UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

JUDITH CASTILLO,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 7:20-CV-123
	§	
BOSTON SCIENTIFIC CORPORATION,	§	
	§	
Defendant.	§	

OPINION AND ORDER

The Court now considers the motion to dismiss[1] and the memorandum in support of the motion to dismiss[2] (hereafter, collectively "motion to dismiss")[3] filed by Boston Scientific Corporation ("Defendant"). The Court also considers the response[4] filed by Judith Castillo ("Plaintiff") and the reply filed by Defendant.[5] After considering the motion, record, and relevant authorities, the Court **GRANTS** Defendant's motion to dismiss.

I. BACKGROUND

This is a products liability case. Plaintiff brings this suit against Defendant for injuries and damages allegedly sustained from complications with the Solyx Single Incision Sling System (hereafter the "Product"), a transvaginal mesh product designed, manufactured, and sold by Defendant.[6] On or about February 3, 2017, Plaintiff "had the [Product] implanted at Edinburg

[1] Dkt. No. 10.
[2] Dkt. No. 10-1.
[3] Defendant's motion to dismiss is a one-page document stating the legal standard under which Defendant requests Plaintiff's claims be dismissed. Dkt. No. 10. In contrast, the memorandum in support of the motion to dismiss is an eleven-page document attached to the motion to dismiss which acts as a substantive motion to dismiss. Dkt. No. 10-1. Accordingly, the Court will refer to the motion and memorandum collectively as the "motion to dismiss."
[4] Dkt. No. 16.
[5] Dkt. No. 17.
[6] Dkt. No. 1 at 1–2, ¶¶ 1–4 (Plaintiff's complaint).

Regional Medical Center in Edinburg, Texas"[7] to treat urinary frequency and stress urinary incontinence.[8] "Within months" of having the Product implanted, Plaintiff alleges she experienced pain during sex, cramping, discolored discharge, and chronic urinary tract infections.[9] On November 5, 2019, more than two-and-a-half years after implantation, Plaintiff alleges that "a vaginal exam revealed an extrusion of the [Product]," which then "had to be excised from [Plaintiff's] body."[10]

Plaintiff alleges that the Product "contain[s] polypropylene mesh . . . [which] is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving the [Product]."[11] Plaintiff cites to a July 2011 Food and Drug Administration ("FDA") safety communication and publication;[12] a July 2011 FDA White Paper; and a December 2011 American College of Obstetricians and Gynecologists and American Urogynecology Society Joint Committee Opinion[13] to ultimately allege that Defendant "knew that the [Product], as designed, manufactured, distributed, sold and/or supplied by Defendant, [was] defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing,"[14] which resulted in Plaintiff experiencing "significant mental and physical pain and suffering . . . permanent injury . . . and financial or economic loss[es], including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages."[15] Plaintiff also provides that her experience with Defendant's product was not an isolated incident,

[7] *Id.* at 14, ¶ 56.
[8] Dkt. No. 16 at 1 (Plaintiff's response to the motion to dismiss). Plaintiff's complaint contains a few sentences of facts actually pertaining to Plaintiff and her Product implantation. The Court looks to Plaintiff's response to the motion to dismiss for any details regarding Plaintiff's experience with the Product.
[9] *Id.*
[10] *Id.*
[11] Dkt. No. 1 at 3, ¶ 10.
[12] *Id.* at 4, ¶¶ 15-16.
[13] *Id.* at 5–6, ¶¶ 21–25.
[14] *Id.* at 13, ¶ 54.
[15] *Id.* at 14, ¶ 59.

noting that "[i]n 2012, the Judicial Panel on Multi-District Litigation created *In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation No. 2326*, in the United States District Court, Southern District of West Virginia," a multidistrict litigation proceeding ("MDL") involving various mesh products designed and sold by Defendant.[16] Plaintiff provides that over 26,000 cases were filed in the MDL as of August 5, 2020, but that "plaintiffs may no longer direct file claims against Defendant Boston Scientific Corporation in the MDL."[17]

Because Plaintiff was not permitted to file her suit in the MDL, Plaintiff filed suit in this Court on May 12, 2020, bringing causes of action against Defendant for (1) negligence; (2) "strict liability – design defect;" and (3) "strict liability – failure to warn."[18] Plaintiff bases her negligence claim on negligent design, manufacturing, and failure to warn.[19] Plaintiff seeks "compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which [she is] entitled."[20] Defendant filed the instant motion to dismiss for failure to state a claim on July 17, 2020;[21] Plaintiff responded on August 7, 2020;[22] and Defendant replied on August 14, 2020.[23] The motion is now ripe for review.

The Court turns first to preliminary matters regarding both parties' lack of compliance with the Federal Rules of Civil Procedure, before turning to its analysis.

II. CAUTIONARY NOTE

The Court first addresses the parties' noncompliance with Federal Rules of Civil

[16] Dkt. No. 1 at 1–2.
[17] *Id.*
[18] *Id.* at 14–24.
[19] *Id.* at 14–19, ¶¶ 60-65.
[20] *Id.* at 24.
[21] Dkt. No. 10.
[22] Dkt. No. 16.
[23] Dkt. No. 17.

Procedure ("Rule") 7(b)(2) with regard to (1) Defendant's motion to dismiss,[24] (2) Plaintiff's response,[25] and (3) Defendant's reply.[26] Rule 7(b)(2) provides that "[t]he rules governing captions and other matters of form in pleadings apply to motions and other papers." Rule 10(b) in turn provides that "[a] party must state its claims or defenses in numbered paragraphs, each limited as far as practicable to a single set of circumstances."

The motion to dismiss and all responsive pleadings do not have numbered paragraphs, hindering the Court's reference to the parties' arguments. The Court cautions the parties that future submissions should consistently number each paragraph to properly comply with the rules. The Court now turns to its analysis.

III. ANALYSIS

a. Legal Standard

To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face."[27] Although this does not require extensive detail, the pleading must contain "more than labels and conclusions" and go beyond "a formulaic recitation of the elements."[28] The Court regards all well-pled facts as true; however, conclusory allegations are not entitled to the same presumption of truth.[29] These well-pled facts are viewed in the light most favorable to the plaintiff.[30] Courts first disregard from their analysis any conclusory allegations as not entitled to the assumption of truth,[31] and then undertake the "context-specific" task of determining whether the remaining well-pled allegations give rise to an entitlement of relief to an

[24] Dkt. Nos. 10, 10-1.
[25] Dkt. No. 16.
[26] Dkt. No. 17.
[27] *In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 205 (5th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007), cert. denied, 552 U.S. 1182 (2008) (internal quotations omitted)).
[28] *See Twombly*, 550 U.S. at 555.
[29] *See R2 Invs. LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005).
[30] *Id.*
[31] *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009).

extent that is plausible, rather than merely possible or conceivable.[32] The Court may dismiss a complaint if the complaint fails to state a claim upon which relief can be granted on its face, or if the pleading does not assert enough facts to support a plausible claim for relief.[33]

As to any question of state law, this Court, *Erie*-bound, must adhere to grounds of relief authorized by the state law of Texas.[34] Absent a decision by a state's highest tribunal, the decisions by Texas courts of appeals are controlling "unless [the Court] is convinced by other persuasive data that the highest court of the state would decide otherwise."[35]

b. Legal Analysis

"Texas law recognizes three types of product[s] liability claims: (1) defective design, (2) defective manufacture, and (3) inadequate warning or failure to warn."[36] "Under Texas law, a plaintiff can recover in a products liability action under three theories: (1) strict liability; (2) negligence; and (3) breach of warranty."[37]

It is customary and proper for a plaintiff to plead strict liability and negligence as alternative theories, as Plaintiff does here.[38] However, "[a] negligence claim is a distinct cause of action from a strict products liability claim.[39] "The care taken by the supplier of a product in its

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[32] *Id*. at 679–80.
[33] *See In re Katrina*, 495 F.3d at 205.
[34] *See Exxon Co. U.S.A, Div. of Exxon Corp. v. Banque De Paris Et Des Pays-Bas,* 889 F.2d 674, 675 (5th Cir. 1989); *see also Erie R.R. Co. v. Tompkins,* 304 U.S. 64 (U.S. 1938).
[35] *Exxon,* 889 F.2d at 675 (quoting *West v. AT&T,* 311 U.S. 223, 237 (1940)) (internal quotation marks omitted).
[36] *Blackmon v. Am. Home Prod. Corp.,* 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004) (citing *Hanus v. Tex. Utils. Co.,* 71 S.W.3d 874, 878 (Tex.App.—Fort Worth 2002, no pet.); *Coleman v. Cintas Sales Corp.,* 40 S.W.3d 544, 548 (Tex.App.—San Antonio 2001, pet. denied)).
[37] *Romo v. Ford Motor Co.*, 798 F. Supp. 2d 798, 805 (S.D. Tex. 2011) (citing *Dion v. Ford Motor Company*, 804 S.W.2d 302, 309 (Tex.App.-Eastland 1991)).
[38] *Garrett*, 850 F.2d at 256. "[A]lthough a negligence claim requires a different showing from a strict liability claim, a manufacturer logically cannot be held liable for failing to exercise ordinary care when producing a product that is not defective because: (1) if a product is not unreasonably dangerous because of the way it was manufactured, it was not negligent to manufacture it that way and (2) even if the manufacturer was somehow negligent in the design or production of the product, that negligence cannot have caused[6] the plaintiff's injury because the negligence did not render the product "unreasonably dangerous." *Id.* at 257.
[39] *Simien v. C. R. Bard, Inc.*, No. 1:20-CV-131, 2020 WL 4922331, at *9 (E.D. Tex. Aug. 20, 2020) (citing *McLennan v. Am. Eurocopter Corp.*, 245 F.3d 403, 431 (5th Cir. 2001); *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d

preparation, manufacture, or sale, is not a consideration in strict liability; this is, however, the ultimate question in a negligence action."[40] "Strict liability looks at the product itself and determines if it is defective," while "[n]egligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production."[41]Accordingly, the Court will consider Defendant's arguments in support of dismissal concerning Plaintiff's strict liability claims for design defect and failure to warn, before turning to the motion to dismiss as it pertains to Plaintiff's negligence claim. However, the Court notes that the parties constantly conflate their arguments regarding the sufficiency of Plaintiff's claims under negligence and strict liability theories. Thus, the Court will attempt to discern which arguments are relevant to its analyses of Plaintiff's strict liability and negligence claims.

Prior to addressing each claim individually, the Court must address an argument found throughout Defendant's motion to dismiss relating to all of Plaintiff's claims. In the motion, Defendant notes that "Plaintiff's Complaint is identical to three other complaints involving various pelvic mesh products—including those manufactured by a company other than [Defendant]—except for three paragraphs that allege Plaintiff was implanted with the [Product], experienced alleged complications, and had the mesh removed."[42] In arguing that Plaintiff's pleadings are vague, Defendant repeatedly points out that Plaintiff's complaint refers to "the Mesh Products," a seemingly general term that Defendant interprets as referring to all mesh products.[43] Defendant argues that Plaintiff's complaint, in so far as it refers to mesh products generally, does not make specific allegations related to Defendant's Product.[44] However, while

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420, 437 (Tex. 1997); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995); *Gonzales v. Caterpillar Tractor Co.*, 571 S.W.2d 867, 871-72 (Tex. 1978)).
[40] *Gonzales*, 571 S.W.2d at 871.
[41] *Id.*
[42] Dkt. No. 10-1 at 1.
[43] *Id.* at 1–2.
[44] *Id.*

Defendant is correct that Plaintiff's complaint is an unimpressive form complaint that has been widely filed in this District and others,[45] Plaintiff's complaint specifies that the term "Mesh Products" refers to "Defendant's Solyx Single Incision Sling System."[46] Accordingly, each sentence of Plaintiff's complaint which makes an allegation as to "Mesh Products" refers specifically to Defendant's Product.[47]

However, the Court recognizes that the choice to refer to Defendant's singular product as "the Mesh Products" was likely intended to make the complaint as general as possible, supporting Defendant's contention that the complaint, taken as a whole, is a vague form complaint that only refers to Plaintiff's actual experience with the implantation of Defendant's specific Product in three of seventy-seven paragraphs. Plaintiff admits this much is true in the response to the motion to dismiss, stating:

> In its motion, the Defendant makes much ado about the Plaintiff's Complaint being substantially similar to three other complaints filed against Defendant. This should not come as a surprise. The cases all involve the same common questions of fact and similar injuries; and would have been filed in the same MDL, using the same short form and master complaint had the MDL not been closed for direct filing.[48]

The mere fact that Plaintiff's case could have been commenced in the MDL does not excuse the filing of a complaint so general that only three of seventy-seven paragraphs refer to Plaintiff and her actual experience with Defendant's Product. Most of the facts pertaining to Plaintiff's case can only be found in the response to the motion to dismiss, and even these statements are limited.

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[45] Defendant cites to three cases in which identical complaints have been filed: *Dubay v. Bos. Sci. Corp.*, No. 3:20-cv-01374-N (N.D. Tex. May 28, 2020); *Luther v. Bos. Sci. Corp.*, No. 4:20-cv-05085-SJM (E.D. Wash. May 22, 2020); *Donnon v. Bos. Sci. Corp. & C.R. Bard Inc.*, No. 2:20-cv-01281-JJT (D. Ariz. Jun. 29, 2020). Dkt. No. 10-1 at 1, n. 1. This Court is aware of additional cases in which substantially similar, if not identical, complaints have been filed. *See* Case No. 7:19-cv-187, *Villarreal v. American Medical Systems, Inc., et al*; Case No. 7.19-ccv-295, *Jimenez v. Boston Scientific Corp.*

[46] Dkt. No. 1 at 3, ¶ 8 ("The Solyx Single Sing System manufactured by Defendant (hereinafter referred to collectively as the "Mesh Products") is considered Class II medical devices.").

[47] *Id.*

[48] Dkt. No. 16 at 2.

While a vague form complaint in and of itself does not warrant dismissal, the Court cannot help but acknowledge the lack of effort exhibited in this case.

The Court now considers Defendant's other arguments in support of dismissal, turning first to the arguments pertaining to Plaintiff's strict liability design defect claim.

i. Strict Liability

1. Design Defect

To recover on a design defect claim in Texas, a plaintiff must show: (1) the product was defectively designed so as to render it unreasonably dangerous; (2) the defect was the producing cause of the injury for which the plaintiff seeks recovery; and (3) a safer alternative design existed.[49] Under Texas law, a safer alternative design is "one that would have prevented or significantly reduced the risk of the claimant's personal injury . . . without substantially impairing the product's utility."[50] Such safer alternative design "must also be economically and scientifically feasible,"[51] and cannot be a "substantially different product."[52] Moreover, a plaintiff "must show the safety benefits from [the] proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety."[53] Regardless of whether a plaintiff brings a design defect claim under a theory of strict liability or negligence, she must plead the existence of a "safer alternative design" in order to state a claim for relief.[54]

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[49] *Simien*, No. 1:20-CV-131, 2020 WL 4922331, at *8 (citing *Emery v. Medtronic, Inc.*, 793 F. App'x 293, 295 (5th Cir. 2019); *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig*., 888 F.3d 753, 765 (5th Cir. 2018)).

[50] *In re DePuy Orthopaedics, Inc.* 888 F.3d at 765 (citing TEX. CIV. PRAC. & REM. CODE ANN. § 82.005(b)).

[51] *Id.* at n. 6 (citing *Honda of Am. Mfg. Inc. v. Norman*, 104 S.W.3d 600, 608 (Tex. App.—Houston [1st Dist.] 2003, pet. denied).

[52] *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 770 (Tex. App.—Houston [14th Dist.] 2009, no pet.); *Shears*, 911 S.W.2d at 385; *In re DePuy Orthopaedics, Inc.* 888 F.3d at 766; *Romo*, 798 F. Supp. 2d at 807 (citing *Goodrich Tire Co. v. Martinez,* 977 S.W.2d 328, 335 (Tex.1998)) ("Design defects are evaluated in light of the economic and scientific feasibility of safer alternatives.").

[53] *In re DePuy Orthopaedics, Inc.* 888 F.3d at 765-66 (citing *Casey*, 770 F.3d at 331).

[54] *Kia Motors Corp. v. Ruiz*, 432 S.W.3d 865, 875 (Tex. 2014) (holding that a negligent design claim required a showing of "safer alternative design"); *Cofresi v. Medtronic, Inc.*, 450 F. Supp. 3d 759 (W.D. Tex. 2020) (finding that Plaintiff's design defect claim failed under theories of strict liability and negligence because the plaintiff failed

Defendant argues that Plaintiff fails to plead facts sufficient to state a strict liability design defect claim.[55] First, Defendant argues Plaintiff "does not plausibly allege that the implanted [Product] was defective or unreasonably dangerous," because "she alleges only that 'Mesh Products,' generally, are defective" and fails to "allege anything about how these generalized purported design flaws relate to her injuries."[56] Second, Defendant argues that "Plaintiff has not plausibly pleaded that any defect caused her alleged injuries," and that "[c]ausation is an essential element in design defect claims, whether based in negligence or strict liability."[57] Finally, Defendant argues that "Plaintiff fails to plausibly allege that the [Product] was unreasonably dangerous and that a safer alternative design existed at the time of her implanting surgery."[58] Defendant asserts that Plaintiff's conclusory allegation that "'[f]easible and suitable alternatives to the [Product] have existed at all times relevant that do not present the same frequency or severity of risks as [does the Product]'" is insufficient to fulfill the alternative design element of a design defect claim.[59]

In support of her argument that this claim is sufficiently pled, Plaintiff points to her complaint listing "specific reasons why the [Product's] design is unreasonably dangerous: the use of polypropylene material in the [Product,] the design of the [Product] to be inserted into and through an area of the body with high levels of bacteria, biochemical issues with the design of

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to show a "safer alternative design" existed); *Brockert*, 287 S.W.3d at 771 ("Failure to raise a fact issue concerning a safer alternative design disposes of all of [the plaintiff's] design-defect claims, including her negligent-design-defect claim.").

[55] While Defendant does not specify that these arguments are made in regard to Plaintiff's strict liability design defect claim, Defendant addresses Plaintiff's negligence claim separately and thus, the Court takes Defendant's arguments related to design defect as addressing Plaintiff's strict liability design defect claim.

[56] Dkt. No. 10-1 at 6.

[57] *Id.* at 7.

[58] *Id.*

[59] *Id.* at 8 (citing Dkt. No. 1 at 12, ¶ 42).

the [Product,] the design of the arms and anchors, the inelasticity of the [Product] and so forth."[60] Plaintiff also argues that she adequately pleaded that the Product implanted in her caused her injuries,[61] and alleges in the complaint that she experienced "significant mental and physical pain and suffering," permanent injury, substantial medical treatment, and financial and economic loss "[a]s a direct and proximate result of the [Product's] aforementioned defects."[62] The Court agrees with Plaintiff that as to the Product's design defect rendering it unreasonably dangerous and to producing cause, Plaintiff sufficiently pleads the first and second elements of design defect.

Yet, Plaintiff's pleadings for design defect under a theory of strict liability fail on the third element. Plaintiff argues she pleaded that a safer alternative design existed at the time of implantation by stating "[f]easible and suitable alternatives to the [Product,] have existed at all times relevant that do not present the same frequency or severity of risks as do the [Product]."[63] Plaintiff's *strict* liability design defect claim cannot survive because Plaintiff fails to plead the existence of a "safer alternative *design*." Plaintiff instead opts for "feasible available designs,"[64] "feasible alternative treatments,"[65] and "[f]easible and suitable alternatives,"[66] which are both factually and legally insufficient. These do not constitute alternative designs for the Product but simply alternatives to using the Product. Plaintiff's allegations are also conclusory and do not actually identify any safer design or product. Moreover, Texas law clearly dictates a "safer

[60] *Id.* at 7 (citing Dkt. No. 1 at 15–26, ¶ 63). Plaintiff cites to her list of particular injuries contained in the negligence section of her complaint. This list is also contained in the strict liability design defect section. Dkt. No. 1 at 8–10, ¶ 37.
[61] *Id.*
[62] Dkt. No. 1 at 21, ¶ 71.
[63] Dkt. No. 16 at 8 (citing Dkt. No. 1 at 12, ¶ 42).
[64] Dkt. No. 1 at 22, ¶ 74(m).
[65] *Id.* at 7, ¶ 34.
[66] *Id.* at 12, ¶ 42.

alternative design" cannot be a substantially different product."[67] Plaintiff's complaint mentions an FDA communication and White Paper that reference "traditional non-mesh repair,"[68] but even if the Court were to accept this as a safer alternative to the Product, this amounts to a substantially different product because it does not contain mesh. In sum, Plaintiff fails to plead non-conclusory facts to suggest a "safer alternative design" exists.

Plaintiff's failure to sufficiently plead a "safer alternative design" also precludes her design defect claim under a negligence theory. For a design defect to exist under both strict liability and negligence theories, Plaintiff must allege a "safer alternative design."[69] Thus, because Plaintiff fails to plead a "safer alternative design," her design defect claim also fails under a theory of negligence.

Accordingly, Plaintiff fails to state a claim for design defect under a negligence or strict liability theory. Thus, the Court **GRANTS** Defendants' motion as to Plaintiff's design defect claim under both theories. The Court now turns to Plaintiff's strict liability failure to warn claim.

2. Failure to Warn

"Texas law requires a plaintiff alleging a failure to warn claim to prove that "(1) a risk of harm is inherent in the product or which may arise from the intended or reasonably anticipated use of the product; (2) the product suppliers actually knew or should have reasonably foreseen the risk of harm at the time the product was marketed; (3) the product contains a marketing

[67] *Brockert*, 287 S.W.3d at 770; *Caterpillar Inc.*, 911 S.W.2d at 385; *In re DePuy Orthopaedics, Inc.* 888 F.3d at 766.

[68] Dkt. No. 1 at 5, ¶ 20; 6, ¶ 23 ("The FDA White Paper further stated that 'these products are associated with serious adverse events. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair.'").

[69] *See Kia Motors Corp.*, 432 S.W.3d at 875 (holding that a negligent design claim required a showing of "safer alternative design"); *Cofresi*, 450 F. Supp. 3d at 759 (finding that Plaintiff's design defect claim failed under theories of strict liability and negligence because the plaintiff failed to show a "safer alternative design" existed); *Brockert*, 287 S.W.3d at 771 ("Failure to raise a fact issue concerning a safer alternative design disposes of all of [the plaintiff's] design-defect claims, including her negligent-design-defect claim.").

defect; (4) the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and (5) the failure to warn must constitute a causative nexus in the product user's injury."[70]

Defendant argues Plaintiff's strict liability failure to warn claim is barred by the learned intermediary doctrine, because "Plaintiff's [c]omplaint lacks any plausible allegations that [Defendant] failed to provide [Plaintiff's] physicians with any warning that would have changed her physicians' decision to use the [Product]."[71] Defendant also argues Plaintiff's failure to warn claim is too vague because her complaint makes allegations regarding Defendant's failure to warn the "medical community," rather than Plaintiff's physicians.[72]

Texas courts apply the learned intermediary doctrine to medical products liability claims.[73] Pursuant to this doctrine, "a product manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers."[74] However, a manufacturer may still be held liable for injuries sustained by the plaintiff if (1) the warning to the physician was inadequate; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury.[75] To overcome the learned intermediary doctrine, "plaintiffs must show that, but for the inadequate warning, their doctors would have recommended different treatment, or provided additional warnings that would have led plaintiffs to withhold consent.[76] "A plaintiff's pleadings are insufficient when they do not identify the

[70] *Miles v. Bos. Sci. Corp.*, No. CV H-19-4319, 2020 WL 3871329, at *6 (S.D. Tex. July 9, 2020) (citing *Wright v. Ford Motor Co.*, 508 F.3d 263, 274-75 (5th Cir. 2007)).
[71] Dkt. No. 10-1 at 5 (citing *Gonzalez*, 930 F. Supp. 2d at 818). Defendant also argues Plaintiff's failure to warn claim is too vague because it makes allegations against the "medical community." *Id.* at 3–4. The Court addresses this argument in another section of the instant Order.
[72] Dkt. No. 10-1 at 3–4.
[73] *Id.* (citing *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999)).
[74] *Porterfield*, 183 F.3d at 467–68.
[75] *Miles*, No. CV H-19-4319, 2020 WL 3871329, at *6 (citing *Porterfield*, 183 F.3d at 468).
[76] *In re DePuy Orthopaedics, Inc.* 888 F.3d at 774 (citing *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208, 214 (5th Cir. 2008); *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006)) (internal citations omitted).

warning that her doctor received, allege how it was inadequate, demonstrate that a different warning would have changed the doctor's actions, or otherwise include facts necessary to allege the failure to warn caused her injury."[77]

In response, Plaintiff does not dispute that the learned intermediary doctrine applies. However, Plaintiff argues that she "has plausibly pleaded that the Defendant failed to adequately warn her physician of the risks associated with the [Product]."[78] In response to Defendant's argument that Plaintiff's claims against "the medical community at large"[79] are insufficient, Plaintiff directs the Court's attention to her complaint, which makes allegations regarding Defendant's failure to warn "Plaintiff's healthcare providers, and the medical community."[80] Plaintiff argues that her allegation that Defendant failed "to adequately warn or instruct Plaintiff and her healthcare providers" regarding the Product's dangerous propensities is sufficient to support her failure to warn claim.[81] The Court agrees.

However, Plaintiff cannot overcome the learned intermediary doctrine to hold Defendant liable because she does not identify any warning given to her physician, does not allege how the warning was inadequate, and does not demonstrate that a different, better warning would have affected her physician's decision to use the Product to treat Plaintiff.[82] Moreover, Plaintiff also does not plead any facts to plausibly suggest that Defendant's inadequate warning or failure to warn was a producing cause of the Plaintiff's injuries.[83] Rather, Plaintiff's allegations are once again conclusory, as she relies solely on her vague allegation that Defendant failed "to

[77] *Miles*, No. CV H-19-4319, 2020 WL 3871329, at *6 (citing *Gonzalez*, 930 F. Supp. 2d at 818).
[78] Dkt. No. 16 at 4.
[79] Dkt. No. 10-1 at 2.
[80] Dkt. No. 16 at 4–5; Dkt. No. 1 at 13, ¶ 53.
[81] Dkt. NO. 16 at 4 (citing Dkt. No. 1 at 10, ¶ 38).
[82] *See Miles*, No. CV H-19-4319, 2020 WL 3871329, at *6 (citing *Gonzalez*, 930 F. Supp. 2d at 818).
[83] *Id.* (citing *Porterfield*, 183 F.3d at 468).

adequately warn or instruct Plaintiff and her healthcare providers" regarding the Product's dangerous propensities.[84]

For the aforementioned reasons, Plaintiff fails to state a claim for failure to warn under a theory of strict liability. Thus, the Court **GRANTS** Defendants' motion as to Plaintiff's strict liability failure to warn claim. The Court now turns to Plaintiff's negligence claim.

ii. Negligence

Plaintiff alleges Defendant negligently manufactured and designed the Product, and "negligently failed to warn or instruct Plaintiff and/or her health care providers" of the Product's dangers.[85] Where a products liability claim is based on negligence, the plaintiff must demonstrate that (1) the manufacturer owed a legal duty to the plaintiff; (2) the manufacturer breached that duty; (3) the plaintiff suffered an injury as a result of the breach; and (4) the defendant's actions were a proximate cause of the injury.[86]

The Court has already found herein that Plaintiff fails to state a claim for design defect under a theory of negligence because she fails to plead a "safer alternative design." The Court has also found that Plaintiff fails to identify an inadequate warning or to plead any facts necessary to suggest that Defendant's inadequate warning or failure to warn caused her injuries. Thus, it is also true that Plaintiff's failure to warn claim cannot survive under a negligence theory because Plaintiff has not satisfied the causation element by stating facts to suggest Defendant's failure to warn caused her injuries.[87] Accordingly, the Court need only consider whether Plaintiff's negligent manufacture claim survives Defendant's motion to dismiss.

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[84] Dkt. No. 1 at 10, ¶ 38.
[85] *Id.* at 14–17, ¶¶ 61–64.
[86] *Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 923 (S.D. Tex. 2005) (citing *Mosley v. Excel Corp.*, 109 F.3d 1006, 1009 (5th Cir.1997)).
[87] *See id.* at 923 ("The Court, even under a strict liability standard, has concluded that [Defendant] did not fail to adequately warn of the dangers presented by Accutane, and that such a failure, if any, was not a cause of any legally cognizable injury.").

"Products liability premised upon a showing of negligence [] focuses upon the conduct of the manufacturer in placing that product into the stream of commerce, and requires a determination of whether that conduct complies with the applicable standard of care."[88] In negligence-based products liability actions, a manufacturer typically owes a duty of reasonable or ordinary care, which is thought to be breached when the manufacturer "fail[s] to do that which a reasonable and prudent manufacturer engaged in the manufacture of like or similar equipment would have done under the same or similar circumstances, or doing that which a manufacturer with ordinary prudence would not have done under the same or similar circumstances."[89]

Whether a plaintiff seeks recovery based on negligence or strict liability, the burden is on the plaintiff to prove that the injury resulted from a defect in the product.[90] Thus, it follows that just as a design defect claim under a negligence theory requires a plaintiff to sufficiently plead the existence of a design defect, a plaintiff bringing a negligent manufacturing claim must plead the existence of a manufacturing defect. A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.[91]

Defendant argues that "Plaintiff's negligence claim [] fails because Plaintiff has not plausibly pleaded that [Defendant] breached any duty owed and has failed to tie any alleged breach to her alleged injuries."[92] Defendant argues that "Plaintiff does not assert or explain how any alleged act or omission by Defendant— specific to the [Product]—breached a governing standard of care. [] Nor does Plaintiff causally connect the particular manner in which any

[88] *McLennan*, 245 F.3d at 431 (citing *Syrie v. Knoll Int'l*, 748 F.2d 304, 306 (5th Cir.1984)).
[89] *Gonzales*, 571 S.W.2d at 870.
[90] *Ford Motor Co. v. Miles*, 141 S.W.3d 309, 315 (Tex. App. 2004).
[91] *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004) (citing *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 844 (Tex.2000); *Grinnell*, 951 S.W.2d at 434).
[92] Dkt. No. 10-1 at 8–9 (citing *W. Invests., Inc. v. Urena*, 162 S.W.3d 547, 550 (Tex. 2005)).

alleged breach proximately caused her particular injuries."[93] Defendant also asserts that Plaintiff's allegation that Defendant "'was negligent in its design, manufacture, testing, and/or inspection of its [Product]'" is conclusory.[94]

Finally, Defendant argues that Plaintiff does not plead any allegations necessary to state a claim for a manufacturing defect:

> [Plaintiff's] negligence claim also fails because she has not plausibly pleaded the existence of a manufacturing defect. To state a claim for manufacturing defect, Plaintiff must plausibly plead that the product at issue 'deviates from the specifications or planned output in a manner that renders it unreasonably dangerous' and that it was 'defective when it left the hands of the manufacturer' and resulted in Plaintiffs' alleged injuries.[95]

In response, Plaintiff argues that she sufficiently alleges all elements of a negligence claim in her complaint.[96] Plaintiff argues she pleaded the existence of a duty sufficiently when she stated, "Defendant had a duty to individuals, including Plaintiff, to use reasonable care in designing manufacturing, marketing, labeling, packaging, and selling the [Product.]"[97] Plaintiff argues she sufficiently alleges breach by pleading that Defendant breached its duty of care by failing to design, manufacture, test, inspect, and provide an adequate warning regarding the product "so as to avoid an unreasonable risk of harm to women in whom the [Product] was implanted."[98] Finally, Plaintiff argues she sufficiently pleaded causation and damages when she included the following allegation in her complaint:

> As a direct and proximate result of the [Products'] aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, including multiple procedures to correct her injuries and will likely undergo further medical treatment and procedures, has suffered financial or economic loss,

[93] *Id.* at 10.
[94] *Id.* at 9 (citing Dkt. No. 1 at 14, ¶ 62).
[95] *Id.* (citing *Miles*, No. CV H-19-4319, 2020 WL 3871329, at *5).
[96] Dkt. No. 16 at 8 (citing *Boudreaux v. Swift Transp. Co.*, 402 F.3d 536, 538 (5th Cir. 2005)).
[97] *Id.* (citing Dkt. No. 1 at 14, ¶ 61).
[98] *Id.* (citing Dkt. No. 1 at 14–15, ¶ 62).

> including but not limited to obligations for medical services and expenses, and/or lost income and other damages.[99]

Plaintiff does not respond to Defendant's argument that she fails to plead the existence of a manufacturing defect.

Here, Plaintiff does not allege that the Product suffered from a manufacturing defect or that this defect was the cause of Plaintiff's injuries. At no point does Plaintiff argue that the Product implanted inside of her deviated from Defendant's original specifications or planned output to make it unreasonably dangerous or capable of causing Plaintiff's injuries. All of Plaintiff's allegations related to negligence and manufacturing are conclusory and related to the overall design of the Product. In fact, it appears from Plaintiff's allegations that the Product implanted in Plaintiff was consistent with Defendant's original design and does not deviate from Defendant's planned output. Thus, because Plaintiff fails to allege any manufacturing defect, Plaintiff's claim for negligent manufacturing is subject to dismissal.

Moreover, the Texas Supreme Court has held that "[n]egligent design *and* manufacturing claims are predicated on the existence of a safer alternative design for the product" and "[a]bsent an alternative design, a claim for negligent design or manufacturing fails as a matter of law."[100] Thus, even if Plaintiff sufficiently alleged a manufacturing defect, Plaintiff has still failed to identify a safer alternative design. Accordingly, the Court **GRANTS** Defendants' motion to dismiss as to Plaintiff's negligence claim.

iii. Leave to Amend

Plaintiff embeds in her response to Defendant's motion to dismiss an alternative request for leave to amend any deficiencies in her complaint, "if the Court agrees with Defendant."[101] The Court finds amendment unwarranted here. Plaintiff provides no basis or detail for the

[99] *Id.* (citing Dkt. No. 1 at 21, ¶ 71).
[100] *Grinnell*, 951 S.W.2d at 437 (citing *Gonzales*, 571 S.W.2d at 871–72) (emphasis added).
[101] Dkt. No. 16 at 3.

requested amendment and fails to apprise the Court of what additional facts Plaintiff would provide in an amended complaint. Plaintiff's request fatally mirrors similar requests denied by district courts and subsequently affirmed by the Fifth Circuit.[102] Thus, the Court **DENIES** Plaintiff's request for leave to amend.

IV. HOLDING

For the reasons stated herein, the Court hereby **GRANTS** Defendant's motion to dismiss[103] and **DISMISSES WITH PREJUDICE** Plaintiff's claims in their entirety. A final judgment will issue pursuant to Rule 54.

IT IS SO ORDERED.

DONE at McAllen, Texas, this 18th day of September, 2020.

Micaela Alvarez
United States District Judge

[102] *Edionwe v. Bailey*, 860 F.3d 287, 294 (5th Cir. 2017), *cert. denied*, 138 S. Ct. 687 (2018) (where appellant's motion to amend stated "[i]f the Court is inclined to dismiss any portion of Plaintiff's complaint for failure to state a claim, Plaintiff requests leave of court to amend his complaint to cure the alleged pleading deficiencies identified by Defendants . . . .") (citing *Gentilello v. Rege*, 627 F.3d 540, 546 (5th Cir. 2010)).
[103] Dkt. No. 10, 10-1.