UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

DENISE PIERRE, ET AL.	**CIVIL ACTION**
VERSUS	**NO. 17-12196**
MEDTRONIC, INC., ET AL.	**SECTION "B"(1)**

ORDER AND REASONS

Defendants Medtronic Inc. and Covidien LP. filed a Motion to Dismiss (Rec. Doc. 25) Plaintiffs' First Amended Complaint (Rec. Doc. 19). Plaintiffs Denise Pierre and Floyd Baham timely filed an opposition. Rec. Doc. 27. Defendants then sought, and were granted, leave to file a reply. Rec. Doc. 33. For the reasons discussed below,

IT IS ORDERED that the Defendants' motion to dismiss (Rec. Doc. 25) is **DENIED** with respect to Plaintiffs' construction or composition defect, design defect, and redhibition claims and **GRANTED** with respect to all other claims. Plaintiffs shall have twenty-one (21) days to amend to address the deficiencies identified in this Order and Reasons. If Plaintiffs do not correct those deficiencies within twenty-one (21) days, the deficient claims will be **DISMISSED WITH PREJUDICE.**

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

On November 17, 2016, Plaintiff Denise Pierre underwent surgery to correct a ventral hernia. *See* Rec. Doc. 19 ¶ 9. The surgeons used a piece of Parietex ProGrip Self Fixating Mesh to

close the hole in Pierre's abdominal wall. *See id.* The piece of mesh purportedly measured 20 centimeters by 15 centimeters. *See id.* Pierre was readmitted to the hospital on December 4, 2016, because the mesh had allegedly become infected and begun to detach from Pierre's abdominal wall. *See id.* ¶ 10. Pierre alleges that she received treatment for complications from the mesh in June and July of 2017, and that she continued to suffer from these complications when the First Amended Complaint was filed in December 2017. *See id.* ¶¶ 11-13. Pierre's father, Floyd Baham, is also a plaintiff and seeks damages for loss of consortium. *See id.* ¶ 111.

Plaintiffs lodge various allegations against Defendants about the safety of the mesh. *See* Rec. Doc. 19. First, Plaintiffs allege that the mesh used in Pierre's surgery was improperly sterilized, in violation of Defendants' sterilization procedures, before being sent to the hospital where Pierre's surgery took place. *See id.* ¶¶ 58, 59. Plaintiffs' complaint states that, because the mesh was improperly sterilized, Pierre developed a severe infection following her surgery. *See id.* ¶¶ 60, 62.

Second, Plaintiffs allege that Defendants failed to adequately warn about infection and the chance that the mesh would contract after surgery. *See id.* ¶¶ 66, 71. Plaintiffs claim that, if Defendants had adequately warned Pierre's surgeon, the surgeon would not have used the mesh. *See id.* ¶¶ 72, 75.

Third, Plaintiffs allege that two design features of the mesh were unnecessarily dangerous. According to Plaintiffs, the mesh was made out of polyester and incorporated "thousands of micro-grips" to secure the mesh once it was implanted. *See id.* ¶ 83. This design allegedly caused unnecessary pain when the mesh contracted after surgery, *see id.* ¶ 83, and facilitated infection by lowering the body's pH around the mesh, *see id.* ¶ 57. The complaint asserts that "practical and feasible alternative designs" were available to Defendants when they manufactured the mesh that was used in Pierre's surgery. *Id.* ¶ 86.

Fourth, Plaintiffs allege that Defendants expressly warranted that the mesh was "adequately tested," "safe and fit for its intended purposes, was of merchantable quality, . . . and did not produce dangerous side effects . . . ." *Id.* ¶ 91. Plaintiffs further allege that the previously-discussed design and production defects violated these express warranties. *See id.* ¶¶ 92, 95. Plaintiffs finally posit that they relied on Defendant's express warranties when deciding to use the mesh and would not have done so otherwise. *See id.* ¶ 96.

Fifth, Plaintiffs allege that the previously discussed design and production defects rendered the mesh useless, such that Plaintiffs would not have purchased the mesh if they had known of the defects. *See id.* ¶¶ 100-02. Defendants moved to dismiss all claims for failure to state a claim. *See* Rec. Doc. 25.

LAW AND ANALYSIS

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a plaintiff's complaint "must contain 'enough facts to state a claim to relief that is plausible on its face.'" *Varela v. Gonzalez*, 773 F.3d 704, 707 (5th Cir. 2014) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When deciding whether a plaintiff has met his or her burden, a court "accept[s] all well-pleaded factual allegations as true and interpret[s] the complaint in the light most favorable to the plaintiff, but '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements' cannot establish facial plausibility." *Snow Ingredients, Inc. v. SnoWizard, Inc.*, 833 F.3d 512, 520 (5th Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (some internal citations and quotation marks omitted).

Plaintiff alleges four claims under the Louisiana Products Liability Act (LPLA) and one other state law claim. To prevail under the LPLA, a plaintiff must show that (1) the defendant manufactured the product, (2) the plaintiff's damage was "proximately caused by a characteristic of the product," (3) the characteristic made the product "unreasonably dangerous," and (4) the plaintiff's damage resulted from a reasonably anticipated use of the product. *See* La. Rev. Stat. § 9:2800.54(A). A product can

be unreasonably dangerous (1) "in construction or composition,"[1] (2) "in design,"[2] (3) because there is an inadequate warning,[3] or (4) because it failed to "conform to an express warranty."[4] *See id.* § 9:2800.54(B). A plaintiff bears the burden of proving all elements of an LPLA claim. *Id.* Plaintiff has brought an LPLA claim under each theory of unreasonable dangerousness.

Plaintiffs have adequately pled that Defendants are manufacturers under the LPLA. A manufacturer includes an "entity who is in the business of [producing, making, fabricating, constructing, [or] designing] a product for placement into trade or commerce." La. Rev. Stat. § 9:2800.53(1). The definition also encompasses an "entity who labels a product as his own or who otherwise holds himself out to be the manufacturer of the product." *Id.* § 9:2800.53(1)(a). Plaintiffs allege that "Defendants manufactured, supplied, distributed, formulated, prescribed, marketed, and sold" the Parietex ProGrip Self Fixating Mesh. *See* Rec. Doc. 19 ¶ 5; *see also* Rec. Doc. 19 ¶¶ 6, 7, 17. Therefore, Plaintiffs have stated facts that, if true, establish that Defendants are manufacturers under the LPLA.

Plaintiffs have also adequately pled that Pierre was injured by a reasonably anticipated use of Defendants' product. Plaintiffs

[1] *See* La. Rev. Stat. § 9:2800.55.
[2] *See* La. Rev. Stat. § 9:2800.56.
[3] *See* La. Rev. Stat. § 9:2800.57.
[4] *See* La. Rev. Stat. § 9:2800.58.

allege that Pierre was injured when Defendants' mesh was used during her hernia surgery. *See id.* ¶¶ 9-13. Plaintiffs also allege that Defendants intended the mesh to be used in hernia repair surgery. *See id.* ¶ 17. Therefore, Plaintiffs have alleged that any injuries Pierre suffered from the mesh were the result of a reasonably anticipated use.

Plaintiff's first LPLA claim is for a "construction or composition" defect. *See* Rec. Doc. 19 ¶¶ 52-63 (citing La. Rev. Stat. § 9:2800.55). "A product is unreasonably dangerous in construction or composition if, 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. Rev. Stat. Ann. § 9:2800.55. A plaintiff "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. 2013). A deviation is material when it "increases the propensity for injury . . . ." *Roman v. W. Mfg., Inc.*, 691 F.3d 686, 698 (5th Cir. 2012). A plaintiff must also show how the alleged deviation caused the plaintiff's injury. *See Rayford v. Karl Storz Endoscopy Am., Inc.*, No. 15-2835, 2016 WL 4398513, at *4-5 (W.D. La. June 22, 2016).

Here, Plaintiffs allege that the mesh had a construction or composition defect because it deviated from Defendants' specifications when it was improperly sterilized. *See* Rec. Doc. 19 ¶¶ 56-59. Plaintiffs allege that Defendants designed their mesh to be sterilized with ethylene oxide before the mesh is sent to hospitals. *See id.* ¶ 56. Plaintiffs also allege that the failure to properly sterilize the mesh caused an infection, which is one of injuries allegedly suffered by Pierre. *See id.* ¶ 58. Therefore, Plaintiffs have explained Defendants' sterilization procedures, stated a deviation from those procedures, plausibly claimed that the deviation increased the risk of injury, and alleged that the deviation in fact caused injury. This is sufficient to state a claim for a construction or composition defect under the LPLA. *See Lyles*, 871 F.3d at 311. But, to be clear, this claim does not provide an avenue for Plaintiffs to attack Defendants' sterilization procedures generally, rather it is only viable insofar as Plaintiffs allege that the *deviation* from Defendants' sterilization procedures caused injury. *See* La. Rev. Stat. Ann. § 9:2800.55.

Plaintiff's second LPLA claim is for a "design defect." *See* Rec. Doc. 19 ¶¶ 79-89 (citing La. Rev. Stat. § 9:2800.56). To state a claim for a design defect, a plaintiff must plead that "there existed an alternative design for the product that was capable of preventing the [plaintiff's] damage" and that the benefits of

adopting the alternative design outweighed the costs, both in terms of any increased burden on the manufacturer and any decreased utility of the product. *See* La. Rev. Stat. § 9:2800.56. Plaintiffs allege that Defendants' mesh was made out of polyester, which is allegedly weaker than polypropylene, the material used by other mesh manufacturers. *See* Rec. Doc. 19 ¶ 83. Plaintiffs further allege that, because polyester is weaker than polypropylene, the standard method for securing surgical mesh is ineffective. *See id.* Whereas stronger mesh can be secured with "tacks or sutures[,]" neither works with Defendants' mesh because both would tear the weak polyester mesh. *See id.* Plaintiffs allege that, to solve this problem, Defendants' designed their mesh with "thousands of micro-grips" so no sutures or tacks would be needed. *Id.* Plaintiffs ultimately allege that Defendants' mesh caused more pain than mesh secured with tacks or sutures because Defendants' mesh has "thousands" of points of contact with a patient's abdominal wall, each of which is painfully pulled on when the mesh contracts after surgery. *See id.*

These allegations state a claim for a design defect under the LPLA insofar as the defect alleged is Defendants' combination of polyester mesh and thousands of micro-grips. *See id.* Plaintiffs have stated that this design caused pain, which is one of the injuries alleged. Moreover, Plaintiffs have stated that other mesh manufacturers avoid the pain suffered here by using a different

mesh material and securing the mesh with tacks or sutures. *See id.* These allegations state that there is an alternate design for Defendants' product that is both commercially feasible and would have prevented Pierre's pain. Therefore, Plaintiffs' Amended Complaint includes facts sufficient to state a claim for a design defect under the LPLA. *See* La. Rev. Stat. § 9:2800.56. However, Plaintiffs' design defect claim does not encompass the allegation that the mesh design caused infection by lowering the pH in Pierre's abdomen. *See* Rec. Doc. 19 ¶ 57. In contrast to the allegations about the use of polyester and micro-grips, the allegations about lowering a patient's abdominal pH include no facts to suggest the existence of a feasible alternative design that would prevent the alleged injury. *See id.*

Plaintiffs' third LPLA claim is for inadequate warning. *See* Rec. Doc. 19 ¶¶ 64-78 (citing La. Rev. Stat. § 9:2800.57). "To recover for a failure to warn . . . , a plaintiff must show: (1) that the defendant failed to warn the [plaintiff's] 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 the plaintiff's injury." *Hargrove v. Boston Sci. Corp.*, No. 13-3539, 2014 WL 4794763, at *11 (E.D. La. Sept. 24, 2014). Here, Plaintiffs allege that the warning given to Pierre's physician did not accurately describe the risk of two complications, that use of the mesh could

lead to infection and that the mesh would contract after surgery. *See* Rec. Doc. 19 ¶¶ 66, 71. Plaintiffs also allege that Defendants' failure to warn Pierre and her surgeon caused the surgeon to use Defendants' mesh during the surgery. *See id.* ¶¶ 75, 77.

Plaintiffs' inadequate warning claim fails because it is implausible and lacks requisite factual detail. First, Plaintiffs tether their claim about infection to a marketing document that they claim lacks adequate warnings about infection. *See* Rec. Doc. 19 ¶ 66 n.2. But Plaintiffs offer no facts to plausibly suggest that Pierre's surgeon relied, or any competent surgeon would rely, on this marketing document when deciding whether to perform surgery. Furthermore, the document itself includes numerous references to scientific papers and, importantly, "Instructions For Use" of Defendants' mesh. These references indicate that Defendants did not rely solely, if at all, on the marketing document to warn users of the risks associated with its products. Plaintiffs' total reliance on the marketing document to claim that Defendants did not warn of a common surgical complication is implausible, especially given that Plaintiffs would have been alerted to other more relevant documentation of risks had they fully examined the marketing document.

Aside from referring to the marketing document, Plaintiffs provide no information about what warning Pierre's surgeon received and no information about how that warning was deficient.

While a "[p]laintiff is not required to detail what an adequate warning would be and how an adequate warning would have caused [the] [p]laintiff's treating physician to act differently[,]" a "[p]laintiff is required to allege that [d]efendants did not adequately warn [p]laintiff'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 [p]laintiff's injuries." *Lewis v. Baxter Int'l Inc.*, No. 16-16391, 2017 WL 661324, at *4-5 (E.D. La. Feb. 17, 2017).

While Plaintiffs allege that Pierre did not know that Defendants' mesh might contract after surgery, Plaintiffs do not make the same allegation about Pierre's surgeon. *See* Rec. Doc. 19 ¶ 71. All that Plaintiffs allege is that "[t]he warnings that were given by Defendants failed to properly warn . . . Petitioner's treating/implanting physicians[] of the increased risks of permanent physical injuries as outlined herein." *Id.* Though a closer call than Plaintiffs' arguments about the risk of infection, this allegation is too broad to state a claim because it does not identify (1) which aspects of the product warranted a warning and (2) what injuries resulted from the failure to warn. *See Lewis*, 2017 WL 661324, at *4-5; *Doe v. AstraZeneca Pharm., LP*, No. 15-438, 2015 WL 4661814, at *4 (E.D. La. Aug. 5, 2015) (dismissing

failure to warn claim because of "vagueness" about which "specific adverse effects" warranted a warning).

Plaintiffs' fourth LPLA claim is for breach of an "express warranty." *See* Rec. Doc. 15 ¶¶ 43-49 (citing La. Rev. Stat. § 9:2800.58). "A product is unreasonably dangerous when it does not conform to an express warranty . . . if the express warranty has induced the [plaintiff] or another person or entity to use the product and the [plaintiff]'s damage was proximately caused because the express warranty was untrue." La. Rev. Stat. § 9:2800.58. An express warranty is 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." La. Rev. Stat. § 9:2800.53(6).

An express warranty is not a "general opinion about or general praise of a product." *Id.* Moreover, representations that a product is "safe" or "effective and safe for its intended use" do not create an express warranty because such statements are nothing beyond a general opinion or praise. *See Doe v. AstraZeneca Pharm. LP*, No. 15-438, 2015 WL 4661814, at *4 (E.D. La. Aug. 5, 2015); *Corley v. Stryker Corp.*, No. 13-2571, 2014 WL 3375596, at *5 (W.D. La. May 27, 2014). Plaintiffs fail to state a claim for breach of an express warranty because they only allege that Defendants

warranted "that the Product was safe and fit for its intended purposes, was or merchantable quality, had been adequately tested, and did not produce dangerous side effects . . . ." Rec. Doc. 19 ¶ 91. These are the types of generic expressions of opinion and praise that fail to state a claim under the LPLA. *See* La. Rev. Stat. § 9:2800.53(6) ("general opinion about or general praise of a product" is not an express warranty); *Doe*, 2015 WL 4661814, at *4 (explaining that similar statements did not state a claim under the LPLA); *Corley*, 2014 WL 3375596, at *5 (same).

Because Plaintiffs have adequately alleged that Defendants' product was defective under the LPLA, Plaintiffs' redhibition claim may also be viable. Under Louisiana law, a plaintiff has a cause of action for redhibition when a product has defects that "render [] the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had [s]he known of the defect." La. Civ. Code art. 2520. Such a defect gives the buyer "the right to obtain rescission of the sale." *Id.*

A plaintiff may make a claim under the LPLA and in redhibition; however, redhibition is available only to the extent the plaintiff seeks to recover the value of the product or other economic loss. *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 251 (5th Cir. 2002). As discussed above, Plaintiff has adequately alleged that Defendants' mesh had some defect that rendered it useless and that she would not have used Defendants' mesh had she

known of such defect. *See* Rec. Doc. 19 ¶¶ 100, 102. However, Plaintiff's damages as to this claim are limited to the cost of the product and other economic damages that Plaintiff suffered. *See Guillory v. Pellerin*, No. 07-1683, 2009 WL 1010816, at *2 (W.D. La. Apr. 14, 2009) (citing *Aucoin v. S. Quality Homes, LLC*, 984 So. 2d 685, 692 (La. 2008)); *Barrette v. Dow Agrosciences, LLC*, No. 02-1677, 2002 WL 31365598, at *3-4 (E.D. La. Oct. 18, 2002).

Plaintiff's remaining claims for breach of warranty of fitness for ordinary use, negligence, breach of implied warranty, negligent misrepresentation, and negligent design are precluded by the LPLA. The LPLA sets forth the "exclusive theories of liability for manufacturers for damage caused by their product." La. Rev. Stat. § 9:2800.52. "A [plaintiff] 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 th[e] [LPLA]." *Id.* Therefore, Plaintiff's remaining non-LPLA claims must be dismissed. *See Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1248, 1250-51 (affirming dismissal of claims for "negligence, fraud by misrepresentation, market share liability, breach of implied warranty of fitness and civil conspiracy" because of the LPLA's exclusivity provision); *see also, e.g.*, *Stroderd v. Yamaha Motor Corp., U.S.A.*, No. 04-3040, 2005 WL 2037419, at *2-3 (E.D. La. Aug. 4, 2005) (dismissing a plaintiff's "negligent repair and

breach of contract claims" because of the LPLA's exclusivity provision).

Finally, Plaintiffs state in their First Amended Complaint that they seek, *inter alia*, attorney's fees and punitive damages. Under Louisiana law, punitive damages are permitted only where expressly authorized by statute. *See Int'l Harvester Credit v. Seale*, 518 So.2d 1039, 1041 (La. 1988). Neither the LPLA nor the Civil Code articles on redhibition allow recovery of punitive damages. *See Bladen v. C.B. Fleet Holding Co.*, 487 F. Supp. 2d 759, 770-71 (W.D. La. Apr. 25, 2007); *Cheeks v. Bayer Corp.*, No. Civ. A. 03-132, 2003 WL 1748460, *1-2 (E.D. La. Mar. 28, 2003).

The remedies under the LPLA and redhibition diverge in that the LPLA does not allow recovery of attorney's fees, but redhibition does. *See* La. Rev. Stat. § 9:2800.53(5) (LPLA); La. Civ. Code art. 2545 (redhibition). However, for a claim in redhibition, attorney's fees may be awarded only "for the pure economic loss and not for the damages recovered pursuant to the LPLA." *See De Atley v. Victoria's Secret Catalogue, LLC*, 2004-0661, p.4 (La. App. 4 Cir. 5/14/04); 876 So. 2d 112, 115.

New Orleans, Louisiana, this 23rd day of April, 2018.

SENIOR UNITED STATES DISTRICT JUDGE