UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

KIMBERLY PELLEGRIN	CIVIL ACTION
VERSUS	NO. 17-12473
C.R. BARD, ET AL.	SECTION "R" (4)

ORDER AND REASONS

Defendants Medtronic, Inc. and Covidien, LP move to dismiss plaintiff's complaint.[1] For the following reasons, the Court grants the motion.

I. BACKGROUND

This case arises out of an allegedly defective product manufactured by defendants.[2] Plaintiff Kimberly Pellegrin alleges she was diagnosed on October 23, 2014 with gastritis, gastroparesis, and diabetes.[3] Plaintiff asserts that on October 25, 2014, she was rushed to the hospital and further diagnosed with a "perforated duodenal ulcer."[4] She alleges she was also suffering from tachycardia, hypotension, sepsis, acute kidney injury,

1 R. Doc. 5.
2 R. Doc. 1 at 3 ¶ 11.
3 *Id.* at 3 ¶ 13.
4 *Id.* at 3 ¶ 14.

abnormal coagulation profile, and gastrointestinal bleeding.[5] That same day, plaintiff underwent surgery to repair the perforated ulcer and was implanted with defendants' allegedly defective product, Parietex Composite Mesh.[6] She does not allege the purpose for which the product was implanted.

Confusingly, plaintiff's opposition to defendants' motion provides a different medical diagnosis and different dates for plaintiff's surgery. The Court notes that the complaint appears to be a near-verbatim copy of two other complaints recently filed against defendants. *See* No. 17-6075 (E.D. La. June 23, 2017); No. 17-11836 (E.D. La. Nov. 6, 2017). Plaintiff now states in her opposition that she underwent "hernia repair surgery" in March 2014 and again in July 2015, and that during both surgeries she was "repaired" with defendants' product.[7] The Court relies only on the factual information provided in the complaint. *See Goodwin v. Hous. Auth. of New Orleans*, No. 11-1397, 2013 WL 3874907, at *9 n. 37 (E.D. La. July 25, 2013) (noting that it is "inappropriate to raise new facts and assert new claims in an opposition to a motion to dismiss"). In any event, the alternative information provided by plaintiff in her opposition would not alter the Court's analysis or conclusions. It does, however, undermine the credibility of her counsel, who

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5 *Id.*

6 *Id.*

7 *See* R. Doc. 19 at 2.

is obligated under Rule 11 not to file a pleading containing factual assertions that do not have evidentiary support or will not have such support after discovery. *See* Fed. R. Civ. P. 11(b)(3).

Plaintiff alleges that defendants' product caused her to experience "severe and permanent bodily injuries," including "excruciating abdominal pain and swelling, difficulty walking, and physical pain."[8] She alleges that at some point she underwent subsequent surgery "to remove and/or repair the damage" cause by defendants' product.[9] Plaintiff alleges that defendants' product contains "numerous defects," and specifically states that the product "abrades tissues" and does not perform its intended purpose.[10] Plaintiff does not allege that she experienced tissue abrasion.

On November 14, 2017, plaintiff sued Medtronic, Covidien, C.R. Bard, Inc., and Davol, Inc. for damages. The complaint brings claims under various provisions of the Louisiana Products Liability Act (LPLA), La R. S. §§ 9:2800.51, *et seq.*, and for redhibition, La. Civ. Code arts. 2520, *et seq*. On March 6, 2018, plaintiff voluntarily dismissed all claims against C.R. Bard

8 R. Doc. 1 at 3 ¶ 15.
9 *Id*. at 3 ¶ 16.
10 *Id*. at 4 ¶ 17.

and Davol.[11] The remaining defendants now move to dismiss plaintiff's complaint.[12]

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." *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

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11 R. Doc. 15.
12 R. Doc. 5.

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

Defendants move to dismiss the complaint for two reasons. First, defendants argue plaintiff's claims are prescribed under the applicable statute of limitations. Second, defendants argue that plaintiff has failed to plead sufficient factual support to satisfy the pleading standard required by *Iqbal* and *Twombly*.

A. Prescription

Plaintiff's products liability claims are subject to the general one-year prescriptive period applicable to delictual actions under Louisiana law. La. Civ. Code art. 3492. The prescriptive period "commences to run from the day injury or damage is sustained." *Id*. Under Louisiana law, "damages are said to be sustained 'when the damage has manifested itself with sufficient certainty to support accrual of a cause of action.'" *Jenkins v. Bristol-Myers*

Squibb Co., 689 F. App'x 793, 795 (5th Cir. 2017) (quoting *Cole v. Celotex Corp.*, 620 So. 2d 1154, 1156 (La. 1993)); *see also Grenier v. Med. Eng'g Corp.*, 243 F.3d 200, 203-04 (ruling that the plaintiff's cause of action under the LPLA accrued once she had "suffered some physical injury" because of the defendant's allegedly defective product). "Prescription is an affirmative defense, and defendants bears the burden of its proof at trial." *Ducre v. Mine Safety Appliances, Inc.*, 963 F.2d 757, 760 (5th Cir. 1992). If a complaint reveals on its face that the prescriptive period has run, "the burden shifts to the plaintiff to prove a suspension or interruption of the prescriptive period." *Younger v. Marshall Indus., Inc.*, 618 So. 2d 866, 869 (La. 1993); *see also Eastin v. Entergy Corp.*, 865 So. 2d 49, 54 (La. 2004).

The complaint alleges that plaintiff was implanted with defendants' product over three and a half years ago during surgery on October 25, 2014,[13] and that she experienced "severe and permanent bodily injuries" because of the implant.[14] Plaintiff also asserts she has undergone "subsequent surgeries" to repair the damage defendants' product has caused.[15] Importantly, the complaint does not provide any indication of when plaintiff first experienced her alleged injuries, or when plaintiff's "subsequent

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13 R. Doc. 1 at 3 ¶ 14.
14 *Id.* at 3 ¶ 15.
15 *Id.* at 3 ¶ 16.

surgeries" were performed. Accordingly, the Court cannot determine from the face of the complaint when plaintiff's injuries manifested and her cause of action accrued. *See Jenkins*, 689 F. App'x at 795. Because the prescriptive period commences on the day the cause of action accrues, the Court cannot find plaintiff's claims facially prescribed.

Defendant argues that plaintiff's claim is facially prescribed because the prescriptive period started on the date of plaintiff's surgery over three and a half years ago.[16] But that is not correct. Plaintiff's cause of action accrued, and thus the prescriptive period commenced, when plaintiff "first suffered some physical injury." *Grenier*, 243 F.3d 200, 203-04. Plaintiff does not provide a date on which she first experienced her alleged injuries. The Court cannot infer from other information provided in the complaint whether the onset of plaintiff's injuries was immediate upon the implantation of the product or developed later. Nor can the Court determine when she had revision surgery.

Plaintiff's redhibition claim is subject to a one-year prescriptive period beginning from the date the buyer discovers the alleged defect. La. Civ. Code art. 2534(A)(1), (B). As with plaintiff's claims under the LPLA, the

[16] *See* R. Doc. 5-1 at 13.

redhibition claim is not facially prescribed because the complaint does not allege when plaintiff first experienced her injuries.

Plaintiff should note, however, that it is only the vagueness of her complaint that prevents the Court from finding her claims facially prescribed. Plaintiff alleges she underwent surgery more than three years before filing this complaint, during which she was implanted with defendants' allegedly defective product. Because plaintiff does not allege when and how her injuries manifested themselves, her date of injury cannot be ascertained. In any amended complaint, the Court directs plaintiff to include specific allegations explaining what injuries she suffered and when she first experienced those injuries.

B. Sufficiency of the Pleading

1. *The Louisiana Products Liability Act*

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). The statute 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.* § 9:2800.54(B)(1-4). Thus, the LPLA limits the plaintiff to four theories of recovery: construction/composition defect, design defect, inadequate warning, and breach of express warranty. The complaint includes causes of action for each of these theories of recovery. The Court next considers whether plaintiff's allegations satisfy the LPLA.

a. Construction or composition

To establish a claim for defective construction or composition, 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. Plaintiff alleges that defendants' product "was sold in a defective

condition"[17] which created "a high risk of unreasonable and dangerous injuries . . . including that the material in the product abrades tissues."[18] But her complaint lacks any factual allegations as to *how* the particular product with which she was implanted deviated from defendants' specifications, performance standards, or identical products manufactured by defendants. Nor does plaintiff allege how any such defect would cause the product to abrade tissues or that her tissues were in fact abraded, causing her injuries. Rather, the complaint merely includes a conclusory allegation that the product "deviated in a material way from defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula."[19]

Federal courts applying the LPLA have made clear that defective construction or composition claims require more than conclusory allegations, and will not survive motions to dismiss without allegations of how the product is defective and how this defect caused the plaintiff's injuries. *See, e.g.*, *Aucoin v. Amneal Pharm., LLC*, No. 11-1275, 2012 WL 2990697, at *10 (E.D. La. July 20, 2012) (granting motion to dismiss plaintiff's defective construction or composition claim because plaintiff did

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17 R. Doc. 1 at 11 ¶ 51.
18 *Id.* at 4 ¶ 17.
19 *Id.* at 12 ¶ 52.

not allege that product deviated from production standards or identical products); *Watson v. Bayer Healthcare Pharm., Inc.*, No. 13-212, 2013 WL 1558328, at *4 (E.D. La. Apr. 11, 2013) (granting motion to dismiss plaintiff's defective construction or composition claim because plaintiff did not allege how product deviated from production standards or how the unknown defect caused her alleged injuries); *Kennedy v. Pfizer, Inc.*, No. 13-3132, 2014 WL 4093065, at *3 (W.D. La. Aug. 15, 2014) (same); *Becnel v. Mercedes-Benz USA, LLC*, No. 14-0003, 2014 WL 4450431, at *4 (E.D. La. Sept. 10, 2014) (same). Plaintiff's conclusory allegations therefore do not rise to the level of plausibility required by *Twombly* and *Iqbal*. Thus, plaintiff's defective construction or composition claim must be dismissed.

b. Inadequate warning

For inadequate warning claims, Louisiana applies the "learned intermediary doctrine." *Stahl*, 283 F.3d at 265; *see also Willett v. Baxtern Int'l Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991) (applying the "learned intermediary doctrine" in an LPLA action against a medical device manufacturer). 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.

To prevail on an inadequate warning claim, 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.

Plaintiff alleges that defendants' product contained insufficient warning of the "high risk" of "dangerous injuries" it could cause, in particular that the product "abrades tissues."[20] Plaintiff further alleges that had "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."[21] These conclusory allegations amount to "naked assertions

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20 R. Doc. 1 at 14 ¶ 66.

21 *Id*. at 15 ¶ 68.

devoid" of the "factual enhancement" necessary to survive a motion to dismiss. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). In particular, the plaintiff fails to assert that the product's characteristic that may cause damage (its supposed high risk of abrading tissues[22]) actually caused her injuries. There is no indication in the complaint that plaintiff's tissues were abraded at any point since her surgery, let alone as a result of defendants' product, or that an abrasion was the cause of her injury. Thus, plaintiff fails to assert that the alleged inadequate warning is causally connected to her injuries, which renders her inadequate warning claim implausible. *See Iqbal*, 556 U.S. at 678; *see also Watson*, 2013 WL 1558328, at *5 (dismissing plaintiff's inadequate warning claim because the complaint failed to "allege facts suggesting how [defendant's] allegedly inadequate warning caused [plaintiff's] specific injury"). These deficiencies require the Court to dismiss plaintiff's inadequate warning claim.

c. Defective design

Next, plaintiff alleges that defendants' product was unreasonably dangerous in its design. To establish the elements for this claim, the plaintiff must allege that:

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22 *Id.* at 14 ¶ 66.

> (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. R. S. § 9:2800.56.

Plaintiff alleges the product was "defective in its design"[23] particularly because it "abrades tissues,"[24] and that there existed "practical and feasible alternative designs that would have prevented"[25] plaintiff's injuries. These conclusory statements also fail to satisfy the pleading standard required by *Iqbal* and *Twombly*. Plaintiff fails to sufficiently allege what aspect of defendants' product design caused it to abrade tissues, how the alleged defect contributed to her specific injuries, or what other alternative designs existed at the time of her surgery. *See Flournoy v. Johnson & Johnson*, No. 15-5000, 2016 WL 6474142, at *3 (E.D. La. Nov. 2, 2016) (plaintiff's conclusory allegation that "there existed an alternate design for the product that was capable of preventing" plaintiff's injuries was insufficient to sustain a defective design claim); *Watson*, 2013 WL 1558328, at *4-5 (dismissing complaint that failed to allege how defendant's design was defective and

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23 R. Doc. 1 at 15-16 ¶ 73.
24 *Id.* at 16 ¶ 76.
25 *Id.* at 17 ¶ 79.

what aspect of the defective design caused plaintiff's injuries). Accordingly, plaintiff's defective design claim contains an insufficient allegation that an alternative design existed, and the claim must be dismissed.

d. 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's allegations are plainly insufficient to state a breach of express warranty claim. Plaintiff alleges that defendants made express representations to plaintiff, plaintiff's physicians, "other consumers," and the "medical community" that defendants' product is safe to use and does not "produce dangerous side effects."[26] Plaintiff further alleges that she allowed defendants' product to be implanted into her "as a result" of these representations,[27] and that her injuries were a "direct and proximate result"[28] of the alleged breach of warranty.

Plaintiff's claim for breach of warranty is nothing more than a "threadbare recital[] of the elements of [the] cause of action, supported by mere conclusory statements." *Iqbal*, 556 U.S. at 678. In particular, plaintiff's vague and conclusory allegations fail to specify the contents of defendants' representations or how they were factually untrue or inadequate. While plaintiff is not required to identify the exact language used in the warranty, she must specify the warranty in question and explain why the warranty is untrue. *See Flournoy*, 2016 WL 6474142, at *3 (plaintiff's breach of warranty claim dismissed for failing to sufficiently "identify the contents of any warranty"); *see also Robertson v. AstraZeneca Pharm., LP*, No. 15-438, 2015

26 R. Doc. 1 at 18 ¶ 84.
27 *Id.* at 19 ¶ 89.
28 *Id.* at 20 ¶ 90.

WL 5823326, at *5 (E.D. La. Oct. 6, 2015) (plaintiff's allegation that defendant made representations in "materials presented to the FDA" was not specific enough to state a claim for breach of warranty); *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). Because plaintiff has failed to satisfy the pleading standard for her breach of express warranty claim, that claim must also be dismissed.

2. *Redhibition*

The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products," La. R. S. § 9:2800.52, and damages for personal injury from defective products cannot be recovered from manufacturers in redhibition. But redhibition remains available against a manufacturer to 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. 2001).

As with plaintiff's claims under the LPLA, plaintiff's redhibition claim must be dismissed because the complaint fails to sufficiently allege how defendants' product was defective. *See Guidry v. Janssen Pharm., Inc.*, No. 15-4591, 2016 WL 633673, at *5 (E.D. La. Feb. 17, 2016) (dismissing redhibition claim for plaintiff's failure to allege facts that would allow the Court to "plausibly recognize any particular defect" in defendant's product).

C. Leave to Amend

Lastly, plaintiff requests leave to amend her complaint in the event the Court finds her claims prescribed or insufficiently pleaded.[29] 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). Leave to amend, however, "is by no means

[29] R. Doc. 19 at 11-12.

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

The Court finds that none of these factors militate against granting leave to amend. The Court grants plaintiff leave to amend her complaint within twenty-one (21) days of the entry of this order.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS defendants' motion to dismiss. Plaintiff's claims are DISMISSED WITHOUT PREJUDICE. Plaintiff has 21 days to amend her complaint. Failure to timely amend will result in dismissal of the complaint with prejudice.

New Orleans, Louisiana, this 20th day of June, 2018.

Sarah Vance

SARAH S. VANCE
UNITED STATES DISTRICT JUDGE