UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

KIRBY RHODES	CIVIL ACTION
VERSUS	NO. 18-10667
COVIDIEN LP, ET AL.	SECTION "R" (2)

ORDER AND REASONS

Before the Court is defendants Covidien LP's and Medtronic, Inc.'s motion to dismiss plaintiff Kirby Rhodes's complaint, which asserts various causes of action arising from injuries allegedly caused by defendants' products.[1] The Court dismisses all of plaintiff's claims, except for his construction or composition defect claim.

I. BACKGROUND

This case arises out of allegations that defendants designed and manufactured two defective products.[2] According to the complaint, on October 23, 2017, plaintiff underwent surgery to repair a hernia, during which a Parietex Composite Mesh was implanted into his abdomen.[3]

1 R. Doc. 7.
2 R. Doc. 1-1.
3 *Id.* at 4 ¶ 7.

Nonparty Dr. David Rau allegedly performed the surgery.[4] Plaintiff alleges that Dr. Rau initially attempted to use an applicator to implant the mesh, but that the applicator "malfunctioned."[5] After it malfunctioned, Dr. Rau allegedly removed the mesh from the applicator, and placed the mesh onto plaintiff's anterior abdominal wall without it.[6] Defendants manufacture both the Parietex Composite Mesh and the applicator.[7]

Plaintiff alleges that months after the surgery, in June 2018, he noticed that his stomach was protruding in the same manner it had before his surgery.[8] Dr. Rau allegedly evaluated plaintiff on July 11, 2018.[9] During this examination, Dr. Rau allegedly disclosed to plaintiff that the applicator had failed during surgery, and that he had to "spread the mesh by other means."[10] Plaintiff alleges that Dr. Rau admitted that he "should have placed the mesh more to the left" when he implanted it, and that he wishes he had used a "larger mesh."[11] Plaintiff further alleges that Dr. Rau told him that the mesh

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4 *Id.*

5 *Id.* at 4-5 ¶ 8. Defendants explain in their brief that the applicator used during the procedure was a positioning system known as AccuMesh. R. Doc. 7-1 at 11.

6 R. Doc. 1-1 at 4-5 ¶ 8.

7 *See generally id.*; R. Doc. 7-1 at 6.

8 R. Doc. 1-1 at 5 ¶ 10.

9 *Id.* at 5-6 ¶ 13.

10 *Id.*

11 *Id.*

may have moved inside his abdomen when plaintiff "coughed or sneezed."[12] On August 3, 2018, plaintiff was allegedly examined by Dr. James Wooldridge.[13] Dr. Wooldridge allegedly told plaintiff that his "hernia was unfortunately protruding out of [his] intestine," which would not occur "if the hernia mesh [had been] placed properly" so that it would "be maintained in its original position."[14]

Plaintiff alleges that "[a]s a result of the implantation of the unreasonably dangerous and defective Parietex Composite Mesh and its applicator, [he] suffered injuries including, but not limited to, scarring, pain, potential infection, and the need for future hernia surgical repair."[15] Plaintiff asserts that the mesh is defective because it is "weak" and "known to unravel[,] causing the polyester fiber to detach and travel to other parts of the body inciting an inflammatory response."[16] Plaintiff brings claims against defendants under various provisions of the Louisiana Products Liability Act (LPLA), La R.S. 9:2800.51, *et seq.*;[17] for redhibition under La.

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12 *Id.*
13 *Id.* at 6 ¶ 14.
14 *Id.*
15 *Id.* ¶ 15.
16 *Id.* at 6-7 ¶ 18.
17 *Id.* at 8-10 ¶¶ 26-41.

Civ. Code arts. 2520, *et seq*.;[18] for negligence;[19] for breach of warranty of fitness for ordinary use;[20] and for breach of implied warranty of merchantability and fitness.[21] Plaintiff states in his opposition that he has separately brought a medical malpractice suit against Dr. Rau, and that this suit is a "companion suit."[22]

Defendants move to dismiss plaintiff's complaint for failure to state a claim upon which relief can be granted, under Federal Rule of Civil Procedure 12(b)(6).[23]

II. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead "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)). A claim is facially plausible when the plaintiff pleads facts that allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged."

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18 *Id*. at 10 ¶¶ 46-49.
19 *Id*. ¶¶ 43-45.
20 *Id*. at 10-11 ¶¶ 50-53.
21 *Id*. at 11 ¶¶ 54-57.
22 R. Doc. 14 at 1.
23 R. Doc. 7.

Id. at 678. A court must accept all well-pleaded facts as true and must draw all reasonable inferences in favor of the plaintiff. *See Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009).

A legally sufficient complaint must establish more than a "sheer possibility" that the plaintiff's claim is true. *Iqbal*, 556 U.S. at 678. It need not contain detailed factual allegations, but it must go beyond labels, legal conclusions, or formulaic recitations of the elements of a cause of action. *Id*. In other words, the face of the complaint must contain enough factual matter to raise a reasonable expectation that discovery will reveal relevant evidence of each element of the plaintiff's claim. *Lormand*, 565 F.3d at 257. The claim must be dismissed if there are insufficient factual allegations to raise a right to relief above the speculative level, *Twombly*, 550 U.S. at 555, or if it is apparent from the face of the complaint that there is an insuperable bar to relief, *Jones v. Bock*, 549 U.S. 199, 215 (2007).

III. DISCUSSION

A. Non-LPLA Claims

In Louisiana, the LPLA provides the exclusive theories of liability of a manufacturer for damages caused by its product. La. R.S. 9:2800.52. A plaintiff may not recover from a manufacturer in tort under any theory of

liability that is not set forth in the LPLA. *Id.*; *see also Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 261-62 (5th Cir. 2002). Plaintiff includes three non-LPLA claims that are precluded by the statute: negligence, breach of warranty of fitness for ordinary use, and breach of implied warranty of merchantability and fitness.[24] These claims are therefore dismissed with prejudice.[25]

B. LPLA Claims

The LPLA provides that a manufacturer "shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. R. S. 9:2800.54(A). A product is unreasonably dangerous for the purposes of the statute "if and only if" it is unreasonably dangerous either (1) in construction or composition, (2) in design, (3) because of inadequate warning, or (4) because of nonconformity to an express warranty. *Id.* at 9:2800.54(B)(1-4). Thus, the LPLA limits the plaintiff to four theories of recovery: construction or composition defect, design defect, inadequate

[24] R. Doc. 1-1 at 10-11.

[25] Plaintiff concedes in his opposition that these three claims are barred, and does not oppose their dismissal. R. Doc. 14 at 4.

warning, and breach of express warranty. The complaint includes causes of action under each of these theories.

1. Construction or Composition Defect

To establish a claim for defective construction or composition, a plaintiff must establish that, "at the time the product left its 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. A claimant must show "not only what a manufacturer's specifications or performance standards are for a particular product, but how the product in question materially deviated from those standards so as to render it unreasonably dangerous." *Lyles v. Medtronic Sofamor Danek, USA, Inc.*, 871 F.3d 305, 311 (5th Cir. 2017) (internal quotation marks omitted). A claimant must also show that the alleged defect was the cause-in-fact of his injury, as well as the "most probable cause." *See Wheat v. Pfizer, Inc.*, 31 F.3d 340, 342 (5th Cir. 1994).

Plaintiff alleges that both the Parietex Composite Mesh and the applicator were defective in composition and construction.[26] Plaintiff's allegation with respect to the applicator fails. Plaintiff alleges that the

[26] R. Doc. 1-1 at 8 ¶¶ 26-29.

applicator "malfunctioned" during his surgery, but he does not articulate with any specificity how the applicator failed. *See Dendinger v. Covidien LP*, No. 18-4168, 2018 WL 4462579, at *2 (E.D. La. Sept. 18, 2018) (dismissing the plaintiff's composition defect allegations because the complaint was "devoid of factual allegations as to how the products were unreasonably dangerous"). Plaintiff instead essentially recites the elements of his cause of action without explaining how the applicator was defective. This allegation is therefore dismissed. *See Iqbal*, 556 U.S. at 678.

But plaintiff has stated a cause of action with respect to the Parietex Composite Mesh. Plaintiff alleges that the mesh is defective because the polyester in the product is "weak" and "known to unravel," which causes the "polyester fiber to detach and travel to other parts of the body."[27] Plaintiff also alleges that the mesh implanted into his abdomen moved off of his hernia sometime after his surgery. Dr. Rau allegedly informed plaintiff that immediately after surgery the mesh "covered the actual hernia," but that afterward plaintiff "could have coughed or sneezed and made the mesh move further to the right."[28] Plaintiff further alleges that his hernia was protruding out of his intestine post-surgery as a result of the mesh's failure to "be

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27 *Id.* at 6-7 ¶ 18.

28 *Id.* at 5-6 ¶ 13.

maintained in its original position."[29] Viewing these allegations together and drawing all reasonable inferences in plaintiff's favor, plaintiff adequately alleges (1) how the mesh is defective (*i.e.*, the polyester is weak, which causes the mesh to detach and travel to other parts of the body), and (2) that this alleged defect caused his injury (*i.e.*, the mesh moved from its original position and allowed his hernia to protrude from his intestine). Plaintiff thus states a construction or composition defect claim. *See Pierre v. Medtronic, Inc.*, No. 17-12196, 2018 WL 1911829, at *3 (E.D. La. Apr. 23, 2018) (allegation that the defendant failed to sterilize its mesh, which allegedly caused the plaintiff to suffer an infection, stated a composition defect claim).

Plaintiff does not explicitly state what the performance standards were for the Parietex Composite Mesh. But by claiming that the mesh is defective because it detaches from its original position and moves to other parts of the body, plaintiff implicitly states that the mesh deviated from defendants' performance standards. According to the United States Food and Drug Administration (FDA), non-absorbable surgical mesh like the Parietex Composite Mesh "will remain in the body indefinitely and is considered a permanent implant."[30] In defendants' premarket notification of intent to

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[29] *Id.* at 6 ¶ 14.

[30] *Hernia Surgical Mesh Implants*, U.S. FOOD & DRUG ADMIN. (Feb. 4, 2018), https://www.fda.gov/medical-devices/implants-and-

market the Parietex Composite Mesh, they noted that the mesh "provides long term reinforcement of soft tissues."[31] Because the mesh is considered a "long term" reinforcement, it follows that its performance standard is to remain in place on the patient's hernia, and not move to other parts of the body.

Lastly, as defendants point out, plaintiff's complaint also contains several allegations that appear to place blame on his surgeon, Dr. Rau, rather than the mesh itself. Plaintiff states in his opposition that he has separately brought a medical malpractice suit against Dr. Rau, and that this case is a "companion suit."[32] But allegations suggesting that Dr. Rau improperly placed the mesh during surgery are consistent with an assertion that the mesh's defects were still a substantial factor in the mesh's movement after plaintiff's surgery, such that the mesh was both a cause-in-fact and the most probable cause of plaintiff's injuries. *See Wheat*, 31 F.3d at 342; *Westchester Fire Ins. Co. v. Haspel-Kan. Inv. P'ship*, 342 F.3d 416, 420 (5th Cir. 2003)

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prosthetics/hernia-surgical-mesh-implants. As defendants point out, the Court may take judicial notice of publicly-available documents produced by the FDA. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011).

[31] 510(k) Summary of Safety and Effectiveness, Parietex Composite Mesh (April 19, 2011), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf11/K110816.pdf. The Court may also take judicial notice of this document. *See Funk*, 631 F.3d at 783.

[32] R. Doc. 14 at 1.

(cause-in-fact determination under Louisiana law is whether the defendant's actions were a "substantial factor in bringing about the harm" to the plaintiff (citing *Lasyone v. Kansas City S. R.R.*, 786 So. 2d 682, 691 (La. 2001))). Plaintiff's complaint may not be artfully pleaded, but the Court must draw all reasonable inferences in plaintiff's favor at this stage of the proceedings. *Lormand*, 565 F.3d at 232. When doing so, the Court finds that plaintiff has stated a construction or composition defect claim under the LPLA, and denies defendants' motion to dismiss this claim.

2. Inadequate Warning

To state an inadequate warning claim under the LPLA, a plaintiff must allege "(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." *Willet v. Baxtern Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991). The plaintiff must state 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; *see also Stahl*, 283 F.3d at 265 (noting that Louisiana follows the "learned intermediary doctrine," in which

a manufacturer need only warn the patient's physician, not the patient himself, of the device's potential harm).

Plaintiff alleges that defendants "knew or should have known of the defective nature" of the Parietex Composite Mesh and the applicator, but did "not adequately warn[] the FDA, the general public, the medical community, or plaintiff" of these defects.[33] Plaintiff's claim fails because he does nothing more than recite the elements of his cause of action. *See Iqbal*, 556 U.S. at 678. He does not allege how defendants' alleged failure to warn specifically caused his injuries—*i.e.*, facts showing that a "proper warning would have changed the decision of the treating physician." *Willet*, 929 F.2d 1099; *Hargrove v. Bos. Scientific Corp.*, No. 13-3539, 2014 WL 4794763, at *11 (E.D. La. Sept. 24, 2014) (the plaintiffs' conclusory allegations failed to assert how the alleged inadequate warning caused their injuries). Plaintiff's inadequate warning claim must therefore be dismissed.

3. Design Defect

To establish the elements for a design defect claim, a plaintiff must allege that:

> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and

[33] R. Doc. 1-1 at 7 ¶ 23.

> (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. R.S. 9:2800.56.

Plaintiff's design defect claim applies to the Parietex Composite Mesh only, not the applicator.[34] Plaintiff alleges that the Parietex Composite Mesh is defective because it "breaks down after coming in contact with moisture and tears easily during handling."[35] He further alleges that the polyester fabric on the mesh is known to "detach and travel to other parts of the body inciting an inflammatory response."[36] These allegations may assert a defect with the product, but plaintiff does not allege with enough specificity that there existed an alternative design of the mesh that could have prevented his injuries. Plaintiff only obliquely alleges that defendants "knew or should have known that Parietex Composite Mesh was considerably more harmful and inadequate than other meshes or methods for hernia repair."[37] But this allegation does not specifically identify any alternative design. The Court therefore dismisses plaintiff's design defect claim. *See Iqbal*, 556 U.S. at 678;

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34 *Id.* at 9 ¶¶ 32-33.
35 *Id.* at 6-7 ¶ 18.
36 *Id.*
37 *Id.* at 7 ¶ 22.

Dendinger, 2018 WL 4462579, at *2 (dismissing design defect claim for the plaintiff's failure to adequately explain what alternative design existed at the time of his surgery).

4. Breach of Express Warranty

Under the LPLA, a manufacturer of a product that is unreasonably dangerous because it does not conform to an express warranty about the product is liable for damages caused by that non-conformity. La. R.S. 9:2800.58. To establish a breach of express warranty claim, a plaintiff must show that (1) there was an express warranty made by the manufacturer about the product; (2) the express warranty induced the plaintiff to use the product; and (3) the plaintiff's damage was proximately caused because the express warranty was untrue. *Id.*; *see also Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002). The LPLA defines "express warranty" as "a representation, statement of alleged fact or promise about a product . . . that represents, affirms or promises that the product . . . possesses specified characteristics or qualities or will meet a specified level of performance." La. R. S. 9:2800.53(6). The statute adds that "general opinion[s]" or "general praise" of a product do not qualify as express warranties. *Id.*

Plaintiff alleges that defendants misrepresented the applicator and mesh as "safe and effective treatment[s] for hernias."[38] This allegation is not enough to claim a breach of express warranty under the LPLA. Numerous courts have found that a general allegation that defendants marketed their product as "safe" or "effective" is not sufficient to state this claim. *See, e.g.*, *Doe v. AstraZeneca Pharm., LP*, No. 15-438, 2015 WL 4661814, at *4 (E.D. La. Aug. 5, 2015) (plaintiff's allegation that defendant represented to the market that defendant's product was "safe" and "effective" did not satisfy pleading standard); *Flournoy v. Johnson & Johnson*, No. 15-5000, 2016 WL 6474142, at *3 (E.D. La. Nov. 2, 2016) (plaintiff's breach of warranty claim dismissed for failing to sufficiently "identify the contents of any warranty"). Plaintiff's claim also fails because he does not allege how any warranty induced him to use the applicator or mesh, or how his injury was caused by defendants' allegedly untrue warranty. *See Flournoy*, 2016 WL 6474142, at *3. Plaintiff's express warranty claim is therefore dismissed.

C. Redhibition

As already mentioned, the LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. R.S. 9:2800.52. But redhibition remains available against a manufacturer to

[38] *Id.* ¶ 21.

recover economic loss. *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 251 (5th Cir. 2012) ("Courts have interpreted the LPLA as preserving redhibition as a cause of action only to the extent the claimant seeks to recover the value of the product or other economic loss."). A plaintiff suing in redhibition must prove that "(1) the thing sold is absolutely useless for its intended purposes[,] or that its use is so inconvenient that it must be supposed that he would not have bought it had he known of the defect; [and] (2) that the defect existed at the time he purchased the thing, but was neither known [n]or apparent to him . . . ." *Alston v. Fleetwood Motor Homes of Ind.*, 480 F.3d 695, 699 (5th Cir. 2007) (citing *Dalme v. Blockers Mfd. Homes, Inc.*, 779 So. 2d 1014, 1028 (La. App. 3 Cir. 2001)).

Plaintiff's redhibition claim must be dismissed for two reasons. First, he does not allege that he has suffered any economic loss in connection with the mesh or applicator. Plaintiff does not state that he directly purchased the mesh or applicator, or whether the cost for the products was passed along to him in his medical expenses. Because plaintiff can only recover his economic losses in connection with the products' alleged defects, his failure to allege any economic loss dooms his claim. Second, plaintiff does not assert anywhere in his complaint that had he known of the products' defects, he would not have "purchased" them. *Cf. Flournoy*, 2016 WL 6474142, at *5

(plaintiff's allegation that had she "been aware of the defects contained in the subject implant devices, she would not have purchased or allowed implanting said implant devices," coupled with an allegation that the devices were defective, was "minimally sufficient" to state a redhibition claim). Because plaintiff has not asserted all of the elements of a redhibition claim, the Court dismisses the claim.

D. Leave to Amend

Lastly, plaintiff requests leave to amend his complaint in the event the Court finds that he has failed to allege his claims with the specificity *Iqbal* and *Twomby* require.[39] The Court will "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a). The Supreme Court has held that "[i]f the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962). But leave to amend "is by no means automatic." *Halbert v. City of Sherman*, 33 F.3d 526, 529 (5th Cir. 1994). The Court considers multiple factors, including "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to

[39] R. Doc. 14 at 10.

the opposing party by virtue of allowance of the amendment, [and] futility of amendment." *Foman*, 371 U.S. at 182.

Plaintiff is denied leave to amend his claims for negligence, breach of warranty of fitness for ordinary use, or breach of implied warranty of merchantability and fitness, because any amendment of those claims would be futile. *See Dendinger*, 2018 WL 4462579, at *1 (in a suit against a manufacturer, dismissing state law negligence claim with prejudice). These claims are therefore dismissed with prejudice.

But the Court finds that none of the Rule 15 factors militates against granting leave to amend his other claims that the Court dismisses in this order. Those claims are therefore dismissed without prejudice. Plaintiff must file any amended complaint within twenty-one (21) days of the entry of this order.

IV. CONCLUSION

For the foregoing reasons, defendants' motion to dismiss is GRANTED IN PART and DENIED IN PART. Plaintiff's inadequate warning, design defect, breach of express warranty, and redhibition claims are DISMISSED WITHOUT PREJUDICE. Plaintiff's claims for negligence, breach of warranty of fitness for ordinary use, and breach of implied warranty of

merchantability and fitness, are DISMISSED WITH PREJUDICE. The Court denies defendants' motion to dismiss plaintiff's construction or composition defect claim. Any amended complaint must be filed within twenty-one (21) days of the entry of this order.

New Orleans, Louisiana, this 17th day of May, 2019.

Sarah Vance

SARAH S. VANCE
UNITED STATES DISTRICT JUDGE