UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

SHEILA BROOKS CIVIL ACTION

VERSUS

AMGEN, INC. NO.: 18-cv-00657-BAJ-EWD

RULING AND ORDER

Before the Court is the **Motion to Dismiss, (Doc. 5),** filed by Defendant, Amgen, Inc., seeking an order from this Court dismissing Sheila Brooks' claims against it pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). Plaintiff, Sheila Brooks, opposes the motion. (Doc. 17). Defendant filed a Memorandum in Reply. (Doc. 18). Plaintiff also plead an alternative request for leave of court to file an amended petition, or should the Court grant Defendant's motion, that the dismissal be without prejudice to allow Plaintiff the opportunity to refile her complaint. (Doc. 17 at pp. 13-14). Oral argument is not necessary to rule upon this motion. The Court has jurisdiction pursuant to 28 U.S.C. § 1332. For the reasons stated herein, the **Motion to Dismiss, (Doc. 5),** is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Sheila Brooks ("Plaintiff" or "Brooks") commenced the instant action in the Twenty-Third Judicial District for the Parish of Ascension on May 30, 2018, against Amgen, Inc. ("Defendant" or "Amgen"), seeking damages for injuries allegedly arising out of the injection of Prolia/Denosumab, a drug manufactured by Defendant. (Doc.

1-2 at ¶¶ III, IV). On June 27, 2018, Defendant timely removed the action to the United States District Court for the Middle District of Louisiana based on diversity jurisdiction. (Doc. 1). Plaintiff's claims include inadequate warning, manufacturing of a defective product, and defective design. (Doc. 1-2 at ¶¶ X, XI).

Plaintiff's petition alleges that on May 30, 2017, she received an injection of Prolia/Denosumab in Gonzales, Louisiana, to treat osteoporosis, administered by Dr. Haytham Kawji. (Doc. 1-2 at ¶¶ III, IV). "Within a few weeks", Plaintiff noticed "swelling in and around her mouth" and her "teeth began to come loose and break". (Doc. 1-2 at ¶ V). Plaintiff claims that she sought medical attention and was told that she "had jaw necrosis as a result of the injection of Prolia". *Id.* Plaintiff alleges that her jaw had "necrotized to the point where her jaw had to be replaced and reconstructed". She underwent surgery and treatment was ongoing at the time she filed her petition. (Doc. 1-2 at ¶ VI). Plaintiff claims that her injuries and resulting damages were caused by the injection of Prolia, which is allegedly manufactured by Defendant. (Doc. 1-2 at ¶¶ VIII, IX).

Plaintiff specifically alleges in her petition:

> X.
>
> Prolia/Denosumab is unreasonably dangerous in its manufacture and design in that the medication is known to cause bone necrosis and in particular jaw necrosis. The condition in Prolia/Denosumab which causes bone necrosis existed at the time that it was manufactured.
>
> XI.
>
> Because of the known side-effects of jaw necrosis, Defendant, Amgen, Inc., should have warned the users and/or administrators of the serious side-effects of Prolia/Denosumab. Had Sheila Brooks been aware of the

> potential side-effects from the administration of Prolia/Denosumab, she would have never taken the medication.

(Doc. 1-2 at ¶¶ X, XI).

II. LEGAL STANDARD

A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint against the legal standard set forth in Rule 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief". Fed.R.Civ.P. 8(a)(2). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'". *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Determining whether a complaint states a plausible claim for relief [is]. . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. "[F]acial plausibility" exists "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly,* 550 U.S. at 556). Hence, the complaint need not set out "detailed factual allegations," but something "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action" is required. *Twombly*, 550 U.S. at 555.

Further, the United States Supreme Court has noted that Rule 12(b)(6) requires dismissal whenever a claim is based on an invalid legal theory:

> Nothing in Rule 12(b)(6) confines its sweep to claims of law which are obviously insupportable. On the contrary, if as a matter of law 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations,'. . . a claim must be dismissed, without

> regard to whether it is based on an outlandish legal theory, or on a close but ultimately unavailing one.

Neitzke v. Williams, 490 U.S. 319, 327 (1989) (internal citations omitted). When a complaint fails to satisfy these principles, "this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court". *Cuvillier v. Sullivan*, 503 F.3d 397, 401 (5th Cir. 2007) (quoting *Twombly*, 550 U.S. at 558).

III. ANALYSIS

A. Louisiana Products Liability Act

The Louisiana Products Liability Act ("LPLA") establishes "the exclusive theories of liability for manufacturers for damage caused by their products." La.Rev.Stat. Ann. § 9:2800.52. Thus, a claimant may not recover on the basis of any theory not set forth in the LPLA. *Jefferson v. Lead Indus. Assoc., Inc.*, 106 F.3d 1245, 1250-51 (5th Cir. 1997).

To properly state a claim under the LPLA, a plaintiff has the burden of proving that: (1) the defendant is a manufacturer; (2) the damage sustained was proximately caused by a characteristic of a product that made it "unreasonably dangerous" in one of four ways; and (3) that injury resulted from a reasonably anticipated use. La.Rev.Stat. Ann. § 9:2800.54. A product may be held to be unreasonably dangerous because of: (1) defective design; (2) defective composition or construction; (3) inadequate warning; or (4) breach of an express warranty. La.Rev. Stat. Ann. §9:2800.54(B).

Defendant argues that Plaintiff's Petition does not indicate whether her claims arise under the LPLA and that any claims that sound in theories other than those under the LPLA must be dismissed. (Doc. 5-1 at pp. 3-4). Plaintiff concedes that her action is brought under the LPLA. (Doc. 17 at p. 5, "Plaintiff's action is obviously based on the LPLA."). Therefore, it is not necessary for the Court to address whether Plaintiff's claims should be dismissed on this basis.

Plaintiff's allegations invoke three theories under the LPLA: (1) inadequate warning; (2) defective composition or construction; and (3) defective design. Defendant seeks dismissal of Plaintiff's claims pursuant to each of these theories.

1. Inadequate Warning Claim and the Learned Intermediary Doctrine

For inadequate warning claims, Louisiana applies the "learned intermediary doctrine". *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 265 (5th Cir. 2002); *see also Willett v. Baxtern Int'l Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991). Under this doctrine, a manufacturer "discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm" from the device. *Stahl*, 283 F.3d at 265 (citing *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987)). Accordingly, "the manufacturer has no duty to warn the patient, but need only warn the patient's physician". *Willet*, 929 F.2d at 1098. Louisiana applies the learned intermediary doctrine to products liability claims involving prescription drugs. *See, e.g., Allgood v. SmithKline Beecham Corp.*, 314 F.Appx. 701, 702 (5th Cir. 2009) (unpublished but persuasive).

To prevail on an inadequate warning claim, the plaintiff must demonstrate: "(1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of plaintiff's injury." *Id.* at 1098-99. This causation requirement means that the plaintiff must show that "a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product." *Id.* at 1099.

Defendant relies upon *Pellegrin v. C.R. Bard*, *Lussan v. Merck Sharp & Dohme Corp.*, and *Huffman v. Squibb,* arguing the application of the learned intermediary doctrine and for the dismissal of Plaintiff's claim of inadequate warning. *Pellegrin v. C.R. Bard*, No. CIV.A. 17-12473, 2018 WL 3046570 (E.D. La. June 20, 2018); *Lussan v. Merck Sharp & Dohme Corp.*, No. CIV.A. 17-3086, 2017 WL 2377504 (E.D. La. June 1, 2017); and *Huffman v. Squibb*, No. CIV.A. 16-3714, 2016 WL 6024532 (E.D. La. Oct. 14, 2016).

In *Pellegrin v. C.R. Bard*, the plaintiff alleged that the defendants' product contained insufficient warning of the "high risk" of "dangerous injuries" it could cause. The plaintiff further alleged that had the "defendants adequately warned the plaintiff's healthcare providers of the risks associated with the product, the healthcare providers, acting as reasonably prudent healthcare providers, would have elected not to use the product." *Id.* at *4. The Eastern District court found, "These conclusory allegations amount to 'naked assertions devoid' of the 'factual

enhancement' necessary to survive a motion to dismiss." *Id.* at *4 (citing *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557)). The court dismissed the plaintiff's inadequate warning claim on a Rule 12(b)(6) motion.

Similarly, in *Lussan v. Merck Sharp & Dohme Corp.*, the Eastern District granted a motion to dismiss pursuant to Rule 12(b)(6) regarding the inadequate warning of a medical implant. The plaintiff merely asserted that any warnings were "insufficient". The plaintiff did not plead specific risks that were not disclosed to her doctor, nor did the plaintiff allege that but for the insufficient warning, her doctor would not have prescribed the product. The court found these deficiencies fatal to the plaintiff's claim. *Id.* at *3.

However, in *Huffman v. Squibb*, the Eastern District court denied the defendants' motion to dismiss, finding that the plaintiff sufficiently plead a claim for inadequate warning and applied the learned intermediary doctrine. In *Huffman v. Squibb*, the plaintiff alleged, "that the defendants intentionally concealed or downplayed the. . . side effects" of the prescription drug, while at the same time promoting the drug "without adequately disclosing the potential risks." *Id.* at *2.

The Court highlights its opinion in *Lahaye v. Astrazeneca Pharmaceuticals, LP*, No. CIV.A. 14-00111, 2015 WL 1935947 (M.D. La. Apr. 28, 2015). *Lahaye v. Astrazeneca Pharmaceuticals* came before this Court on removal. The plaintiff amended her petition after removal to more specifically plead her products liability claims, including one of inadequate warning. The defendants filed a motion to dismiss and argued that the learned intermediary doctrine applied. This Court noted

that the defendants correctly asserted the learned intermediary doctrine and that the plaintiff's amending complaint remained "somewhat sparse"; however, this Court found that the amended complaint specifically alleged: (1) that the label on the prescribed medication did not properly warn the plaintiff or her treating physician of the possible "deleterious side effects" caused by ingesting the medication or the relationship between the medication and her specific condition, (*id.* at *3); (2) that the nature of the "alleged defect" is the long-term consumption of the medication which increases the risk of extreme conditions, (*id.* at *4); (3) that the medication was "not appropriately and sufficiently tested," (*id.* at *4); (4) that the United States Food and Drug Administration issued a communication notifying the public that the use of medications like the one at issue may be associated with the plaintiff's condition, (*id.* at *4); (5) that medical publications revealed an increase in this infection among users of this same medication, (*id.* at *4); (6) that neither the plaintiff, nor her treating physician were aware of the side effects that could result from long-term use of this medication, (*id.* at *4); (7) that the defendants failed to warn users of the nature of the product and breached its duty with its actions and omissions to the plaintiff and her treating physician, (*id.* at *5); and (8) that neither the product's package insert, nor the *Physician's Desk Reference* properly alerted the plaintiff or her physician of the relationship between the medication and the injury or to other potential risks and side effects, (*id.* at *5). Based on these findings, this Court denied the defendants' motion to dismiss.

Here, the Court finds that less is alleged on the face of Plaintiff's petition than in *Lahaye v. Astrazeneca Pharmaceuticals*, and that the prongs of the learned intermediary doctrine are not met and/or cannot be inferred from the face of the petition. The sole allegations in Plaintiff's petition regarding a warning are that Defendant "should have warned the users and/or administrators of the serious side-effects of Prolia/Denosumab" and if Plaintiff had "been aware of the potential side-effects from the administration of Prolia/Denosumab, she would have never taken the medication". (Doc. 1-2 at ¶ XI). No allegation is made as to whether the treating physician would have prescribed Prolia or not. Finding this to be insufficient, the Court grants Defendant's motion to dismiss. However, the Court is mindful that Plaintiff has not amended her petition to date and that stating more specific allegations in a pharmaceutical products liability case may be difficult at this stage. *See Winslow v. W.L. Gore & Assoc. Inc.*, No. CIV.A. 10-116, 2010 WL 866184, at *2 (W.D. La. Jan. 21, 2011) *report and recommendation adopted as modified sub nom. Winslow v. W.L. Gore & Associates, Inc.*, No. CIV.A. 10-116, 2011 WL 873562 (W.D. La. Mar. 11, 2011).

Therefore, the Court dismisses Plaintiff's claim of inadequate warning without prejudice.

2. Manufacturing Defect Claim

To state a viable claim that a product is "unreasonably dangerous in construction or composition", a plaintiff must demonstrate that at the time the product left the manufacturer's control, the product "deviated in a material way from

the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La.Rev.Stat. Ann. § 9:2800.56.

Plaintiff's petition alleges, "Prolia/Denosumab is unreasonably dangerous in its manufacture. . . in that the medication is known to cause bone necrosis and in particular jaw necrosis. The condition in Prolia/Denosumab which causes bone necrosis existed at the time that it was manufactured." (Doc. 1-2 at ¶ X). Defendant argues that Plaintiff failed to allege that the Prolia administered to her was manufactured differently than how Prolia is manufactured generally. (Doc. 5 at p. 6).

Plaintiff argues that she plead sufficient facts "like the plaintiff in *Hargroves*" [sic] to show that Prolia is unreasonably dangerous. (Doc. 17 at p. 7). However, as Defendant correctly points out in reply to Plaintiff's opposition (Doc. 18 at p. 4), the court in *Hargrove v. Boston Scientific*, No. CIV.A. 13-3539, 2014 WL 4794763 (E.D. La. Sept. 24, 2014), found that the plaintiff's complaint alleged that the product at issue was different from others in the same product line. *Id.* at * 9.

Here, Plaintiff alleges that Prolia was unreasonably dangerous in its manufacturing and that this condition existed at the time it left the manufacturer's control. However, the petition does not reflect any allegation that the Prolia that was administered to Plaintiff deviated from the manufacturer's specifications or standards or from any other Prolia manufactured at any time. While the Court acknowledges that Plaintiff may not be able to plead with specificity how the Prolia

administered to her was improperly manufactured at this stage of the proceeding, the Court does not glean a sufficient general allegation of a manufacturer defect from the face of Plaintiff's petition. For these reasons, the Court grants Defendant's motion and dismisses Plaintiff's claim of a manufacturer defect without prejudice.

3. Design Defect Claim

To state a viable claim that a product is "unreasonably dangerous in design," a plaintiff must demonstrate that at the time the product left the manufacturer's control, (1) there existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) the likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. La.Rev.Stat. Ann. § 9:2800.56.

Defendant argues that Plaintiff's design defect claim should be dismissed because Plaintiff failed to allege any alternative design. (Doc. 5 at p. 7).

Plaintiff alleges in her petition, "Prolia/Denosumab is unreasonably dangerous in its. . . design in that the medication is known to cause bone necrosis and in particular jaw necrosis. The condition in Prolia/Denosumab which causes bone necrosis existed at the time that it was manufactured." (Doc. 1-2 at ¶ X). Plaintiff argues that she has plead sufficient facts to show that Prolia is unreasonably dangerous. (Doc. 17 at p. 7).

The Court finds that Plaintiff has alleged that Prolia was unreasonably dangerous in design and that this defect existed at the time Prolia left the manufacturer's control. While the Court acknowledges that Plaintiff's allegations are barebones, it appears that Plaintiff has at least implicitly plead an alternative design–Prolia or any other medication for osteoporosis that does not cause jaw necrosis resulting in a jaw replacement and reconstructive surgery. Additionally, this matter is only in its very initial stages. No discovery has been conducted. In a pharmaceutical products liability matter, it is almost impossible to specifically plead an alternative design without the benefit of discovery and expert consultation. *See Winslow v. W.L. Gore & Assoc, Inc., supra.*

Based on the foregoing, the Court finds that Plaintiff's petition has met the Rule 12(b)(6) standard at this preliminary stage. Accordingly, Defendant's motion to dismiss Plaintiff's design defect claim is denied.

IV. CONCLUSION

Accordingly,

IT IS ORDERED that the **Motion to Dismiss, (Doc. 5),** is **GRANTED IN PART** and **DENIED IN PART**. Specifically, the Court dismisses Plaintiff's inadequate warning and manufacturer defect claims without prejudice.

Baton Rouge, Louisiana, this 8th day of February, 2019.

JUDGE BRIAN A. JACKSON
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA