UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ALTON SINGLETARY, ET AL	**CIVIL ACTION**
VERSUS	**NO: 19-13108**
COVIDIEN, L.P., ET AL	**SECTION: "S" (1)**

ORDER AND REASONS

Before the court is defendants' **Motion to Dismiss** (Rec. Doc. 26). Plaintiffs oppose the motion, and seek leave to amend the complaint.

IT IS HEREBY ORDERED that plaintiffs shall have **15 days** from entry of this order to amend their complaint to adequately allege claims for failure to warn, breach of express warranty, and loss of consortium;

IT IS FURTHER ORDERED that in all other respects, the motion is **DENIED**.

BACKGROUND

Plaintiff, Alton Singletary ("plaintiff"), has sued Covidien, LP ("Covidien") and Medtronic, Inc. ("Medtronic") (collectively, "defendants") for damages he suffered as a result of the implantation of mesh hernia repair devices manufactured by the defendants. Plaintiff underwent his first inguinal hernia repair in March 2017, for which his surgeon, Dr. James Redmann, used a product called Covidien ProGrip Self Fixating Mesh. Plaintiff alleges that after 2017 surgery, the mesh began tearing away from his tissue to which it had been secured, and the polyester material from which it was made began to shrink and contract, pulling on plaintiff's tissues, organs and nerves. He underwent a second repair of his recurrent right inguinal hernia

with Covidien Parietex Plug and Patch Mesh in March 2019, which did not resolve his symptoms. Plaintiff alleges that he experiences excruciating abdominal pain, difficulty walking, shooting, poking, and burning pains in his abdomen, constant discomfort, swelling, adhesions and the loss/non-viability of his testicle. He further alleges that he will likely have to undergo additional surgeries to remove the mesh products.

According to plaintiff and his doctor, the second surgery was required by the failure of the Pro-Grip Mesh used in the first surgery. His surgeon has opined as follows:

> On March 14, 2017, I repaired an inguinal hernia on Mr. Alton Singletary robotically using the Covidien Pro Grip Mesh. As per the manufacturer's representative's instructions, no tacking was used as it was deemed unnecessary due to the absorbable "feet" on the back of the mesh which would grip the patient's muscle after placement. He returned in February, 2019, with a CT scan showing recurrence of his right inguinal hernia. I then repaired his recurrent hernia with an open procedure and mesh plug and patch on March 18, 2019. He developed a firm testicle postoperatively which has been managed by his urologist. The need for a second procedure was likely due to the failure of the absorbable "feet" on the ProGrip mesh to adhere to the muscle without additional tacking. The manufacturer has since changed its recommendations to include additional tacking when placing the Pro Grip mesh due to numerous recurrences and surgeons' and patients' dissatisfaction. I think Mr. Singletary had to undergo a second repair due to the mesh failure which increased his chance of testicular compromise. Had the first mesh remained fixed, he would not have required a second higher risk procedure.

Rec. Doc. 38-1, Report of Dr. Redmann.[1]

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[1]In ruling on a 12(b)(6) motion, the district court "may also consider documents attached to either a motion to dismiss or an opposition to that motion when the documents are referred to in the pleadings and are central to a plaintiff's claims." Brand Coupon Network, L.L.C. v. Catalina Mktg. Corp., 748 F.3d 631, 635 (5th Cir. 2014). In this case, Dr. Redmann's report is not specifically referenced in the complaint (in fact, his Report is dated August 18, 2020, and the Amended Complaint was filed March 11, 2020) but Dr. Redmann and his choice of defendants' products is referred to in the amended complaint, the Report is attached to the opposition to the motion, and his opinion is central to plaintiff's claims.

Plaintiff filed suit against the defendants alleging claims under the Louisiana Products Liability Act ("LPLA") and in redhibition. Catherine Singletary has filed a claim for loss of consortium.

Defendants have moved for dismissal under Rule 12(b)(6), arguing that plaintiff has failed to adequately plead the elements of a claim under the LPLA. They further allege that Catherine Singletary has not stated a claim for loss of consortium.

APPLICABLE LAW

Standard of Review

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a motion to dismiss a complaint for failure to state a claim upon which relief can be granted. "To survive a Rule 12(b)(6) motion to dismiss, 'enough facts to state a claim for relief that is plausible on its face' must be pleaded." In re Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir. 2007) (quoting Bell Atl. v. Twombly, 550 U.S. 544 (2007). A claim is plausible on its face when the plaintiff pleads facts from which the court can "draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the

allegations in the complaint are true (even if doubtful in fact)." Twombly, 550 U.S. 544, 555 (citations omitted). The court "must accept all well-pleaded facts as true and view them in the light most favorable to the non-moving party." In re S. Scrap Material Co., LLC, 541 F.3d 584,

587 (5th Cir. 2008). However, the court need not accept legal conclusions couched as factual allegations as true. Iqbal, 556 U.S. at 678.

In considering a motion to dismiss for failure to state a claim, a district court may consider only the contents of the pleading and the attachments thereto. Collins v. Morgan Stanley Dean Witter, 224 F.3d 496, 498 (5th Cir. 2000) (citing Fed. R. Civ. P. 12(b)(6)). However, the district court "may also consider documents attached to either a motion to dismiss or an opposition to that motion when the documents are referred to in the pleadings and are central to a plaintiff's claims." Brand Coupon Network, L.L.C. v. Catalina Mktg. Corp., 748 F.3d 631, 635 (5th Cir. 2014).

Louisiana Products Liability Act

The Louisiana Products Liability Act ("LPLA") "establishes the exclusive theories of liability for manufacturers for damages caused by their products." La. Rev. Stat. § 9:2800.52. Under the LPLA, a manufacturer of a product is "liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when the damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." Id. at § 9:2800.54. To prevail on a LPLA claim, a plaintiff must prove: (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 the characteristic made the product unreasonably dangerous in one of the four ways provided in the statute; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. Jefferson v. Lead Industries Ass'n, Inc., 106 F.3d 1245, 1251 (5th Cir. 1997)

(citing generally J. Kennedy, A Primer on the Louisiana Products Liability Act, 49 LA. L. REV. 565 (1989)); La. Rev. Stat. § 9:2800.54.

Liability may be imposed when a product is found to be unreasonably dangerous in (1) construction or composition, (2) design, (3) inadequate warning or (4) nonconformity with an express warranty. La. Rev. Stat. §§ 9:2800.55, 9:2800.56, 9:2800.57, 9:2800.58. In the present case, plaintiff has alleged liability under all four theories of recovery; defendant has moved to dismiss all four claims.

It is undisputed that Covidien manufactured the mesh products in question. However, defendants argue that plaintiffs have failed to adequately allege that Alton Singletary's injuries were proximately caused by a characteristic of the mesh, and that plaintiffs have not adequately alleged that the mesh was unreasonably dangerous under the LPLA.

DISCUSSION

With respect to the proximate causation allegations, plaintiff has alleged the cause of Alton Singletary's recurrent right inguinal hernia needing operative repair on March 18, 2019 was the failure of the Parietex ProGrip Self Fixating Mesh to perform its intended purpose as designed by the defendant manufacturer, and the product not conforming to the defendants' express representations of its intended use. He further alleges that after the first surgery, due to contraction of the microgrips, the mesh began tearing away from the tissue to which the mesh had been secured pulling on plaintiff's tissues, organs, and nerves, and causing plaintiff to undergo a revision surgery in 2019, which caused further significant pain and distress. These allegations sufficiently state that defects in the mesh caused injury to plaintiff. The court thus

turns to a consideration of plaintiff's four theories of liability under the LPLA.

Construction and composition defect

To prevail on a claim that a product is "unreasonably dangerous" in its "construction or composition" under the LPLA, a plaintiff must show 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. Rev. Stat. § 9:2800.55; see also Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 261 (5th Cir. 2002).

Plaintiff's amended complaint alleges that the mesh implants materially deviated from the manufacturer's performance standards, because, inter alia, the implants shrunk and contracted after implantation, which they were not designed to do. Accordingly, plaintiff has stated a claim for defect in construction or composition.

Design defect

A plaintiff alleging a design defect must show: "(1) there existed an alternative design that was capable of preventing the claimant's damage, and (2) the risk avoided by the alternative design outweighed the burden of its adoption by the manufacturer and any adverse effect the alternative design would have on the product's utility." Marable v. Empire Truck Sales of Louisiana, LLC, 221 So. 3d 880, 895 (La. App. 4 Cir. 6/23/17) (citing La. Rev. Stat. § 9:2800.56). In this case, plaintiff has alleged that the mesh implants have numerous defects, including, inter alia, the propensity of the polyester mesh material to unravel, fray, or tear after the mesh products are implanted into the patient; the tendency for the polyester mesh material to

shrink and retract inside the body causing the mesh to pull on tissues and nerves inside the patient's body; the tendency for the mesh product to erode into the spermatic cord causing non-viability of testicle; as well as the tendency for the products to adhere to tissue, organs and nerves inside the body, making it difficult to remove the mesh products from the body. The amended complaint also explicitly alleges that there are numerous practical and feasible alternative designs that would have prevented or reduced the risk of plaintiffs' injuries, for instance, using a stronger material than polyester, such polypropylene, or a design that uses sutures rather than numerous tacks to fix the mesh. The amended complaint also references feasible alternative designs by noting that other manufacturers have patented mesh product designs that do not contain the defects present in the ProGrip and Plug and Patch mesh used in Alton Singletary's hernia repair surgeries. Accordingly, plaintiffs have adequately stated an LPLA claim for defective design.

Inadequate warning

Defendants contend that plaintiffs have failed to state a failure to warn claim because they have not identified the allegedly inadequate warnings, or explained why such warnings were deficient.

In failure to warn cases involving prescription medical devices, Louisiana courts apply the learned intermediary doctrine. "Under this doctrine, a [medical device] manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a [medical device]." Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 264 (5th Cir. 2002);

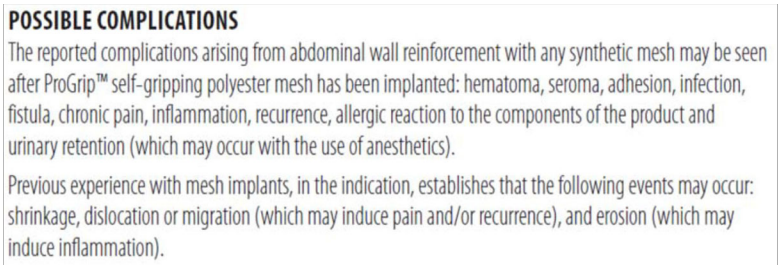
see also, La. Rev. Stat. 9:2800.57(A). In Stahl, the United States Court of Appeals for the Fifth Circuit explained:

> [T]here is a two-prong test governing inadequate-warning claims under the LPLA when the learned intermediary doctrine is applicable. First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.

283 F.3d at 264. Further, a manufacturer has a continuing duty to provide an adequate warning after the product leaves its control if the manufacturer obtains actual knowledge of "a characteristic that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had [it] acted as a reasonably prudent manufacturer." La. Rev. Stat. 9:2800.57(C).

Plaintiffs allege that the warnings provided to Alton Singletary's treating/implanting physicians were improper because they did not reflect the full extent of the potential health complications and adverse health consequences associated with the products, including the propensity of the polyester mesh material to unravel, fray, or tear after implantation; the tendency for the polyester mesh material to shrink and retract inside the body causing the mesh to pull on tissues and nerves inside the patient's body; the tendency for the mesh product to erode into the spermatic cord causing non-viability of testicle; and the tendency for the products to adhere to tissue, organs and nerves inside the body, making it difficult to remove the mesh products from the body. Plaintiffs further allege that if Singletary's doctors had been so warned, they would not have used the mesh products they did.

The following warning was included in the Instructions for Use for the ProGrip mesh product:

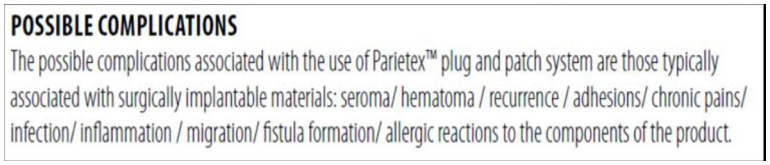


POSSIBLE COMPLICATIONS

The reported complications arising from abdominal wall reinforcement with any synthetic mesh may be seen after ProGrip™ self-gripping polyester mesh has been implanted: hematoma, seroma, adhesion, infection, fistula, chronic pain, inflammation, recurrence, allergic reaction to the components of the product and urinary retention (which may occur with the use of anesthetics).

Previous experience with mesh implants, in the indication, establishes that the following events may occur: shrinkage, dislocation or migration (which may induce pain and/or recurrence), and erosion (which may induce inflammation).

The Plug and Patch mesh product warned:



POSSIBLE COMPLICATIONS

The possible complications associated with the use of Parietex™ plug and patch system are those typically associated with surgically implantable materials: seroma/ hematoma / recurrence / adhesions/ chronic pains/ infection/ inflammation / migration/ fistula formation/ allergic reactions to the components of the product.

Thus, the manufacturer did provide warnings for many of the issues with the mesh that plaintiff complains of, namely, shrinkage, erosion, adhesion, and recurrence of the hernia.

However, plaintiff also argues that defendants did not warn Singletary's surgeon that additional tacking or sutures may be needed to permanently affix the mesh, and that it had become aware of that fact from surgeons implanting the mesh. This is not specifically alleged in plaintiff's amended complaint; rather, it is an argument based on the Report from Dr. Redmann which was issued after filing of the Amended Complaint. Dr. Redmann's report states that "per the manufacturer's . . . instructions no tacking was used as it was deemed unnecessary due to the absorbable 'feet' on the back of the mesh which would grip the patient's muscle after placement." Rec. Doc. 38-1. Dr. Redmann went on to the note that the manufacturer has since changed its recommendation to include additional tacking when placing the Pro Grip mesh due to numerous

recurrences and surgeons' and patients' dissatisfaction." Id.

If alleged, these statements appear sufficient to state a claim that the warnings did not address the need for tacking to secure the mesh, a risk that the manufacturer had become aware of over time via reports from surgeons, and suggests that plaintiff's surgeon may well have used an alternate product, had such a warning been made. Accordingly, plaintiff is allowed to amend his complaint once more under Rule 15(a)(2), to attempt to state his failure to warn claim with the required specificity.

4. Breach of express warranty

To state claim for a breach of express warranty claim, a plaintiff must allege that: (1) the manufacturer made an express warranty about the product; (2) the express warranty induced the plaintiff to use the product; (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. Gen. Motors Corp., 278 F.3d 448, 452 (5th Cir. 2002).

Under the LPLA, an "express warranty" is "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). A "general opinion about or general praise of a product" is not an express warranty. Id.

In moving to dismiss, defendants argue that plaintiff has failed to state a claim because he has not identified any statement that constitutes an express warranty, and that the amended

complaint instead references broad, nonspecific statements not attributed to a specific source. Relying on the Redmann report, plaintiff argues (although he did not so allege in his amended complaint) that defendants expressly represented to his implanting surgeon that the mesh was self-fixating and no sutures or tacking were to be utilized when implanting the mesh, and that it would remain internally attached to Singletary from the self-fixating micro-grips/feet on the back of the mesh which would grip the patient's muscle after placement. Thus, plaintiff contends that he and his implanting surgeon relied upon the express warranties made by the defendants when deciding to utilize the Parietex Mesh for plaintiff's hernia repair, and determined that no sutures/tacking were required, because that was expressly warranted to the surgeon by the defendant and its representatives. He further argues that as a direct result of the defendants' breach of these express warranties, plaintiff suffered injuries and damages in theform of a revision surgery, testicular compromise, and continues to suffer ongoing pain. Because these arguments are supported by the Redmann reprort, as with the failure to warn claim, plaintiff is allowed to amend his complaint to adequately allege his breach of express warranty claim.

Catherine Singletary's Loss of Consortium claim

Defendants also argue that Catherine Singletary should be dismissed for lack of standing. The amended complaint makes no mention of her claim, although it incorporates by reference from the original complaint. The sole allegation in the original complaint concerning Ms. Singletary is: "The conduct of Defendants directly and/or proximately caused Petitioner, Catherine Singletary, to suffer severe and painful personal injuries and damages, which presently include, but are not limited to: a. loss of consortium; and, b. all other elements of damages and

injuries, as may be shown at the trial of this matter."

This conclusory allegation does not allege any specific facts to show that any loss was suffered or what Catherine Singletary's actual damages were. Further, while "[d]amages may include loss of consortium, service, and society, [they are] recoverable by the same respective categories of persons who would have had a cause of action for wrongful death of an injured person." La. Civil Code art. 2315(B). While spouses are eligible to make such a claim, "there can be no recovery for loss of consortium damages for a prenuptial injury that manifested itself before the marriage." Morales v. Davis Bros. Constr. Co., Inc., 706 So.2d 1048 (La. Ct . App.1998). Catherine Singletary does not allege her relationship to Alton, nor, if she is his spouse, include the date of their marriage. Accordingly, as pleaded, plaintiff Catherine Singletary's loss of consortium claim is inadequate, however, she will be granted an opportunity to amend to cure any defects, if possible.

CONCLUSION

Plaintiff has adequately pleaded a design defect claim and a claim for defective composition and construction under the LPLA. Plaintiff has advanced colorable arguments, but has not adequately pleaded, a claim for failure to warn and breach of express warranty, and has requested the opportunity to amend and set forth more specific allegations. The same is true of Catherine Singletary's loss of consortium claim. Discovery has not begun, and the court finds there has not been undue delay, bad faith, or repeated failures to cure deficiencies on previous amendments. See Fed. Rule Civ. Pro. 15(a). Nor will allowing amendment impose undue prejudice on the opposing party. Accordingly, the court will allow plaintiffs 15 days to amend

their complaint and attempt to adequately allege the deficient claims. Therefore,

IT IS HEREBY ORDERED that plaintiffs shall have **15 days** from entry of this order to amend their complaint to adequately allege claims for failure to warn, breach of express warranty, and loss of consortium;

IT IS FURTHER ORDERED that in all other respects, the motion is **DENIED**.

New Orleans, Louisiana, this 16th day of April, 2021.

MARY ANN VIAL LEMMON
UNITED STATES DISTRICT JUDGE