Compl. ¶ 76. Plaintiffs further allege that due to Defendants' negligent and tortious acts, Mr. Smith's injuries have impaired the "protection, care and assistance, society, companionship, affection, love, comfort, support, guidance and other benefits of the marital relationship." Id. This Court is satisfied that Plaintiffs have alleged legally cognizable claims under Rhode Island negligence and strict product liability law. See Skaling, 742 A.2d at 288; Scittarelli, 415 A.2d at 1046. Therefore, Plaintiffs' Loss of Consortium claim survives Defendants' motion to dismiss for failure to state a claim. See Desjarlais, 824 A.2d at 1277.

V

Conclusion

In looking at the four corners of the Amended Complaint, this Court finds that Plaintiffs have alleged sufficient legally cognizable claims in all eight counts therein. Under Rhode Island negligence and product liability law, Plaintiffs have alleged that Defendants produced a defective product which caused Mr. Smith's injuries. Plaintiffs have also alleged proximate cause in both their negligence and strict product liability claims. Therefore, Defendants' Rule 12(b)(6) motion to dismiss for failure to state a claim is denied in full. Counsel shall submit an appropriate order for judgment.

RHODE ISLAND SUPERIOR COURT

Decision Addendum Sheet

TITLE OF CASE:	**Wayne Smith and Rebecca Smith v. Davol Inc., et al.**
CASE NO:	**PC-2008-8307**
COURT:	**Providence County Superior Court**
DATE DECISION FILED:	**November 28, 2016**
JUSTICE/MAGISTRATE:	**Gibney, P.J.**
ATTORNEYS:	
For Plaintiff:	**Robert W. Smith, Esq.**
For Defendant:	**Mark Nugent, Esq.** **Thomas M. Robinson, Esq.**