UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

CORY JENKINS	*	**CIVIL ACTION**
	*	
VERSUS	*	**NO. 14-2499**
	*	
BRISTOL-MYERS SQUIBB, and OTSUKA AMERICA PHARMACEUTICAL INC.	*	**SECTION "L" (4)**

ORDER AND REASONS

Before the Court is Defendants Bristol-Myers Squibb Company's and Otsuka America Pharmaceutical, Inc.'s Motion to Dismiss. (Rec. Doc. 8). Having reviewed the parties' briefs and the applicable law, the Court now issues this Order & Reasons.

I. BACKGROUND

Plaintiff Cory Jenkins brings this products liability case alleging injures caused by the ingestion of the drug Abilify. Plaintiff filed this case on October 17, 2014 in the 24th Judicial District Court for the Parish of Jefferson, Louisiana. (Rec. Doc. 1-1 at 1). Defendant Bristol-Myers Squibb Company removed the case to this Court pursuant to 28 U.S.C. §§ 1332, 1441, and 1446. (Rec. Doc. 1 at 1). Plaintiff's Petition alleges that he had been prescribed Abilify to treat Bipolar II Disorder, and on or about October 19, 2010, Plaintiff began to take this medication. (Rec. Doc. 1-1 at 3). As a result of taking Abilify, Plaintiff alleges he developed Tardive Dyskinesia around 2013. (Rec. Doc. 1-1 at 3). Tardive Dyskinesia is a neurological disorder characterized by involuntary movements of the face and jaw. Plaintiff contends that "[a]t the present time, [he] [ ] has chronic and continued restlessness and twitching of the upper and lower extremities, facial tics, jaw clenching and clucking, and constant eye blinking." (Rec. Doc. 1-1 at 3).

Plaintiff asserts two separate theories of liability under the Louisiana Products Liability Act ("LPLA"): defective design and failure-to-warn. For Plaintiff's defective design claim, Plaintiff alleges that "the manufacture and marketing of Abilify was unreasonably dangerous in design with the high likelihood that the anticipated use and ingestion of Abilify would cause Tardive Dyskinesia in users such as Plaintiff, Cory Jenkins" and that "[t]he defendants failed to consider an alternative 'design' of said medication that would not cause Tardive Dyskinesia." (Rec. Doc. 1-1 at 4). Plaintiff claims that Defendants failed to adequately warn of the risks associated with Abilify because Defendants failed to properly warn and failed to "outline the appropriate procedures and period testing, including administering the AIMS (Abnormal Involuntary Movement Scale) test, which would alert health care providers as to the development of Tardive Dyskinesia…." (Rec. Doc. 1-1 at 5).

II. PRESENT MOTION

A. Defendants' Motion to Dismiss (Rec. Doc. 8)

Defendants move to dismiss Plaintiff's claims pursuant to Federal Rule of Civil Procedure 12(b)(6). Defendants argue that Plaintiff's defective design claim fails because Plaintiff only plead that Defendants failed to consider an alternative design, and the LPLA requires a plaintiff to establish that "at the time the product left the manufacturer's control, "'there existed an alternative design for the product that was capable of preventing claimant's damage' and that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design." (Rec. Doc. 8-1 at 7) (quoting *Purvis v. Teva Pharm., USA Inc.*, 901 F. Supp. 2d 716, 721 (M.D. La. 2012)). Here, Defendants aver Plaintiff "does not allege that there is a safer alternative design or identify what the design is. Nor does he allege that the risks of the current design outweigh the burdens of switching to the safer alternative. And

nowhere does he attempt to explain how Abilify's design is defective or what aspect of Abilify's design caused his tardive dyskinesia." (Rec. Doc. 8-1 at 7).

Defendants also argue that Plaintiff fails to state a failure-to-warn claim under the LPLA. First, Defendants contend that Plaintiff's Petition does not state a failure-to-warn claim because the Petition "says nothing about the adequacy of the warnings provided to Mr. Jenkin's prescribing physician" and "does not even mention [Plaintiff's] treating physician's name." (Rec. Doc. 8-1 at 9). Second, Defendants argue that Plaintiff does not state a failure-to-warn claim because Plaintiff's Petition fails to allege that Plaintiff's "treating physician would not have prescribed [Plaintiff] Abilify had he or she received a different warning." (Rec. Doc. 8-1 at 10).

B. Plaintiff's Opposition (Rec. Doc. 14)

Plaintiff opposes Defendants' Motion to Dismiss, arguing that his allegations sufficiently state a design defect and a failure-to-warn claim under the LPLA. Regarding Plaintiff's defective design claim, Plaintiff cites the district court in *Lahaye v. Astrazeneca Pharmaceuticals*, which recognized 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." (Rec. Doc. 14 at 4) (quoting 2015 U.S. Dist. LEXIS 55528, at *12-13 (M.D. La. April 28, 2015)).

In response to Defendants' assertion that Plaintiff failed to plead a failure-to-warn claim because he did not identify his prescribing physician, Plaintiff argues that his reference to "health care providers" in his Petition should be read to include his prescribing physician." (Rec. Doc. 14 at 7). Plaintiff further argues that he "does not have to include the identity of his treating physician in the complaint." (Rec. Doc. 14 at 7) (citing *Lahaye*, 2015 U.S. Dist. LEXIS 55528,

at *14). If the Court finds, however, that this allegation is unclear, Plaintiff requests leave of Court to amend his petition to name his prescribing physician. (Rec. Doc. 14 at 8).

Looking to the second failure-to-warn element, Plaintiff contends that "Defendants' argument that Plaintiff must show that but for the warning, the treating physician would not have prescribed Abilify, is inaccurate in that it addresses only part of the LPLA provisions as to what constitutes an inadequate warning." (Rec. Doc. 14 at 8). Rather, Plaintiff avers that he "must show that with an adequate warning, the physician would either have declined to use the product, or have used it in such a manner (e.g. monitoring tests) as to prevent danger (Tardive Dyskinesia)." (Rec. Doc. 14 at 9). Here, Plaintiff contends he alleged that had Defendants given adequate warnings, he would not have contracted Tardive Dyskinesia, which means that either his physician would not have prescribed the drug or that his physician would have properly monitored him during treatment. (Rec. Doc. 14 at 9).

C. Defendants' Reply (Rec. Doc. 22)

Defendants reply with leave of Court. Defendants dispute Plaintiff's assertion that he can satisfy the element of defective design claim under the LPLA by alleging "the defendants failed to consider an alternative design of said medication that would not cause Tardive Dyskinesia." (Rec. Doc. 22 at 2) (internal quotations omitted). Defendants argue that this is insufficient because the allegation "says nothing about whether a safer alternative design actually existed at the time [Plaintiff] took Abilify" and because Plantiff's Petition "says nothing about whether the risk of tardive dyskinesia outweighed the burdens of adopting the unidentified alternative." (Rec. Doc. 22 at 2). Defendants contend that Plaintiff's reliance on *Lahaye* is not persuasive because *Lahaye* is an "outlier" and "[f]ederal courts in Louisiana routinely dismiss product liability claims involving prescription drugs and medical devices where, as here, the plaintiff

fails to allege the existence of a safer alternative design." (Rec. Doc. 22 at 3).

Defendants re-urge their position that Plaintiff's Petition does not state a failure-to-warn claim. First, Defendants argue that Plaintiff must allege that his treating physician was not adequately warned and that Plaintiff "cannot satisfy this element by alleging that the defendants failed to adequately warn 'health care providers' generally." (Rec. Doc. 22 at 6). Second, Defendants argue that Plaintiff's "bald claim that had the defendants provided additional warnings or instructions, he would not have contracted tardive dyskinesia is likewise insufficient" because the pleading standard dictates that conclusory allegations are not sufficient. (Rec. Doc. 22 at 6)

III.LAW& ANALYSIS

A. The Standard

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 district court must construe facts in the light most favorable to the nonmoving party. The court must accept as true all factual allegations contained in the complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "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.' 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.* (citation omitted). Dismissal is appropriate only if the complaint fails to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corporation et al. v. William Twombly*, 550 U.S. 544, 570 (2007).

B. LPLA

The Louisiana Products Liability Act ("LPLA") "establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. R.S. § 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.* "Under the LPLA, recovery is not available against a manufacturer if the manufacturer did not produce the offending product." *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182 (5th Cir. 2012).

Under the LPLA, "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 Pharm. Corp.*, 283 F.3d 254, 260–61 (5th Cir. 2002) (citing LA. REV. STAT. § 9:2800.54). 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. La.Rev.Stat. § 9:2800.54(B). Here, Plaintiff contends that Abilify is "unreasonably dangerous" for its defective design and for its failure to provide an adequate warning.

C. Defective Design

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) (Brown, J.).

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 bare 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 manufacture of Abilify was "unreasonably dangerous in design" and that "[t]he defendants failed to consider an alternative 'design' of said medication that would not cause Tardive Dyskinesia." (Rec. Doc. 1-1 at 4). Construing these facts as true, Plaintiff's defective design claim would not be entitled to relief under the LPLA because Plaintiff fails to plead that an alternative design existed that could have prevented Plaintiff's injuries. It is not sufficient under the LPLA to allege that Defendants failed to *consider* an alternative design. While the Court does not agree with Defendants that it is necessary at this early stage for Plaintiff to plead specifics about the alternative design, finding that such a requirement would place a near-impossible burden on Plaintiffs in pharmaceutical litigation, Plaintiff must nevertheless allege that an alternative design existed that would not have caused Plaintiff's injuries. Plaintiff fails to meet this pleading threshold.

Plaintiff's Petition also fails to address the second element of defective design and allege "that the danger of the damage outweighed the burden on the manufacturer of developing the alternative design." La. R.S. § 9:2800.56. Again, the Court recognizes that Plaintiff may be unable to assert specific allegations without the benefit of discovery, but Plaintiff fails to articulate even a bald claim that corresponds to the second element of defective design. Accordingly, the Court will grant Defendants' Motion to Dismiss on Plaintiff's defective design

claim.

D. 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 265-66. "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:

> [D]efendants failed to properly warn of the dangers of developing Tardive Dyskinesia and further failed to outline the appropriate procedures and period testing, including administering AIMS (Abnormal Involuntary Movement Scale) test, which would alert

> healthcare providers, as to the development of Tardive Dyskinesia, a debilitating, permanent and untreatable disorder. If defendants had properly warned of the severity of Tardive Dyskinesia, of the importance of properly monitoring patients using Abilify to prevent the onset of Tardive Dyskinesia, and informed health care providers of what periodic monitoring tests were necessary, Plaintiff would not have contracted Tardive Dyskinesia.

(Rec. Doc. 1-1 at 5). The Court agrees with Plaintiff that the 12(b)(6) standard does not require Plaintiff to identify his treating physician, even though such information is within the Plaintiff's knowledge. Further, the Court finds that "healthcare providers" includes Plaintiff's treating physician, so Plaintiff's claim satisfies the first element of the intermediary doctrine because Plaintiff alleges that Defendants failed to properly warn healthcare providers of the risk of developing Tardive Dyskinesia and of the importance of monitoring.

Looking to the second element of the learned intermediary doctrine, Defendants argue that Plaintiff fails to establish causation between Defendants' alleged inadequate warning and Plaintiff's alleged contraction of Tardive Dyskinesia. The Court disagrees. Plaintiff claims that "[i]f defendants had properly warned of the severity of Tardive Dyskinesia, of the importance of properly monitoring patients using Abilify to prevent the onset of Tardive Dyskinesia, and informed health care providers of what periodic monitoring tests were necessary, Plaintiff would not have contracted Tardive Dyskinesia." (Rec. Doc. 1-1 at 5). The Court infers from these factual allegations that "a proper warning would have changed the decision of the treating physician," and these factual allegations thus satisfy the second element of the learned intermediary doctrine. *Eschete ex rel. Eschete*, 554 F. Supp. 2d at 633-34.

Defendants argue that Plaintiff "'must provide sufficient factual allegations as to why the information provided to the intermediary was inadequate, what information should have been provided, and how that information would have caused the intermediary to act differently which

would have prevented the plaintiff's injury." (Rec. Doc. 22 at 6) (quoting *Bergstresser v. Bristol-Myers Squibb Co.*, No. 12-1464, 2013 WL 6230489, at *8 (M.D. Pa. Dec. 2, 2013) (Mannion, J)). The Court is not persuaded by this argument. As support for this proposition, Defendants rely on a Pennsylvania Court applying the Pennsylvania learned intermediary doctrine. The Pennsylvania Court's analysis is therefore not instructive for this case because the Court must apply Louisiana's learned intermediary doctrine. 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. Plaintiff is merely required to allege that Defendants did not adequately warn Plaintiff's treating physician and that the inadequate warning constituted the proximate warning of Plaintiff's injuries. As already stated, the Court finds that Plaintiff's failure-to-warn claim satisfies this standard and is sufficient to survive Defendant's 12(b)(6) motion.

E. Amend Petition

In Plaintiff's Opposition, Plaintiff requests leave to amend his Petition to cure his inadequate pleading by adding factual clarification. Courts should ordinarily grant a Plaintiff at least one opportunity to amend his complaint before dismissing the 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 to Dismiss (Rec. Doc. 8) is **GRANTED IN PART AND DENIED IN PART**. It is **GRANTED** as to Plaintiff's

defective design claim. It is **DENIED** as to Plaintiff's failure-to-warn claim. 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 21st day of August, 2015.

UNITED STATES DISTRICT COURT JUDGE