UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ROSS LEWIS	*	**CIVIL ACTION**
	*	
VERSUS	*	**No. 16-16391**
	*	
BAXTER INTERNATIONAL INC. and	*	
BAXTER HEALTHCARE CORPORATION	*	**SECTION "L" (3)**

ORDER & REASONS

Before the Court is Defendants Baxter Healthcare Corporation and Baxter International, Inc.'s ("Baxter") Motion to Dismiss, R. Doc. 7. Plaintiff opposes the Motion, R. Doc. 10, and Defendants timely reply. R. Doc. 13. Having reviewed Baxter's arguments and the applicable law, the Court now issues this Order and Reasons.

I. BACKGROUND:

This products liability case arises from injuries Plaintiff allegedly sustained as a result of using Defendants' Dianeal PD Solution while undergoing dialysis treatments. R. Doc. 1 at 4. Dianeal PD Solution is a dialysis solution administered via the abdominal cavity through a catheter to filter waste from the blood. R. Doc. 1 at 6. Defendants' Dianeal PD Solution was recalled due to the presence of mold in the solution, which could cause life-threatening fungal peritoneal infections or sepsis. R. Doc. 1 at 7. Plaintiff claims that after treatment with Dianeal PD Solution, he developed peritonitis and sepsis, which required extensive medical treatment, including nine surgical procedures. R. Doc. 1 at 7.

Plaintiff asserts claims based on the Louisiana Products Liability Act ("LPLA"), as well as state law claims based in negligence, vicarious liability, and the doctrines of respondeat

superior and res ipsa loquitur. R. Doc. 1 at 8-12.

II. PRESENT MOTION

a. Defendant's Motion to Dismiss (R. Doc. 7)

Defendants Baxter Healthcare Corporation and Baxter International, Inc., filed a Motion to Dismiss Plaintiff's claims under Federal Rules of Civil Procedure 12(b)(6) and 8(a)(2). R. Doc. 7-1 at 1. Defendants allege that Plaintiff's factual allegations are mere speculation and do not state a claim upon which relief can be granted. R. Doc. 7-1 at 3. Further, Defendants contend that Plaintiff's non-LPLA negligence claims must be dismissed because the LPLA provides the exclusive remedy for products liability actions against manufacturers under Louisiana law. Finally, Defendants aver that Plaintiff fails to plead facts sufficient to support his claims under the LPLA. R. Doc. 7-1 at 1.

i. Plaintiff's claims do not satisfy Rule 8 of the Federal Rules of Civil Procedure.

First, Defendants move to dismiss Plaintiff's claim because he fails to plead specific facts "regarding the product at issue or Plaintiff's alleged use of the product at issue." R. Doc. 7-1 at 4. Defendants aver the complaint does not indicate how the product was defective or unsafe, how Defendants should have known about any such defect, or what Defendants could have done to test the product and ensure its safety. R. Doc. 7-1 at 4. The general deficiency Defendants allege is that Plaintiff's Complaint contains insufficient factual details to support his claims, and instead relies wholly on conclusory allegations which are insufficient to defeat a motion to dismiss. R. Doc. 7-1 at 4-6.

ii. Plaintiff's state law negligence claims are precluded by the LPLA.

Second, Defendants move to dismiss all of Plaintiff's non-LPLA claims, including his state-law negligence claims, as precluded by the Louisiana Products Liability Act. The LPLA

provides the exclusive remedies available under Louisiana law against the manufacturer of a product. *See* La. Rev. Stat. § 9:2800.54(B); *Stahl v. Novartis Pharm. Corp*., 283 F.3d 254, 261 (5th Cir. 2002). Thus, Defendants allege Plaintiff's non-LPLA negligence claims must be dismissed.

iii. Plaintiff's LPLA claims fail to meet the pleading requirements

Finally, Defendants argue that Plaintiff fails to allege specific facts to support claims under the LPLA. R. Doc. 7-1 at 8. According to Defendant, Plaintiff's construction defect claim must be dismissed because Plaintiff does not provide factual details regarding how the product caused harm, how it was unreasonably dangerous, or how Plaintiff used the product. R. Doc. 7-1 at 8. Defendants argue that the complaint does not include factual allegations to support Plaintiff's claims for design defect, failure-to-warn, or breach of express warranty. Defendants contend that Plaintiff only states conclusory allegations to support these claims, which does not satisfy the standard for pleadings under Rule 12(b)(6). R. Doc. 7-1 at 9.

b. Plaintiff's Response (R. Doc. 10)

Plaintiff opposes the motion, and argues he has provided sufficient direct, indirect, and inferential factual allegations to support his claims. R. Doc. 10. According to Plaintiff, Defendants have already issued a recall for this product, which demonstrates it is defective. Further, he argues that the defect in this case, namely, the leaky container which led to contamination and mold growth, implies an alternative design existed—a container that did not leak. R. Doc. 10 at 6-7. Plaintiff avers that Defendants either knew or should have known their products should have been free of contaminants, as patients used them internally during dialysis. R. Doc. 10 at 8. Thus, Plaintiff contends he has alleged specific facts sufficient to defeat a motion to dismiss. R. Doc. 10 at 10.

Further, Plaintiff argues he has pled facts sufficient to support his claims for respondeat superior, as Defendants' employees were directly responsible for testing and manufacturing the defective product. R. Doc. 10 at 8-9. Similarly, Plaintiff avers that res ipsa should apply in this case, because there are no facts to demonstrate Plaintiff's injuries were the result of his own negligence. R. Doc. 10 at 9.

Finally, Plaintiff argues that the facts support his claims under the LPLA. R. Doc. 10 at 10. First, he argues he has pled sufficient facts to support a claim for defective construction, as the defect in this product was a direct result of holes in the packaging. R. Doc. 10 at 14. Second, he contends that the Complaint contains sufficient facts to support his defective design claims, as he alleges the contamination was caused by holes in the product container. R. Doc. 10 at 15. According to Plaintiff, this leads to the inference that an alternate design existed—one without holes—which would have prevented the defect. R. Doc. 10 at 15. Third, Plaintiff avers that he has pled sufficient facts to support a claim for failure to warn, as the Defendants did not warn about the presence of mold in the PD Solution, and Plaintiff would not have used the product if he had received such a warning. R. Doc. 10 at 16. Finally, Plaintiff argues that the facts in the Complaint allege that the Defendants warrantied the PD Solution was safe for its intended use, while the presence of mold proves that it was not. R. Doc. 10 at 17.

In the alternative, Plaintiff argues that his claims should not be dismissed, but he should be granted leave to amend his Complaint and allege additional facts to support his claims. R. Doc. 10 at 22 (citing Fed. R. Civ. Proc. 15(a)).

c. Defendant's Reply (R. Doc. 13)

Defendants timely reply and re-assert substantially the same arguments as their original motion. R. Doc. 13. Defendants contend that Plaintiff does not dispute that his state law

negligence claims are precluded by the LPLA. R. Doc. 13 at 1. Next, Defendants argue Plaintiff has not pled factual allegations that the PD Solution deviated from the manufacturer's specifications, that Defendants breached, or even made, an express warranty, that an alternative design existed, or how the Defendants failed to warn Plaintiff about any potential hazards. R. Doc. 13 at 2-4. Finally, Defendants argue that res ipsa loquitur, respondeat superior, and vicarious liability are theories of liability, not causes of action, and Plaintiff's claims based on these causes of actions must be dismissed. R. Doc. 13 at 5-6.

III. LAW AND ANALYSIS

a. Federal Rule of Civil Procedure 12(b)(6)

The Federal Rules of Civil Procedure permit a defendant to seek a dismissal of a complaint based on the "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A complaint should not be dismissed for failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Generally, when evaluating a motion to dismiss pursuant to Rule 12(b)(6), the court should not look past the pleadings.

"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 Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The district court must construe facts in the light most favorable to the nonmoving party and must accept as true all factual allegations contained in the complaint. *Ashcroft*, 556 U.S. at 678. "A claim has facial plausibility 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*. A court "do[es] not accept as true conclusory allegations, unwarranted factual inferences, or legal

conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005).

b. Louisiana Products Liability Act

Plaintiff brings four claims under the LPLA: a construction defect, a design defect, failure to warn, and breach of express warranty. To maintain a successful LPLA action, a plaintiff must establish four elements: "(1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product 'unreasonably dangerous;' and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002); *See* La. Rev. Stat. § 9:2800.54(A). The plaintiff bears the burden of proving all elements. La. Rev. Stat. § 9:2800.54(D). As to the third element, a product can be "unreasonably dangerous" (i) in construction or composition; (ii) in design; (iii) for failure to provide an adequate warning; and (iv) for failure to conform to an express warranty. *Id*. La. Rev. Stat. § 9:2800.54 et seq.

c. Analysis

As an initial matter, all of Plaintiff's non-LPLA claims must be dismissed. The LPLA establishes the exclusive theory of liability for manufacturers for damages caused by their products. La. Rev. Stat. § 9:2800.52. Accordingly, "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in [it]." *Id*. Additionally, respondeat superior, vicarious liability, and res ipsa are theories of liability, not causes of action, so to the extent Plaintiff seeks claims under these theories, these claims must also be dismissed. The Court will address each of Plaintiff's claims under the LPLA in turn.

i. Construction Defect

To establish a construction or composition defect claim under the LPLA, a plaintiff must establish that, upon leaving 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. R.S. 9:2800.55. The plaintiff must demonstrate that 1) the defendant is a manufacturer of the product; 2) the product proximately caused the plaintiffs' damage; 3) the damaging characteristic of the product rendered it unreasonably dangerous in construction or composition; and 4) the plaintiff's damages arose from a reasonably anticipated use of the product. *McLaughlin v. Glaxosmithkline, LLC*, No. 12-2946, 2014 WL 669349 at *4 (W.D. La. Jan. 6, 2014); *see also Rollins v. St. Jude Medical,* 583 F.Supp. 2d 790, 800 (W.D. La. 2008) (citing *Gomez v. St. Jude Med. Daig Vid. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006)).

Here, the Plaintiff alleges Defendants manufactured the PD solution, contamination in the solution caused his fungal peritoneal infection and sepsis, the contamination in the solution made it unreasonably dangerous, and Plaintiff's injuries were a direct result of using the product during dialysis, as intended by the manufacturer. R. 1 at 7. It is axiomatic that PD Solution, which is placed in a patient's abdominal cavity through a catheter to filter blood during dialysis, should not become contaminated such that it grows mold. Thus, Plaintiff has alleged facts sufficient to support a claim for a construction defect.

ii. Design Defect

To assert a design defect claim under the LPLA, a plaintiff must establish that, at the time the product left the manufacturer's control, (1) "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage" and (2) that the danger of the

damage outweighed the burden on the manufacturer of adopting the alternative design." La. R.S. § 9:2800.56. *See Roman v. W. Mfg. Inc.*, 691 F.3d 686, 700–01 (5th Cir. 2012); *Jacobson v. Wyeth*, LLC, No. 10–823, 2012 WL 3575293, at *6 (E.D. La. Aug.20, 2012).

The Court is "mindful that much of the evidence in pharmaceutical products liability cases may be in the defendant's possession, and thus, without the benefit of discovery, stating more specific allegations may be nearly impossible at this stage," but Plaintiff's conclusory allegations nevertheless fail to state a claim upon which relief can be granted. *Lahaye*, 2014 WL 6609456, at *5. Plaintiff alleges in his Petition that the Dianeal PD Solution was "unreasonably dangerous in design because there existed alternative designs which would have prevented Plaintiff's injuries and damages." R. 1 at 9. A court "do[es] not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005). Thus, Plaintiff's conclusory allegations are insufficient to state a claim upon which relief can be granted.

To prevail on a defective design claim, Plaintiff must also demonstrate, "that the danger of the damage outweighed the burden on the manufacturer of developing the alternative design." La. R.S. § 9:2800.56. Again, Plaintiff's allegations on this element are conclusory. Plaintiff states that "the likelihood that Defendants' design would cause damages . . . outweighed the burden of adopting an alternative design." Accordingly, the Court finds Plaintiff has not alleged sufficient facts to defeat a motion to dismiss at this time.

iii. Failure-to-warn

"To maintain a failure-to-warn claim, a plaintiff must demonstrate that 'the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of

the product.' " *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002) (quoting La. R.S. § 9:2800.57). "Importantly, such a claim requires the plaintiff to show both: (1) inadequacy of the warning provided *and* (2) that the inadequate warning was the cause of his injuries." *Brocato v. Deputy Orthopaedics*, 2015 WL 854150, at *6 (E.D.La. Feb.25, 2015) (Shushan, M.J.). In cases involving prescription drug product liability, Louisiana applies the "learned intermediary doctrine" to failure-to-warn claims. *Stahl*, 283 F.3d at 265. Courts employ a two-pronged test when the learned intermediary doctrine is applicable: (1) the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that is not otherwise known to the physician, and (2) that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. *Id.* at 26566. "In order to demonstrate causation, '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.' " *Eschete ex rel. Eschete v. Roy*, 554 F.Supp.2d 638, 633–34 (E.D. La. 2008) (quoting *Ferguson v. Proctor & Gamble Pharmaceuticals, Inc.* 353 F.Supp.2d 674, 679 (E.D. La.2004)).

Plaintiff's Petition alleges:

> At the time the Dianeal PD Solution at issue left Defendants' control, it was unreasonably dangerous because [it] possessed characteristics which could cause damage during typical, anticipated use, including a failure to adequately warn individuals, such as Plaintiff, Ross Lewis, of the potential for serious injury if the Dineal PD Solution during normal, typical, and anticipated use. (*sic*)

To allege a failure-to-warn claim upon which relief can be granted under the LPLA, Plaintiff is not required to detail what an adequate warning would be and how an adequate warning would have caused Plaintiff's treating physician to act differently. However, Plaintiff is required to allege that Defendants did not adequately warn Plaintiff's treating physician of risks

associated with the product that are not otherwise known to the patient or physician, and that the inadequate warning constituted the proximate cause of Plaintiff's injuries. Plaintiff's allegations fall short of this standard.

iv. Breach of Express Warranty

Under Louisiana law, "a product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue." R.S. § 2800.58. Thus, the plaintiff must establish that "(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue." *Caboni v. General Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002).

An express warranty is defined as "a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level of performance. 'Express warranty' does not mean a general opinion about or general praise of a product." La. R.S. § 9:2800.53(6).

Here, Plaintiff has alleged that Defendants warrantied their product was "suitable and safe for use." R. 1 at 10. This statement, without more, is insufficient to demonstrate that Defendants made an express warranty beyond generally praising their own product. Further, Plaintiff does not indicate to whom Defendants made such a warranty. As other courts in this district have explained, statements made in promotional or marketing materials are not

warranties. *Robertson v. AstraZeneca Pharmeceuticals, LP*, No. 15-438, 2015 WL 5823326, at *5 (E.D. La. Oct. 6, 2015) (Barbier, J.). Thus, to demonstrate Defendants made a warranty, Plaintiff must allege facts that the warranty was made to a specific audience—other than in promotional and marketing materials. "While Plaintiff is not required to quote the specific language of the warranties, [he] must make more than a general reference to them." *Id.* Plaintiff's allegation that Defendants warrantied their product was "suitable and safe for use" does not contain sufficient factual information to state a claim upon which relief can be granted.

v. Amend Petition

In Plaintiff's Opposition, Plaintiff requests leave to amend his Petition to cure any potential deficiencies in his Complaint by adding factual clarification. Courts should ordinarily grant a Plaintiff at least one opportunity to amend before dismissing a complaint with prejudice for a failure to state a claim. *Hart v. Bayer Corp.*, 199 F.3d 239, 247 n.6 (5th Cir. 2000). Accordingly, the Court will afford Plaintiff thirty (30) days to amend his Petition to address the factual deficiencies.

IV. CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Defendants' Motion, R. Doc. 7, is **GRANTED** in part and **DENIED** in part. It is denied with regard to Plaintiff's construction defect claim under the Louisiana Products Liability Act. However, it is granted with respect to Plaintiff's non-LPLA claims and Counts 1, 3, 4, and 5 of the Complaint are **DISMISSED** in their entirety. Plaintiff has 30 days to file an Amended Complaint with respect to his claims for design defect, failure to warn, and breach of express warranty under the Louisiana Products Liability Act.

IT IS FURTHER ORDERED that Plaintiff is granted leave to amend his Petition within thirty (30) days of this Order to remedy the factual deficiencies identified in this Order & Reasons.

New Orleans, Louisiana this 17th day of February, 2017.

UNITED STATES DISTRICT JUDGE