

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

_____)	
MARIA WILLIAMS,)	
Plaintiff,)	
)	
v.)	C.A. No. 1:20-CV-00544-MSM-LDA
)	
JOHNSON & JOHNSON et al.,)	
Defendants.)	
)	
_____)	

MEMORANDUM AND ORDER

Mary S. McElroy, United States District Judge.

This matter comes before the Court on the defendants’, Johnson & Johnson (“J&J”) and Ethicon, Inc. (“Ethicon”) (together “defendants”), Motion to Dismiss for failure to state a claim upon which relief may be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 12.) The plaintiff, Maria Williams, has alleged claims in her First Amended Complaint (“FAC”) against the defendants in connection with Ms. Williams’ Ethicon¹ Gynecare TVT pelvic mesh (“TVT”)² implant, which was implanted on March 7, 2011. (ECF No. 10 ¶ 2.) J&J and Ethicon have moved to dismiss all but the plaintiff’s Count I negligence claim, “to the extent that it is

¹ Ethicon “is a wholly owned subsidiary of J&J.” (ECF No. 10 ¶ 6.)

² TVT “is a medical device that is generally used to repair weakened or damaged tissue” by being “permanently implanted [in patients] to support the urethra to treat urinary incontinence.” (ECF No. 10 ¶ 13.)

predicated on a failure to warn theory” and her Count IV strict liability claim for failure to warn. (ECF No. 12 at 1.) Ms. Williams filed a Response in Opposition to Defendants’ Motion. (ECF No. 13.) For the following reasons, the Court GRANTS in part and DENIES in part the defendants’ Motion to Dismiss.³

I. BACKGROUND

These facts have been gleaned from Ms. Williams’ First Amended Complaint (“FAC”). On March 7, 2011⁴, Ms. Williams’ physician, Dr. Gretchen Paranya, performed a TVT implant procedure to treat Ms. Williams’ stress urinary incontinence (“SUI”). (ECF No. 10 ¶ 68.) Ms. Williams’ FAC recites the unfortunate history of TVT⁵, detailing the various problems with the product and the complications that its implantation can cause in recipients. Similar mesh products have been used in patients suffering from pelvic organ prolapse (“POP”). *Id.* ¶ 11. In 2008 and 2011, adverse effects caused by contraction or shrinkage of the mesh implanted in POP patients that had been reported to the Food and Drug Administration led the agency to issue a public health notice and later a warning related to pelvic mesh. *Id.* ¶¶ 26, 28. The material used for POP treatment “is the

³ Although the defendants have argued that some of Ms. Williams’ claims are mutually exclusive, Fed. R. Civ. P. 8(2) permits alternative pleading.

⁴ The Court assumes the accuracy of this date but notes that elsewhere in the FAC, Ms. Williams’ implant procedure is described as occurring on October 12, 2011. (ECF No. 10 ¶ 71.)

⁵ According to the FAC, TVT “contains polypropylene mesh, a type of plastic” and “[d]espite claims that this material is inert . . . this mesh material is biologically incompatible with human tissue and promotes an immune response . . . [that] promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of adverse reactions to the mesh.” *Id.* ¶ 15.

same mesh used in the TVT.” *Id.* ¶ 36. Ms. Williams asserts that the risks associated with the POP repairs using polypropylene mesh are the same for SUI repairs using TVT.⁶ Ms. Williams further alleges that she “developed complications arising from the implant . . . including complications necessitating removal, worsening mixed incontinence, pelvic pressure and pain, dyspareunia, difficulty voiding, dysuria, polyuria, frequency, nocturia, urinary tract infections, urgency, abnormal uterine bleeding, severe emotional distress, stress, anxiety, fear, anger, and sadness.” *Id.* ¶ 3.

At some point after receiving the TVT implant, Ms. Williams underwent “corrective surgery” to remove it. *Id.* ¶ 103. Ms. Williams makes the following claims: Count I for negligence “in designing, researching, manufacturing, marketing, labeling, training, inspecting, testing, packaging, supplying, distributing, and selling” TV; Count II for strict liability for defective design; Count III for strict liability for manufacturing defect; Count IV for strict liability for failure to warn; Count V for breach of express warranty; Count VI for breach of implied warranty of merchantability; Count VII for fraudulent concealment; Count VIII for constructive fraud; Count IX for negligent misrepresentation; Count X for common law fraud; Count XI for gross negligence; Count XII for negligent infliction of emotional distress; and Count XIII for unjust enrichment. Ms. Williams’ prayer for relief requests

⁶ In 2019, “the [Food and Drug Administration] ordered all transvaginal POP device manufacturers, including Defendants, to stop selling and distributing POP products immediately” but “has not banned Defendants’ TVT as of the date of [the plaintiff’s FAC] filing.” *Id.* ¶ 40.

damages, including punitive damages, restitution, attorneys' fees and costs, and demands a jury trial. *Id.* at 68.

II. MOTION TO DISMISS STANDARD

On a motion to dismiss, the Court “must assume the truth of all well-plead[ed] facts and give plaintiff the benefit of all reasonable inferences therefrom.” *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007). To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “The relevant question ... in assessing plausibility is not whether the complaint makes any particular factual allegations but, rather, whether ‘the complaint warrant[s] dismissal because it failed *in toto* to render plaintiffs’ entitlement to relief plausible.” *Rodriguez-Reyes v. Molina-Rodriguez*, 711 F.3d 49, 55 (1st Cir. 2013) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 569 n.14 (2007)).

III. DISCUSSION

The defendants have moved to dismiss all counts except those predicated on the failure to warn theories of Count I (negligence) and Count IV (strict liability). To assess the sufficiency of the FAC, the Court addresses each count in turn.

A. Count I – Negligence

Ms. Williams has asserted a negligence claim based on “designing, researching, manufacturing, marketing, labeling, training, inspecting, testing, packaging, supplying, distributing, and selling.” (ECF No. 10 ¶ 80.) The negligence count appears to parallel Ms. Williams’ strict liability claims based on design,

manufacturing, and marketing (or failure to warn).

As mentioned above, the defendants do not seek dismissal of Ms. Williams' negligence claim based on the defendants' failure to warn of the risks associated with TVT. The defendants do, however, ask the Court to dismiss Ms. Williams' negligence claim based on manufacturing. Ms. Williams puts forth both a negligence claim and strict liability claim premised on a manufacturing defect. While strict liability, unlike negligence "will lie due to a manufacturing defect without . . . the additional requirement that defendant knew or should have known of the defect," Ms. Williams has nevertheless asserted both claims. *Guilbeault v. R.J. Reynolds Tobacco Co.*, 84 F. Supp. 2d 263, 280-81 (D.R.I. 2000). Under either theory, however, the plaintiff's manufacturing defect claims fail because she has not sufficiently pleaded "a mistake or accident in the manufacturing process." *Id.* at 281. The Court finds that without facts to support the requisite irregularity in the manufacturing process, the FAC fails to state a claim for relief for negligence in manufacturing. *See id.* at 280-81 (dismissing negligent manufacturing claim because the plaintiff did not assert that an error in the manufacturing process caused the alleged defect).

With the defendants not challenging the sufficiency of the negligent failure to warn claim, and the Court finding insufficient allegations of negligent manufacturing, what remain for the Court's consideration are the other negligence theories associated with the TVT design. "To make a prima facie case of negligence under Rhode Island law, Plaintiffs must show that 1) defendants owed them a legal duty to refrain from negligent activities; 2) Defendants breached that duty; 3) the

breach proximately caused Plaintiffs' injuries; and 4) actual loss or damages resulted." *Gray v. Derderian*, 365 F. Supp. 2d 218, 226 (D.R.I. 2005) (citing *Splendorio v. Bilray Demolition Co.*, 682 A.2d 461, 466 (R.I. 1996)). "In a negligent design claim, 'one can only be liable in negligence if the plaintiff[s] ha[ve] met [their] burden of introducing credible evidence that the defendant[s] knew, or had reason to know, of a defective design or that [they] w[ere] negligent in failing to test or inspect the product prior to sale.'" *Raimbeault v. Takeuchi Mfg. (U.S.), Ltd.*, 772 A.2d 1056, 1063 (R.I. 2001) (quoting *Thomas v. Amway Corp.*, 488 A.2d 716, 721 (R.I. 1985)) (alterations in original).

In support of her negligence claims, Ms. Williams alleges (1) that the defendants owed a duty of "care in designing, researching, manufacturing, marketing, labeling, training, inspecting, testing, packaging, supplying, distributing and selling the Ethicon Gynecare TVT pelvic mesh product implanted in Plaintiff," (2) which they breached when they "failed to avoid an unreasonable risk of harm to women in whom the product was implanted, including the Plaintiff," which in turn (3) caused the injuries Ms. Williams sustained after receiving the TVT implant, and (4) resulted in damages to the plaintiff. (ECF No. 10 at ¶¶ 80-81.) The defendants do not challenge the assertion that they owed a duty to the plaintiff. Their argument in favor of dismissing Ms. Williams' negligence claims simply contends that because her strict liability claims fail, her claims based on negligence fail as well. (ECF No. 12-1 at 9.) This broad challenge seems to center on the defendants' argument that Ms. Williams has failed to link her injuries to her TVT implant and, therefore, failed

to establish proximate cause.

“In most cases, proximate cause is established by showing that but for the negligence of the tortfeasor, injury to the plaintiff would not have occurred.” *Skaling v. Aetna Ins. Co.*, 742 A.2d 282, 288 (R.I. 1999) (citing *Fondedile, S.A. v. C.E. Maguire, Inc.*, 610 A.2d 87, 95 (R.I. 1992)). The FAC identifies ten ways in which the TVT product is known to fail or cause injury. Ms. Williams alleges, albeit with brevity, that after receiving her TVT implant she “subsequently developed complications arising from . . . the TVT . . . including mesh implant complications necessitating removal, worsening mixed incontinence, pelvic pressure and pain, dyspareunia, difficulty voiding, dysuria, polyuria, frequency, nocturia, urinary tract infections, urgency, [and] abnormal uterine bleeding” (ECF No. 10 at ¶ 2-3.) Although the defendants contend that Ms. Williams has not identified the precise way her implant failed and caused her injuries, the Court is satisfied at this stage of litigation that Ms. Williams has adequately pleaded that the TVT implant was the proximate cause of her injuries in light of her allegations that she experienced symptoms that have been associated with TVT after implantation and that she underwent surgery to remove the TVT in order to alleviate those symptoms.

The Motion to Dismiss Count I is GRANTED with respect to negligent manufacturing but is otherwise DENIED.

B. Count II – Strict Liability for Design Defect

The defendants have moved to dismiss Ms. Williams’ strict liability claim for design defect arguing that even if Ms. Williams has plausibly alleged a defect in the

design, she has not plausibly connected the defect to her injuries.

“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 v. Narragansett Elec. Co.*, 283 A.2d 255, 262 (R.I. 1971). In Rhode Island, a plaintiff needs to establish five elements to prevail on a defective design claim:

(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 the 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.

Crawford v. Cooper/T. Smith Stevedoring Co., 14 F. Supp. 2d 202, 211 (D.R.I. 1998).

Ms. Williams has alleged that the polypropylene material used to make TVT “is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants’ TVT pelvic mesh product.” (ECF No. 10 ¶ 15.) She has also alleged that, after receiving her TVT implant, she experienced physical symptoms and underwent surgery to remove the TVT. Defendants challenge the sufficiency of the FAC because Ms. Williams has not articulated “the essential element of causation; i.e., she has not set forth facts that would plausibly link her injuries to a defect in the design of the product.” (ECF No. 15 at 1.) The Court disagrees. Ms. Williams describes a range of design defects

including, but not exclusively, immunological responses to the polypropylene used to make TVT, contraction of TVT once implanted, and degradation of the TVT material. (ECF No. 10 ¶ 93.) These defects, according to the FAC, “are specifically linked to Plaintiff’s above-referenced injuries, such that she underwent reasonable and necessary revision procedure(s).” *Id.* ¶ 96. While the FAC certainly leaves something to be desired, at this preliminary stage of litigation, the Court accepts as true the allegations contained in the complaint. Ms. Williams has adequately alleged a design defect claim and the Motion to Dismiss Count II is DENIED.

C. Count III – Strict Liability for Manufacturing Defect

As mentioned above in connection with Ms. Williams’ negligence claims and along with her design defect claim, the plaintiff tacks on a strict liability claim based on manufacturing defect. Despite Ms. Williams’ argument to the contrary and her suggestion that “the manufacturing process rendered the Gynecare TVT product defective and unreasonably dangerous . . .”, the Court finds that Ms. Williams’ FAC fails to state a manufacturing defect claim. “To establish a manufacturing defect, ‘a plaintiff must show a product defect caused by a mistake or accident in the manufacturing process.’” *Guilbeault*, 84 F. Supp. 2d at 281 (quoting *Swajian v. General Motors Corp.*, 916 F.2d 31, 35 (1st Cir. 1990)) (applying Rhode Island law). Ms. Williams has not presented any facts that support either an accident or mistake in the TVT manufacturing process. Rather, Ms. Williams suggests that the manufacturing process *itself* made the TVT dangerous. Although Ms. Williams uses the words “manufacturing process,” she makes no allegations of any errors or

mistakes during manufacturing that rendered the TVT unsafe. The Motion to Dismiss Count III is GRANTED.

D. Count V – Breach of Express Warranty

According to the FAC, the “Defendants made assurances . . . to Plaintiff, her implanting physician . . . , the general public, hospitals and healthcare professionals that the TVT product was safe and reasonably fit for its intended purposes.” (ECF No. 10 ¶ 130.) Ms. Williams avers that the defendants specifically warranted that “(1) the TVT was safe and effective; (2) the TVT does not shrink or otherwise deform; (3) the TVT does not degrade; and (4) the product may only cause transient or temporary injuries, the TVT can cause chronic injuries.” *Id.* ¶ 139. To prevail on a claim for breach of express warranty, a plaintiff must “prov[e] that the statements or representations made by the seller induced her to purchase that product and that she relied upon such statements or representations.” *Thomas*, 488 A.2d at 720 (citing *Rogers v. Zielinski*, 209 A.2d 706, 708 (R.I. 1965)). At this stage, the Court is satisfied with Ms. Williams’ allegations that the defendants made explicit assurances about the TVT implant and that Ms. Williams’ decision to receive the implant was based on those assurances. It will be up to Ms. Williams to provide evidence as to those warranties, but dismissal is not appropriate at this time.⁷ The Motion to Dismiss

⁷ The Defendants’ citation to *Thomas v. Amway* in support of dismissal is misplaced. There, the Rhode Island Supreme Court “affirm[ed] the trial justice’s decision that plaintiff [could not] recover for breach of express warranty” following a jury trial because she failed to present evidence in support of that claim. *Thomas v. Amway*, 488 A.2d 716, 720 (R.I. 1985). At this preliminary stage the Court recognizes that discovery has yet to be conducted and that Ms. Williams need not prove her claim, only plausibly plead it.

Count V is DENIED.

E. Count VI – Breach of Implied Warranty

In addition to claiming breach of an express warranty, Ms. Williams asserts that the defendants breached the implied warranty of merchantability. “Rhode Island recognizes a cause of action for personal injuries based on breach of the implied warranty of merchantability.” *Castrigano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 783 (R.I. 1999) (citing *Parrillo v. Giroux Co.*, 426 A.2d 1313 (R.I. 1981)). A defendant’s liability for breach of the implied warranty of merchantability depends upon a plaintiff “prov[ing] that the product is defective, that it was in a defective condition at the time it left the hands of the seller, and that said defect is the proximate cause of the injury.” *Lariviere v. Dayton Safety Ladder Co.*, 525 A.2d 892, 896 (R.I. 1987) (quoting *Plouffe v. The Goodyear Tire & Rubber Co.*, 373 A.2d 492, 495 (1977)) (internal quotation marks omitted). As detailed above with respect to Counts I and II, Ms. Williams has sufficiently alleged that the TVT implant she received “was neither merchantable nor suited or fit for its intended use,” that it was “unreasonably dangerous and defective” when it was implanted in her body, and that Ms. Williams “has experienced significant mental and physical pain and suffering,” “including complications necessitating removal, worsening mixed incontinence, pelvic pressure and pain, dyspareunia, difficulty voiding, dysuria, polyuria, frequency, nocturia, urinary tract infections, urgency, abnormal uterine bleeding, severe emotional distress, stress, anxiety, fear, anger, and sadness.” (ECF No. 10 ¶¶ 3, 151, 153, 154). The Court finds the FAC sets out facts sufficient to support a reasonable inference

that the defendants breached the implied warranty of merchantability. The Motion to Dismiss Count VI is DENIED.

F. Fraud Claims: Count VII – Fraudulent Concealment, Count VIII – Constructive Fraud, Count IX – Negligent Misrepresentation, and Count X – Common Law Fraud

Ms. Williams makes four claims based on fraud. These claims are subject to a heightened pleading standard under Federal Rule of Civil Procedure 9(b), which provides that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other conditions of mind of a person may be averred generally.” Fed. R. Civ. P. 9(b). In the First Circuit, this standard requires the pleading to put forth “the who, what, where, and when of the allegedly false or fraudulent representation.” *Rodi v. S. New England Sch. of Law*, 389 F.3d 5, 15 (1st Cir. 2004) (quoting *Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)).

In her Opposition to the instant Motion, Ms. Williams combines Counts VII, VIII, X, and IX into a single argument. She first suggests that “[t]he particularity requirement for these claims should be relaxed since the requisite information was within Defendants’ exclusive knowledge and control, the issues are complex, the fraud occurred over an extended period of time and consists of numerous acts, and discovery is not complete.” (ECF No. 13 at 11) (citing *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 291 (1st Cir. 1987)). Ms. Williams alternatively argues that even if the pleading standard is not relaxed, she has still sufficiently pleaded her

claims sounding in fraud.

As to Count VII, to succeed on a fraudulent concealment claim, the “plaintiff’s burden [is] to show ‘(1) that the defendant made an actual misrepresentation of fact; and (2) that, in making such misrepresentation, the defendant fraudulently concealed the existence of the plaintiff’s cause of action.’” *Boudreau v. Automatic Temperature Controls, Inc.*, 212 A.2d 594, 601 (R.I. 2019) (quoting *Hyde v. Roman Catholic Bishop of Providence*, 139 A.2d 452, 465-66 (R.I. 2016)). The plaintiff’s burden may be satisfied either through evidence “that the defendant made an express representation or engaged in other affirmative conduct ... [which] could induce him or her to rely thereon to his or her disadvantage . . . [however] ‘mere silence or inaction on the part of the defendant does not constitute actual misrepresentation in this context.’” *Id.* at 601-02 (quoting *Hyde*, 139 A.2d at 466) (internal quotation marks omitted). In this case, the FAC relies on very general statements regarding the alleged adverse effects associated with TVT implants and the defendants’ alleged knowledge of those risks. The plaintiff offers no specific or attributable statements related to the TVT implant upon which she relied. Nor does she make any attempt to cure that deficiency in her Opposition. As a result, Ms. Williams’ fraudulent concealment claim does not satisfy Rule 9(b).

With respect to her claim of constructive fraud, Ms. Williams alleges “[a] fiduciary relationship between the parties is established by and through the agency relationship between Plaintiff and her implanting physician,” that “Defendants’ misrepresentations of the above-referenced risks, adverse events, and

contraindications of their TVT device had a tendency to deceive others (including Plaintiff and her implanting physician...,” and that “Defendants’ acts, statements or omissions relating to the above-referenced risks, adverse events, and contraindications of their TVT operate as virtual fraud on individuals, including Plaintiff and her implanting physician.” (ECF No. 10, ¶¶ 176, 177, 185.) These conclusory and unsupported statements are representative of the constructive fraud claim as a whole and do not satisfy the heightened pleading standard for fraud claims.

Next, Ms. Williams asserts a claim of negligent misrepresentation. To succeed, Ms. Williams must establish the following four elements:

- (1) a misrepresentation of a material fact; (2) the representor must either know of the misrepresentation, must make the misrepresentation without knowledge as to its truth or falsity or must make the representation under circumstances in which he [or she] ought to have known of its falsity; (3) the representor must intend the representation to induce another to act on it; and (4) injury must result to the party acting in justifiable reliance on the misrepresentation.

Cruz v. DaimlerChrysler Motors, Corp., 66 A.3d 446, 453 (R.I. 2013) (quoting *Manchester v. Pereira*, 926 A.2d 1005, 1012 (R.I. 2007)) (alteration in original).

“Misrepresentation is often considered a type of fraud,” *Koch v. I-Flow, Corp.*, 715 F. Supp. 297, 304 (D.R.I. 2010) (citing *Rodi*, 389 F.3d at 15), and, where intentional conduct is alleged, it is subject to the Rule 9(b) requirements, *id.* (citing *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 14 (1st Cir. 2009)).

Ms. Williams has, indeed, asserted intentional conduct by the defendants. (ECF No. 10 ¶ 214, 215.) But she has not pleaded with specificity. She alleges that “it was

known or knowable” to the defendants that TVT could cause complications and that the product was unsafe but that the defendants continued to market the product and “knowingly made false claims about the safety and quality...” of the TVT and that these “false claims regarding the true defective nature of the TVT product [were made] so that Plaintiff would rely on these claims....” *Id.* ¶ 204, 207, 210. At no point does the FAC identify a specific representation upon which Ms. Williams relied. Without supporting facts, Ms. Williams’ conclusory negligent misrepresentation claim also fails to comply with Rule 9(b).

Lastly, Ms. Williams makes a common law fraud claim. As with each claim based on fraud, the defendants contend that the FAC lacks the particularity required under Rule 9(b). “To establish a prima facie case of common law fraud in Rhode Island the plaintiff must prove that the defendant made a false representation intending thereby to induce plaintiff to rely thereon, and that the plaintiff justifiably relied thereon to his or her damage.” *W. Reserve Life Assur. Co. of Ohio v. Conreal LLC*, 715 F. Supp. 270, 282 (D.R.I. 2010) (quoting *Zaino v. Zaino*, 818 A.2d 630, 638 (R.I. 2003)) (internal quotation marks omitted). Once more, the FAC does not provide supporting facts to establish a claim grounded in fraud. Ms. Williams asserts that the defendants “intentionally made false claims regarding the true defective nature of the TVT product so that Plaintiff would rely on these claims . . . and Plaintiff justifiably acted or relied upon, to her detriment, the false claims as evidenced by her purchase of Defendants’ TVT pelvic mesh product.” (ECF No. 10 ¶ 210.) Ms. Williams offers no specific statements, let alone assertions of where or when those statements

were made, upon which she relied to her detriment. As a result, Ms. Williams' common law fraud claim fails as well.

Each of these fraud-based claims requires specificity and particularity that is notably absent from the FAC. Ms. Williams' FAC offers conclusory and extremely general allegations which do not establish who made the misrepresentation, what the misrepresentation was, or when and where it was made as required under the heightened pleading standard for fraud. Moreover, Ms. Williams has not established any cognizable grounds for relaxing the pleading standard in this case. She offers only unsupported statements that "the requisite information was within the Defendants' exclusive knowledge and control ..." and "any of the alleged missing details are in the possession of Defendants." (ECF No. 15 at 13.) Counts VII, VIII, IX, and X are, therefore, DISMISSED.

G. Count XI – Gross Negligence

The Rhode Island Supreme Court "has never adopted the doctrine of degrees of negligence." *Labree v. Majori*, 306 A.2d 808, 816 (R.I. 1973) (citing *Leonard v. Bartle*, 135 A. 853 (1927)). This Court understands that "Rhode Island does not distinguish between degrees of negligence, and therefore, does not recognize a separate cause of action for gross negligence." *Corvello v. New England Gas Co.*, 460 F.Supp. 314, 321 (D.R.I. 2006) (citing *Labree*, 306 A.2d at 816). In a recent decision in which a gross negligence claim was permitted, this Court described the circumstances which made the claim appropriate in that particular case and explained that "while Rhode Island generally does not recognize degrees of

negligence, the federal law raised by Defendants does.” *Camelo v. Bristol-Warren Regional School Dist.*, C.A. No. 19-660 WES, 2021 WL949363, *4 (D.R.I. Mar. 12, 2021) (describing one of the defendants’ affirmative defenses based on federal law which “precludes liability for certain negligence claims, but not claims of ‘gross negligence’ or ‘reckless misconduct’”). While Ms. Williams may pursue her negligence claim, Count XI for an independent claim of gross negligence is DISMISSED.

H. Count XII – Negligent Infliction of Emotional Distress

Ms. Williams next seeks relief for negligent infliction of emotional distress. “[T]wo 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.’” *Perrotti v. Gonicberg*, 877 A.2d 631, 636 (R.I. 2005) (quoting *Jalowy v. Friendly Home, Inc.*, 818 A.2d 698, 710 (R.I. 2003)). In addition to being within the “zone-of-danger” or a related bystander, the plaintiff must “suffer[] emotional distress . . . accompanied by physical symptoms.” *Id.* (citing *Reilly v. United States*, 547 A.2d 894, 896 (R.I. 1988)).

The benchmark against which such claims of emotional distress are measured is “extreme and outrageous.” As the Rhode Island Supreme Court emphasized, liability will not be imposed “upon a defendant for infliction of emotional distress absent proof of extreme and outrageous conduct.” *Swerdlick v. Koch*, 721 A.2d 849, 864 (R.I. 1998) (citing *Reilly*, 547 A.2d at 898).

Even assuming Ms. Williams has asserted the requisite emotional and physical effects, the FAC does not set out allegations that rise to “extreme and outrageous.” Indeed, in her Opposition to the defendants’ Motion, Ms. Williams fails to present any argument or point to any relevant allegation in her FAC that suggest either extreme or outrageous conduct “as to be [considered] atrocious and utterly intolerable in a civilized community.” *Id.* at 863. Count XII is, therefore, DISMISSED.

I. Count XIII – Unjust Enrichment

A successful unjust enrichment claim involves three proven elements. “[A] plaintiff must prove: (1) that he or she conferred a benefit upon the party from whom relief is sought; (2) that the recipient appreciated the benefit; and (3) that the recipient accepted the benefit under such circumstances that it would be inequitable for [the recipient] to retain the benefit without paying the value thereof.” *Cote v. Aiello*, 148 A.3d 537, 550 (R.I. 2016) (quoting *Dellagrotta v. Dellagrotta*, 873 A.2d 101, 113 (R.I. 2005)) (alteration in original). A claim of “unjust enrichment is not simply a remedy in contract and tort but can stand alone as a cause of action in its own right.” *Id.* (quoting *Dellagrotta*, 873 A.2d at 113) (internal quotation marks omitted).

At this stage, the Court finds that Ms. Williams has sufficiently pleaded an unjust enrichment claim. Ms. Williams has alleged (1) that she conferred a benefit when she paid for the defendants’ TVT implant; (2) that “Defendants appreciated the . . . financial benefit Plaintiff conferred [upon] them;” and (3) that Ms. Williams did not “receive[] the safe and effective TVT medical device for which she paid.” (ECF No.

10 ¶ 246-249.) The Motion to Dismiss Count XIII is DENIED.

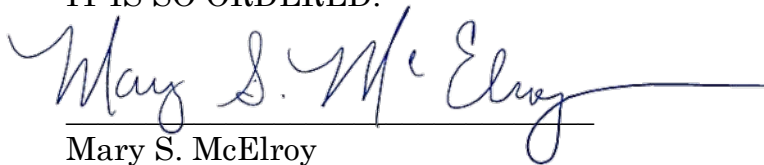
CONCLUSION

For the foregoing reasons the Court GRANTS the defendants' Motion to Dismiss with respect to the following claims:

1. Strict Liability for Manufacturing Defect (Count III);
2. Fraudulent Concealment (Count VII);
3. Constructive Fraud (Count VIII);
4. Negligent Misrepresentation (Count IX);
5. Common Law Fraud (Count X);
6. Gross Negligence (Count IX); and
7. Negligent Infliction of Emotional Distress (Count XII).

With respect to the claims for Negligence (Count I), Strict Liability for Design Defect (Count II); Strict Liability for Failure to Warn (Count IV), Breach of Express Warranty (Count V), Breach of Implied Warranty (Count VI), and Unjust Enrichment (Count XIII), the defendants' Motion to Dismiss is DENIED.

IT IS SO ORDERED.



Mary S. McElroy
United States District Judge
January 18, 2022