IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JANET FEARRINGTON,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. H-19-2366
	§	
BOSTON SCIENTIFIC CORPORATION,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Plaintiff Janet Fearrington ("Plaintiff") asserts claims against defendant Boston Scientific Corporation ("Defendant") for products liability, breach of warranty, fraud, and negligence.[1] Pending before the court is Defendant Boston Scientific's Motion to Dismiss (Docket Entry No. 6) ("Defendant's Motion to Dismiss"). For the reasons explained below, Defendant's Motion to Dismiss will be granted in part and denied in part.

I. Factual and Procedural Background

Defendant is a manufacturer of medical devices. This action involves three devices produced by Defendant: the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx"), the Polyform Synthetic Mesh ("Polyform"), and the Advantage Fit System

[1]See Complaint for Damages and Demand for Jury Trial ("Complaint"), Docket Entry No. 1, pp. 22-33. All page numbers for docket entries in the record refer to the pagination inserted at the top of the page by the court's electronic filing system, CM/ECF.

("Advantage Fit") (collectively, "Pelvic Mesh Products").[2] Defendant designed Obtryx and Advantage Fit to treat urinary incontinence and the Polyform to treat pelvic organ prolapse.[3] The devices contain polypropylene and are intended to be implanted permanently on or about the pelvic floor in women suffering urinary incontinence or pelvic organ prolapse.[4] Doctors implanted Plaintiff with Obtryx and Polyform on February 21, 2006, in Titusville, Florida.[5] Plaintiff was implanted with Advantage Fit on June 26, 2017, in Houston, Texas.[6]

Plaintiff alleges that the Pelvic Mesh Products warp and shrink while inside a woman's body and that the polypropylene material is biologically incompatible with the body, leading to a high risk of injury.[7] She alleges that the Pelvic Mesh Products inflicted serious injury on her that she was not warned of and the risk of which was not justified.[8] Plaintiff filed this action against Defendant on July 1, 2019, seeking actual and punitive damages for her alleged injuries.[9] Plaintiff alleges several

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[2]Complaint, Docket Entry No. 1, p. 3 ¶ 8.

[3]Id. at 19 ¶¶ 62-63.

[4]Id. at 3 ¶ 9; 20 ¶¶ 70, 73.

[5]Id. at 19 ¶ 61.

[6]Id.

[7]Id. at 3 ¶ 9; 8 ¶¶ 31-32.

[8]Id. at 8 ¶¶ 35-36; 21 ¶¶ 76-77.

[9]Id. at 1; 21-22 ¶ 79; 29 ¶ 121.

theories of recovery: products liability for marketing, manufacturing, and design defects; breach of express and implied warranties; negligence; and fraud, fraudulent concealment, and negligent misrepresentation.[10] Defendant moved to dismiss for failure to state a claim on July 31, 2019.[11] Plaintiff responded to the motion on August 21, 2019,[12] and Defendants replied on August 28, 2019.[13]

II. Standard of Review

The Federal Rules of Civil Procedure permit dismissal when a plaintiff fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A Rule 12(b)(6) motion tests the formal sufficiency of the pleadings and is "appropriate when a defendant attacks the complaint because it fails to state a legally cognizable claim." Ramming v. United States, 281 F.3d 158, 161 (5th Cir. 2001), cert. denied sub nom. Cloud v. United States, 122 S. Ct. 2665 (2002). To defeat a motion to dismiss a plaintiff must plead "enough facts to state a claim to relief that is plausible on

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[10]Id. at 22-33.

[11]Defendant's Motion to Dismiss, Docket Entry No. 6; Defendant Boston Scientific Corporation's Memorandum of Law in Support of Motion to Dismiss ("Defendant's Memorandum"), Docket Entry No. 7.

[12]Plaintiff's Response to Defendant Boston Scientific Corporation's Motion to Dismiss ("Plaintiff's Response"), Docket Entry No. 16.

[13]Defendant Boston Scientific Corporation's Reply in Support of Its Motion to Dismiss ("Defendant's Reply"), Docket Entry No. 18.

its face." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007). "Detailed factual allegations" are not required at this stage, but a complaint that establishes the grounds that entitle the plaintiff to relief "requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Id. In ruling on a Rule 12(b)(6) motion the court must "accept the plaintiff's well-pleaded facts as true and view them in the light most favorable to the plaintiff." Chauvin v. State Farm Fire & Casualty Co., 495 F.3d 232, 237 (5th Cir. 2007).

III. Analysis

A. Choice of Law

As a preliminary matter the parties disagree whether Texas or Florida law applies to Plaintiff's claims. Plaintiff contends that because her physicians implanted Obtryx and Polyform in her in Florida in 2006 and all of her injuries resulted from that event, all of her claims should be governed by Florida law.[14] This would include alleged injuries sustained after physicians implanted Advantage Fit in Plaintiff in Texas in 2017, which Plaintiff argues would not have occurred but for Obtryx and Polyform's failures.[15] Defendant argues Texas law should apply because Plaintiff's factual allegations are insufficient to justify applying Florida law.[16]

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[14]Plaintiff's Response, Docket Entry No. 16, pp. 11-12.

[15]Id. at 12.

[16]Defendant's Reply, Docket Entry No. 18, pp. 6-7.

When different state laws may apply, federal courts exercising diversity jurisdiction apply the choice-of-law rules of the forum state. Mayo v. Hartford Life Insurance Co., 354 F.3d 400, 403 (5th Cir. 2004). Texas law requires a claim-by-claim choice of law analysis. Scottsdale Insurance Co. v. National Emergency Services, Inc., 175 S.W.3d 284, 291 (Tex. App.—Houston [1st Dist.] 2004, pet. denied). Texas courts do not engage in choice-of-law analyses unless there is a conflict of laws that affects the outcome of the case. Duncan v. Cessna Aircraft Co., 665 S.W.2d 414, 419 (Tex. 1984). Accordingly, the court will address the parties' choice-of-law arguments on a claim-by-claim basis.

B. Marketing Defect

Plaintiff alleges a strict liability claim against Defendant for alleged failure to warn of the alleged risks to use of the Pelvic Mesh Products.[17] Defendant contends the Plaintiff has not pled sufficient facts that could establish that the alleged failure to warn caused her injuries, especially in light of the learned intermediary doctrine that applies to drugs and medical devices.[18] Plaintiff concedes the learned intermediary doctrine applies but argues that pleading that Defendant knew of alleged dangers to the devices and failed to warn either her or her physicians shows a plausible claim.[19]

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[17]Complaint, Docket Entry No. 1, pp. 22-23.

[18]Defendant's Memorandum, Docket Entry No. 7, pp. 9-10.

[19]Plaintiff's Response, Docket Entry No. 16, pp. 12, 14-15.

A marketing defect occurs where a defendant markets a product without adequately providing warnings as to its dangers. Sims v. Washex Machinery Corp., 932 S.W.2d 559, 562 (Tex. App.—Houston [1st Dist.] 1995, no writ). To state a plausible claim, Plaintiff must plead facts that would show:

> (1) A risk of harm inherent in the product or which may arise from the intended or reasonably anticipated use of the product;
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> (2) the product supplier actually knew or should have reasonably foreseen the risk of harm at the time the product was marketed;
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> (3) the product contains a marketing defect;
>
> (4) the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and
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> (5) the failure to warn must constitute a causative nexus in the product user's injury.

Wright v. Ford Motor Co., 508 F.3d 263, 274-75 (5th Cir. 2007) (citing Sims, 932 S.W.2d at 562). Under the learned intermediary doctrine a medical-device manufacturer satisfies its duty to warn by providing adequate warnings to the prescribing physician. In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Product Liability Litigation, 888 F.3d 753, 775 (5th Cir. 2018); Guzman v. Synthes (USA), 20 S.W.3d 717, 720 n.2 (Tex. App.—San Antonio 1999, pet. denied); see also Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1373 (S.D. Fla. 2007) (recognizing the learned intermediary doctrine under Florida law). The learned intermediary doctrine is not an affirmative defense but part of the case Plaintiff must prove to

establish Defendant violated an owed duty. Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 164 (Tex. 2012). Plaintiff therefore must also plead facts that would show her doctors were inadequately warned and but for those inadequacies her doctors would have recommended different treatment or given Plaintiff counsel that would have led her to withhold consent. In re Depuy Orthopaedics, 888 F.3d at 775.

To satisfy this standard in this type of case, a plaintiff must plead facts such as the actual warning given to physicians, that a different warning would have prevented her physicians from prescribing the Pelvic Mesh Products or at least led to them giving her different information that would have caused her to refuse consent. See Gonzalez v. Bayer Healthcare Pharmaceuticals, Inc., 930 F. Supp. 2d 808, 818 (S.D. Tex. 2013) (dismissing a failure-to-warn claim where the plaintiff did not allege the warning to her physician was inadequate, identify the warning her doctor received, demonstrate a different warning would have changed the doctor's actions, or otherwise allege facts necessary to show the failure to warn caused the injury); cf. Ivory v. Pfizer Inc., Civil Action No. 09-0072, 2009 WL 3230611, at *4 (W.D. La. 2009) (concluding a failure-to-warn claim was adequately pled where the plaintiff provided the warning label and pled specifically how it was deficient).

Plaintiff's Complaint does not identify her treating physicians or facts as to the allegedly deficient warnings

Defendant provided to them. Plaintiff only alleges generally that some of the problems with the Pelvic Mesh Products "were made known to physicians [but] the magnitude severity, and frequency of these problems were not disclosed" and that "Defendant knowingly provided incomplete and insufficient training and information to physicians."[20] She then alleges that she "would not have consented to use Defendant's Pelvic Mesh Products had Defendant given adequate warnings to Plaintiff and Plaintiff's implanting physicians."[21] These conclusory assertions amount to a recitation of the requirements of the learned intermediary doctrine: that Defendant did not adequately warn Plaintiff's physicians, and that but for this failure she would not have been injured by the medical devices. The pleadings therefore do not comport with the pleading requirements established by Twombly and Iqbal and do not support a plausible claim that Defendant failed to warn Plaintiff's physicians and that this failure was the producing cause of her injury. See Gonzalez, 930 F. Supp. 2d at 818.

C. Manufacturing Defect

Plaintiff alleges a products liability claim against Defendant for defective manufacture of the Pelvic Mesh Products.[22] Defendant contends this claim must be dismissed because Plaintiff has alleged

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[20]Complaint, Docket Entry No. 1, pp. 8-9 ¶¶ 35-36; 17 ¶ 51.

[21]Id. at 23 ¶ 84.

[22]Complaint, Docket Entry No. 1, pp. 23-24.

no facts as to how the Pelvic Mesh Products allegedly deviate from their intended specifications.[23] Plaintiff argues that her allegations that the products deform while within the body suffice to maintain her manufacturing defect claim.[24] She also contends that under Florida law applicable to her claims there is no requirement to identify or allege the specific defect that caused the injury.[25]

In Texas a manufacturing defect results when a product deviates "from the specifications or planned output in a manner that renders it unreasonably dangerous." Ford Motor Co. v. Ridgway, 135 S.W.3d 598, 600 (Tex. 2004). "A plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries." Id. Likewise in Florida a manufacturing defect results when it differs from its intended design and fails to perform as safely as its intended design would have. Zanakis v. Scanreco Inc., Case No.: 1:18-cv-21813-UU, 2019 WL 2215816, at *3 (S.D. Fla. 2019) (citing In re Standard Jury Instructions in Civil Cases-Report No. 13-01 (Products Liability), 160 So. 3d 869, 880 (Fla. 2015); Wright v. Howmedica Osteonics Corp., Case No: 5:17-cv-459-Oc-30PRL, 2017 WL 4555901, at *2 n.5 (M.D. Fla. 2017).

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[23]Defendant's Response, Docket Entry No. 7, p. 6.

[24]Plaintiff's Reply, Docket Entry No. 16, pp. 16-17.

[25]Id. at 17.

Plaintiff must therefore allege facts that would show the Pelvic Mesh Products deviated from their planned output or intended design to plausibly allege a manufacturing defect claim under either Texas or Florida law.

Plaintiff relies on Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 597, 605 (11th Cir. 2008), to argue that there is a conflict of laws because Florida does not require her to show the products deviated from their intended design. That case involved a plaintiff who pled a claim in strict products liability without specifying a type of defect, which led the district court to dismiss the suit for failure to state a claim. Id. at 601, 604. The Eleventh Circuit held that since Florida law did not rigidly distinguish between theories of strict products liability there was no requirement for the pleading to segregate marketing, manufacturing, and design defect theories of liability. Id. at 605-06. The circuit court then analyzed the factual allegations in the complaint and concluded the plaintiff had alleged sufficient factual allegations that could support a manufacturing or design defect claim but not a marketing defect claim. Id. at 608-09. Although Bailey teaches that plaintiffs should be afforded flexibility in pleading a Florida strict products liability claim, the court must still analyze the facts pled and determine whether they state a claim under a valid theory of liability. Bailey also predates revisions the Florida Supreme Court made to the Florida Standard Jury Instructions that clarified that a manufacturing defect theory of products liability requires a deviation from the

product's intended design, and other federal courts have held a manufacturing defect claim requires facts pled that would satisfy that element. E.g., Wright, 2017 WL 4555901, at *2 n.5.; see also In re Standard Jury Instructions, 160 So. 3d at 880. The applicability of Florida or Texas law therefore does not affect Plaintiff's federal pleading burden under Rule 8, and the court need not decide choice-of-law on this issue at this stage.

Plaintiff relies on her allegations that the Pelvic Mesh Products were susceptible to deformation and degradation once placed inside the body to state her claim for a manufacturing defect.[26] But Plaintiff has not alleged in any detail the Pelvic Mesh Products' intended designs or specifications, how their manufacture deviated from those designs or specifications, or how such a deviation caused the alleged susceptibility once within the body. Plaintiff's manufacturing defect allegations are therefore impermissibly conclusory and vague, and Plaintiff has not properly stated a claim under Twombly and Iqbal under either Texas or Florida state law. Funk v. Stryker Corp., 631 F.3d 777, 782 (5th Cir. 2011); Wright, 2017 WL 4555901, at *2 n.5.

D. Design Defect

Plaintiff alleges a products liability claim against Defendant for defective design of the Pelvic Mesh Products.[27] Defendant contends this claim must be dismissed because Plaintiff does not

[26]Plaintiff's Response, Docket Entry No. 16, pp. 16-17.

[27]Complaint, Docket Entry No. 1, pp. 24-25.

plead facts that would show the design was unreasonably dangerous and that a safer alternative design existed.[28]

"To recover for a products liability claim alleging a design defect, a plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." Timpte Industries, Inc. v. Gish, 286 S.W.3d 306, 311 (Tex. 2009). Determining whether a product's design is unreasonably dangerous requires a risk-utility analysis that considers:

> (1) the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use;
>
> (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive;
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> (3) the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs;
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> (4) the user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and
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> (5) the expectations of the ordinary consumer.

Id. The plaintiff must also show that a safer alternative design was available as an element of the claim. Id.

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[28]Defendant's Memorandum, Docket Entry No. 7, pp. 13-14.

The court must accept the following alleged facts as true:

- The Pelvic Mesh Products' designed polypropylene material, construction, and intended placement within the body rendered them likely to deform and degrade once placed in the body;[29]

- the Products' tendency to deform or degrade and their placement near sensitive nerves in the body injured Plaintiff by pulling or compressing nerves and injuring her pelvic organs leading to disability;[30] and

- alternative surgical treatments that did not use the products were available to treat Plaintiff's pelvic organ prolapse and stress urinary incontinence.[31]

Plaintiff identifies specifically the chosen material for the products and gives specific examples for each device explaining how their designed placement in the body was defective and produced her injuries. These allegations plausibly allege that the Pelvic Mesh Products' designs were unreasonably dangerous under Texas's risk-utility analysis.

However, under Texas law Plaintiff must also plead that there was a safer alternative design. Timpte Industries, 286 S.W.3d at 311. To satisfy that requirement Plaintiff need only plead facts that the "[product] could have been alternatively designed in a safer manner" and that such alternative designs "were economically and technologically feasible." Ardoin v. Stryker Corp., Civil

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[29]Complaint, Docket Entry No. 1, pp. 3 ¶ 9; 8 ¶¶ 31-32; 10 ¶ 39; 14 ¶ 43.

[30]Id. at 17-18 ¶ 53; 19 ¶¶ 66-68; 20-21 ¶¶ 69-74; 21 ¶ 75.

[31]Id. at 8 ¶ 34.

Action No. 4:18-CV-2192, 2019 WL 4933600, at *3 (S.D. Tex. 2019). Plaintiff's Complaint mentions several alternative treatments: different surgeries that utilize unspecified devices made from other materials or even surgery that only modifies the patient's body without implanting anything.[32] But the availability of alternative treatments or devices does not show that safer, feasible alternative designs were available for the Pelvic Mesh Products themselves.[33] Plaintiff's failure to plead such means she has not stated a claim for which relief can be granted under Texas law.

Plaintiff argues that Florida law governs and does not require design-defect plaintiffs to prove a safer alternative design.[34] In Florida a strict liability claimant must show (1) the manufacturer's relationship to the product in question, (2) the defect and unreasonably dangerous condition of the product, and (3) that such condition caused the user's injuries. West v. Caterpillar Tractor Co., Inc., 336 So. 2d 80, 87 (Fla. 1976). There is no requirement that a plaintiff show a safer alternative design was available. Id.; see also In re Standard Jury Instructions, 160 So. 3d at 880

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[32]Id. at 8 ¶ 34; Plaintiff's Response, Docket Entry No. 16, p. 20.

[33]Plaintiff argues in her response brief that an allegation that the product would have been safer if made from a different material would suffice; however, Plaintiff points to no such allegation in the Complaint.

[34]Plaintiff's Response, Docket Entry No. 16, p. 19.

(providing standard jury instructions for design defect claims with no need for an alternative design to be proven). A conflict between Texas and Florida laws therefore exists on this issue that affects the outcome of her claim, requiring a preliminary choice-of-law determination to decide whether the claim should be dismissed.

Texas courts apply the "most significant relationship test" from sections 6 and 145 of the Restatement (Second) of Conflict of Laws. Torrington Co. v. Stutzman, 46 S.W.3d 829, 848 (Tex. 2000). In tort cases courts must consider the following contacts in determining which state possesses the most significant relationship:

> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and
>
> (d) the place where the relationship, if any, between the parties is centered.

Restatement (Second) of Conflicts of Law § 145 (1971). "The applicable law will usually be the local law of the state where the injury occurred." Id. § 156(2).

Here, the only relevant facts pled are that (1) Plaintiff is a resident of Texas; (2) Defendant is a corporation domiciled in Massachusetts; (3) Obtryx and Polyform were implanted in Plaintiff in Florida in 2006; (4) Advantage Fit was implanted in Plaintiff in

Texas in 2017; (5) Obtryx and Polyform both initially injured Plaintiff; and (6) those injuries resulted in her being implanted with Advantage Fit, which caused her additional injuries. These cursory representations do not permit the court to determine the appropriate choice of law. In particular, Plaintiff does not allege specifically where she sustained injury other than where the devices were initially implanted. Plaintiff does not allege that she was injured when she had surgery; she instead pleads that the injuries occurred because of the Pelvic Mesh Products' failures once they were already in her body over a period of several years but gives no details as to when or where those failures and injuries occurred. Accordingly, the court cannot address the sufficiency of Plaintiff's design defect claim at this time, and the claim must be dismissed without prejudice. See Enigma Holdings, Inc. v. Gemplus International, S.A., Civil Action No. 3:05-CV-1168-B ECF, 2006 WL 2859369, at *2, *8 (N.D. Tex. 2006) (dismissing state law claims without prejudice where the plaintiff failed to plead sufficient facts to permit the court to determine choice of law).

As explained below, Plaintiff will be permitted an opportunity to amend her pleadings. Plaintiff may cure her design defect claim by alleging additional facts that either establish that a feasible alternative design was available or permit the court to conduct a full choice-of-law analysis and conclude that Florida law controls.

E. Express and Implied Warranties

Plaintiff alleges claims against Defendant for breach of both express and implied warranties.[35] Defendant contends these claims fail because Plaintiff does not identify an applicable warranty, does not satisfy the learned intermediary doctrine, and also because Plaintiff either failed to provide pre-suit notice under Texas law or plead facts showing privity of contract under Florida law.[36]

The court agrees that Plaintiff has not pled facts that would show an express warranty. Texas and Florida both adhere to UCC Section 2-313 under which an express warranty is created when an "affirmation of fact or promise [is] made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." Fla. Stat. § 672.313(1)(a); Tex. Bus. & Com. Code § 2.313. Plaintiff pleads only that "Defendant expressly warranted to Plaintiff" and others that the devices "were safe, effective, fit and proper for their intended use."[37] This conclusory allegation is a recitation of the legal standard for the creation of an express warranty. See Twombly, 127 S. Ct. at 1974. The learned intermediary doctrine applies to warranty claims, and Plaintiff's claim must plead facts that would establish that

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[35]Complaint, Docket Entry No. 1, pp. 28-29.

[36]Defendant's Memorandum, Docket Entry No. 7, pp. 16-18.

[37]Complaint, Docket Entry No. 1, p. 29 ¶ 120.

Defendant made warranties to her physicians that it subsequently breached. Gonzalez, 930 F. Supp. 2d at 818. Because Plaintiff does not allege any specific facts as to any communication made by Defendant that constituted the alleged warranty to any specific person, she has not stated a claim for an express warranty for which relief may be granted.

The UCC also requires a buyer to notify the seller of an alleged breach of warranty "within a reasonable time . . . or be barred from any remedy." Fla. Stat. § 672.607(3); Tex. Bus & Com. Code § 2.607(c); Ibarra v. National Construction Rentals, Inc., 199 S.W.3d 32, 37 (Tex. App.—San Antonio 2006, no pet.). This pre-suit notice requirement is a condition precedent to the cause of action and must be pled and proven for the claim to succeed. Morgan v. Medtronic, Inc., 172 F. Supp. 3d 959, 970 (S.D. Tex. 2016). Plaintiff's Complaint pleads no facts that would establish she notified Defendant of the defects within a reasonable amount of time. Plaintiff argues that the FDA's warnings on the use of mesh products to treat stress urinary incontinence and pelvic organ prolapse and a 2013 lawsuit she instituted against Defendant but voluntarily dismissed satisfy the statutory requirement for pre-suit notice. But the statute expressly requires Plaintiff, not the FDA, to provide pre-suit notice, and the Complaint does not mention the 2013 lawsuit much less provide facts that would show it was filed within a reasonable time of Plaintiff's discovering her

injuries. Accordingly, Plaintiff's claims for breach of warranty fail as a matter of law.

Assuming without deciding that Plaintiff is correct that Florida law applies, her claim for breach of implied warranty also fails because she does not allege privity of contract as required under Florida law. Bailey v. Monaco Coach Corp., 168 F. App'x 893, 894 n.1 (11th Cir. 2006) ("Under Florida law, privity of contract is an essential element of a claim for breach of implied warranty."); Montgomery v. Davol, Inc., 2007 WL 2155644, at *2 (N.D. Fla. 2007) (dismissing an implied warranty claim against a medical device not alleged to have been directly sold to the plaintiff).

F. Fraud and Negligent Misrepresentation

Plaintiff alleges Defendant committed fraud, negligent misrepresentation and fraud by concealment by misrepresenting or concealing facts relevant to the safety and efficacy of the Pelvic Mesh Products.[38] Defendant contends Plaintiff has failed to plead her fraud and negligent misrepresentation claims with sufficient particularity. A party alleging fraud "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Rule 9(b)'s heightened pleading requirements also apply to Plaintiff's negligent misrepresentation claim because it is

[38]Complaint, Docket Entry No. 1, pp. 29-33.

based on the same set of alleged facts as the fraud claims: that Defendant misrepresented to Plaintiff, her physicians, and the general public that the Pelvic Mesh Products were safe and effective. Benchmark Electronics, Inc. v. J.M. Huber Corp., 343 F.3d 719, 723 (5th Cir. 2003). To meet Rule 9(b)'s standards, allegations must include the time, place, and contents of the alleged false representations, as well as the identity of the person making the misrepresentation and what was fraudulently obtained. Id. at 724.

Plaintiff argues she has satisfied Rule 9(b)'s requirements by pleading that Defendant "conducted a sales and marketing Campaign to promote the sale of the Pelvic Mesh Products and willfully deceived the Plaintiff, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the [products'] health risks and consequences."[39] Plaintiff pleads no details as to any communications made pursuant to the alleged marketing campaign, from whom the communications originated except generally from the Defendant corporation, or when or where the communications were received by the alleged recipients. Plaintiff only generally alleges that Defendant at some point misrepresented the Pelvic Mesh Products as safe and effective, and this allegation is too broad

[39]Complaint, Docket Entry No. 1, p. 32 ¶ 133; Plaintiff's Response, Docket Entry No. 16, p. 24.

and conclusory to satisfy Rule 9(b)'s heightened standards. Accordingly, Plaintiff's fraud, fraud by concealment, and negligent misrepresentation claims that rely on these allegations fail as a matter of law.

G. Negligence

Plaintiff alleges a state law claim in negligence against Defendant.[40] Defendant contends Plaintiff has not alleged sufficient facts to plausibly support that Defendant breached a duty owed to Plaintiff or that such a breach proximately caused the injuries.

In both Texas and Florida a plaintiff alleging negligence must demonstrate the existence of a duty, breach of that duty, and damages proximately caused by that breach. Western Investments, Inc. v. Urena, 162 S.W.3d 547, 550 (Tex. 2005); Clay Electric Cooperative, Inc. v. Johnson, 873 So. 2d 1182, 1185 (Fla. 2003). Manufacturers may be sued for negligence where they do not exercise ordinary care in the design and production of a product. Syrie v. Knoll International, 748 F.2d 304, 307 (5th Cir. 1984) (citing Gonzales v. Caterpillar Tractor Co., 571 S.W.2d 867, 871 (Tex. 1978)). Defendant argues the Complaint simply alleges Defendant owed a duty to act reasonable in the design and manufacture of the Pelvic Mesh Products and that Defendant breached that duty by

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[40] Id. at 26-27.

negligently and carelessly designing and manufacturing the products.[41] However, Plaintiff's claim for negligence incorporates factual allegations found elsewhere in the Complaint. The court must take the following factual allegations as true:

- Defendant knew that mesh medical devices constructed of polypropylene posed risks to patients because of their material, likelihood to deform, and designed method of implantation;[42]
- Defendant failed to adequately study the risks posed by its own products;[43]
- Defendant knew such risks could cause serious injury in patients receiving the devices;[44] and
- Defendant ignored such risks in its construction or design of the product and thereby caused Plaintiff's injuries.[45]

Defendant complains that Plaintiff has not specifically alleged how Defendant failed to study its products, how it knew of such risks, or how those failures specifically resulted in Plaintiff's injuries. But Rule 8 only requires the Complaint to provide the grounds that entitle Plaintiff to relief, not "detailed factual allegations." Twombly, 127 S. Ct. at 1964. The court concludes

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[41]Defendant's Memorandum, Docket Entry No. 7, pp. 15-16 (citing Complaint, Docket Entry No. 1, pp. 26-27 ¶¶ 103-12).

[42]Complaint, Docket Entry No. 1, pp. 3 ¶ 9; 4-5 ¶¶ 12-14; 7 ¶¶ 27-28; 8 ¶¶ 31-32; 20 ¶ 73.

[43]Id. at 17 ¶ 47.

[44]Id. at 9 ¶ 36; 21 ¶ 76.

[45]Id. at 9 ¶ 36; 20-21 ¶¶ 73-74; 21 ¶ 76.

Plaintiff has stated sufficient facts to plausibly state a claim in negligence.

However, the court agrees with Defendant that Plaintiff's negligence claim cannot rely on any alleged negligent failure to warn as this would be an impermissible circumvention of the learned intermediary doctrine and its bar on Plaintiff's failure-to-warn strict liability claim. Ebel v. Eli Lilly and Co., 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) (applying Texas law); Beale, 492 F. Supp. 2d at 1372 (applying Florida law). Plaintiff's negligence claim may therefore only proceed on her negligent manufacturing theory unless she cures her pleadings to satisfy the learned intermediary doctrine.

H. Punitive Damages

Plaintiff alleges her claims against Defendant entitle her to receive punitive damages.[46] Defendant argues that Plaintiff has not pled facts that could support availability of punitive damages.[47] Punitive damages are available when the evidence shows the defendant acted with fraud, malice, or gross neglect. Tex. Civ. Prac. & Rem. Code. § 41.003. Defendant argues Plaintiff has only pled the legal conclusion that Defendant "showed complete and reckless indifference to and conscious disregard for the safety of

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[46] Id. at 34-35.

[47] Defendant's Memorandum, Docket Entry No. 7, pp. 22-23.

others."[48] But Plaintiff points to several factual allegations that the court must take as true: that Defendant failed to adequately research or anticipate the possible risks and dangers the Pelvic Mesh Products would have, and that Defendant downplayed or omitted those risks despite knowledge that they would cause catastrophic injuries in some individuals such as Plaintiff.[49] These allegations go beyond mere legal conclusions, and dismissal of Plaintiff's claim for punitive damages at this stage is therefore premature.

IV. Conclusion and Order

For the reasons explained above, Plaintiff has failed to state a claim for which relief may be granted except as to her negligence claim. However, federal courts generally give a plaintiff an opportunity to cure pleading defects before dismissing with prejudice unless the defect is incurable. Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co., 313 F.3d 305, 329 (5th Cir. 2002). Plaintiff has not had an opportunity to amend her claims and has requested leave to amend should the court find them deficient.[50] The deficiencies in Plaintiff's claims described above are not clearly incurable and therefore should not be dismissed with prejudice.

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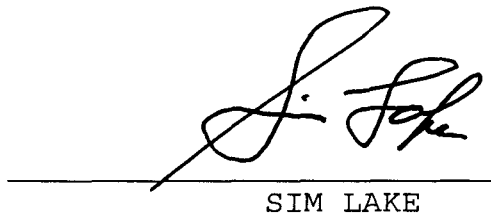
[48] Id.

[49] Complaint, Docket Entry No. 1, pp. 6 ¶ 24; 7 ¶ 25; 8-9 ¶ 35; 9 ¶ 36; 17 ¶ 47.

[50] Plaintiff's Response, Docket Entry No. 16, p. 25.

Accordingly, Defendant Boston Scientific's Motion to Dismiss (Docket Entry No. 6) pursuant to Rule 12(b)(6) is therefore **DENIED** with respect to Plaintiff's claims for negligence and punitive damages, and **GRANTED** with respect to Plaintiff's other claims, which will be dismissed without prejudice. Plaintiff may file an amended complaint to cure the dismissed claims pursuant to a schedule that will be established at the October 18, 2019, pretrial and scheduling conference.

SIGNED at Houston, Texas, on this 16th day of October, 2019.



SIM LAKE
SENIOR UNITED STATES DISTRICT JUDGE