UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ANDREW BRUNO	*	**CIVIL NO. 20-2706**
v.	*	**SECTION: T(4)**
BIOMET, INC. et al.	*	

ORDER AND REASONS

The Court has before it Defendants Biomet Inc. and Zimmer Inc.'s (collectively "Defendants") renewed Motion for Summary Judgment. R. Doc. 154. The Court granted Defendants' prior motion for summary judgment, R. Doc. 66, holding Plaintiff Andrew Bruno's claims to be either prescribed or barred under Louisiana law. R. Doc. 115. However, the Fifth Circuit reversed that holding as to prescription and remanded the case back to this Court for consideration of Defendants' alternate arguments in support of their motion for summary judgment. R. Doc. 128-1. The Court ordered Defendants to rebrief and refile their motion for the Court's consideration following remand. R. Doc. 150. Accordingly, Defendants filed the instant renewed Motion for Summary Judgment. R. Doc. 154.

Plaintiff has failed to respond to Defendant's Motion. However, Plaintiff did respond to Defendants' previously filed motion for summary judgment. *See* R. Doc. 93. Because Defendants' renewed Motion for Summary Judgment reraises several issues raised in their initial motion for summary judgment but unaddressed by this Court, in the interest of equity, the Court has considered Plaintiff's previous opposition to the extent that it is still applicable. Defendants also previously moved the Court for leave to file a reply memorandum in support of their original motion for summary judgment, but the Court did not rule on that motion for leave before entering judgment in Defendants' favor. *See* R. Doc. 100. Thus, in the interest of equity, the Court has also

considered Defendants' proposed reply memorandum. R. Doc 100-1. Having considered the parties' briefing, as well as the applicable law and facts, the Court will **GRANT** Defendants' Motion.

I. BACKGROUND

On December 29, 2016, Plaintiff underwent shoulder surgery at the Ochsner Northshore Medical Center in Slidell, Louisiana. R. Doc. 1-1 at 2. During the operation, Plaintiff's doctor implanted a Biomet Comprehensive Reverse Shoulder (the "Device") manufactured by Defendants into Plaintiff's shoulder. *Id.* at 2–3. The Device was manufactured on January 18, 2016. R. Doc. 72-2. After the surgery, Plaintiff began noticing "drainage" and "redness" around his wound. R. Doc. 1-1 at 3. Plaintiff's doctor treated the wound with antibiotics for several months and, in April of 2017, discovered the presence of "Enterobacter cloacae." *Id.* at 3–4. Due to the presence of this bacteria and the "recurring swelling" of the area surrounding his wound, Plaintiff's doctor performed a "debridement" to drain the wound on May 4, 2017. *Id.* at 4. However, Plaintiff's medical issues returned, and, on January 30, 2018, his doctor again found the presence of Enterobacter. *Id.* Plaintiff continued to take antibiotics, but the swelling and infections persisted for several months. *Id.* at 4–5. On November 16, 2018, Plaintiff's doctor surgically removed the Device. *Id.* at 5.

On August 24, 2018, the Food and Drug Administration ("FDA") sent Defendants a "Warning Letter" notifying them that an FDA inspection, performed over two years after the Device was manufactured, had revealed violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, *et seq.*, with regard to Defendants' cleaning and sterilization. R. Doc. 154-9. Based on these observed violations, the FDA determined that Defendants' "devices are adulterated

. . . in that the methods used in, or the facilities or controls used for, their manufacture, storage, or installation are not in conformity with" federal regulations. *Id.*

On September 25, 2019, Defendants issued a voluntary recall notice for several products and product lots, including component parts of the Device, stating a "supplier who performs final cleaning operations" for Defendants had "received an FDA warning letter earlier th[at] year[,]" following which Defendants had assessed the supplier and determined their supplier's quality standards "were not aligned with Zimmer Biomet's current quality standards." R. Doc. 155-4 at 2. Defendants noted in the letter that "the previous cleaning process could result in elevated levels of bacterial endotoxin and residual debris remaining on the devices[,]" but that "there is not an elevated risk of infection as the sterility of the devices is not impacted." *Id.*

On September 25, 2020, after being notified by the hospital of Defendants' voluntary recall, Plaintiff filed this suit, alleging the Device was "unreasonably dangerous and defective" and had caused him "severe and painful injuries." *Id.* at 6. Specifically, Plaintiff raises claims under the Louisiana Products Liability Act ("LPLA"), arguing Defendants' product is dangerous in composition, dangerous in design, lacked adequate warnings, and failed to conform to an express warranty. *Id.* at 7–8. Plaintiff also argues pursuant to Louisiana Civil Code article 2520 that the Device had a redhibitory defect.[1] *Id.* at 11.

After the Fifth Circuit reversed this Court's holding that Plaintiff's claims were prescribed, Defendants filed the instant Motion. In their renewed Motion for Summary Judgment, Defendants argue Plaintiff cannot support essential elements of his claims under the LPLA based on any of his

[1] At that time, Plaintiff also asserted other Louisiana state law claims for negligence, negligent infliction of emotional distress, and breach of implied warranty. *See* R. Doc. 1-1 at 8–10. However, the Court granted summary judgment to Defendants on those claims, finding them to be barred by the LPLA. R. Doc. 115 at 4–5 ("The LPLA is the exclusive products liability remedy for injured parties in Louisiana, *with an exception for redhibition claims only*") (emphasis added). Plaintiff did not appeal that holding, but only this Court's holding that his other claims were prescribed. *See* R. Doc. 128-1. Thus, the other state law claims are no longer at issue. Nor is Plaintiff's claim for punitive damages, which could have been awarded only under the dismissed negligence claims.

four asserted theories, and that Plaintiff's redhibition claim also fails because Plaintiff cannot show the Device had a "defect" as defined by La. C.C. art. 2520. R. Doc. 154-1.

II. APPLICABLE LAW

Summary judgment is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (citing Fed. R. Civ. P. 56(c)). A court must find "a factual dispute to be 'genuine' if the evidence is such that a reasonable jury could return a verdict for the nonmoving party and a fact to be 'material' if it might affect the outcome of the suit under the governing substantive law." *Voelkel McWilliams Const., LLC v. 84 Lumber Co.*, 2015 WL 1184148, at *5 (E.D. La. Mar. 13, 2015) (quoting *Beck v. Somerset Techs., Inc*., 882 F.2d 993, 996 (5th Cir. 1989)).

The party seeking summary judgment bears the burden of demonstrating the absence of a genuine issue of material fact and all reasonable inferences are drawn in favor of the nonmoving party. *Celotex,* 477 U.S. at 323. When assessing whether a dispute as to any material fact exists, a court considers "all of the evidence in the record but refrains from making credibility determinations or weighing the evidence." *Delta & Pine Land Co. v. Nationwide Agribusiness Ins. Co*., 530 F.3d 395, 398–99 (5th Cir. 2008). However, "unsupported allegations or affidavits setting forth 'ultimate or conclusory facts and conclusions of law' are insufficient to either support or defeat a motion for summary judgment." *Galindo v. Precision Am. Corp*., 754 F.2d 1212, 1216 (5th Cir. 1985); *see also Little v. Liquid Air Corp.,* 37 F.3d 1069, 1075 (5th Cir. 1994). Rule 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an essential

element to that party's case, and on which the party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322. "In such a situation, there can be 'no genuine issue as to any material fact, since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is 'entitled to judgment as a matter of law' because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Id.* at 322–23 (quoting Fed. R. Civ. P. 56(c)).

III. DISCUSSION AND ANALYSIS

The Court will first consider Plaintiff's claims under the LPLA, before moving on to his state law claim for redhibition.

A. The Louisiana Products Liability Act

The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. Stat. Ann. § 9:2800.52. A "claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability" besides claims for products that are: (1) unreasonably dangerous in construction, (2) unreasonably dangerous in design, (3) unreasonably dangerous because of an inadequate warning, or (4) in violation of an express warranty. La. Stat. Ann. §§ 9:2800.52–2800.58. To prevail on an LPLA claim, a plaintiff must show:

> (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.

Becnel v. Mercedes-Benz USA, LLC, 2014 WL 4450431, at *3 (E.D. La. Sept. 10, 2014). "A product is considered 'unreasonably dangerous' in satisfaction of the third element when a plaintiff

shows that it suffers from a 'manufacturing defect, design defect, inadequate labeling, or [when there has been] a breach of express warranty.'" *Id.* (citing *Scianneaux v. St. Jude Med. S.C., Inc.*, 961 F.Supp.2d 808, 813 (E.D. La. 2013)) (alteration original).

Plaintiff alleges the Device was unreasonably dangerous under all four of the LPLA's theories of liability. The Court will consider each argument in turn.

1. Manufacturing Defect

Under Louisiana law, "[a] product is unreasonably dangerous in construction or composition [i.e., has a manufacturing defect,] 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. Stat. Ann. § 9:2800.55. To do so, "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) (citing *Morris v. United Servs. Auto. Ass'n*, 756 So.2d 549, 558 (La. Ct. App. 2000)) (internal quotations omitted). "This is a narrow and demanding test" because the plaintiff must show "that the *particular* product used by the plaintiff deviated from its intended design." *Fuller v. Eisai Inc.*, 513 F. Supp. 3d 710, 720 (E.D. La. 2021) (citing *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1197–98 (E.D. La. 2016) (emphasis original).

Here, Defendants argue Plaintiff has produced no evidence to show what Defendants' specifications or performance standards were for the Device, nor how the Device supposedly deviated from those standards. R. Doc. 154-1 at 13. Plaintiff relies on the report and testimony of

his expert witness Troy Drewry,[2] R. Docs. 156-1; 156-2, and the warning letter and observation form sent to Defendants by the FDA, R. Docs. 154-9; 154-10, to argue he has produced sufficient evidence to create a genuine issue of material fact as to whether the Device deviated from Defendants' standards for the Device. R. Doc. 93 at 10–11. However, Drewry did not test the Device, and explicitly testified that he had not seen Defendants' specifications or performance standards for the Device, stating his opinion that the Device deviated from such standards was based on the FDA's inspections and the fact of Defendants' voluntary recall. R. Doc. 156-2 at 14.

As to Defendants' voluntary recall, which included over 200,000 devices distributed between January 2008 and August 2019, *see* R. Doc. 154-4, this evidence is inadmissible to prove a product design or defect pursuant to Federal Rule of Evidence 407. While experts may rely on inadmissible evidence under some circumstances, *see* Fed. R. Evid. 703, allowing Drewry to opine to a jury as an expert that the Device had a manufacturing defect based on Defendants' recall would undermine the very purpose of Rule 407: to avoid discouraging parties like Defendants from taking remedial actions subsequent to a harm out of concern that those remedial actions will be taken as an admission or proof of fault. *See* Fed. R. Evid. 407, advisory committee notes 1972 proposed rules. Thus, neither the fact of Defendant's recall nor Drewry's opinions based thereupon can create a genuine issue of material fact as to whether the Device had a manufacturing defect.

This leaves the FDA warning letter and observation form. Based on these documents, Drewry states that Defendants "deviated from their specifications regarding cleaning, processing, and sterility" rendering the Device contaminated and defective. R. Doc. 93 at 10 (citing R. Doc. 93-2 at 43–63). Drewry agreed at his deposition that those documents are evidence that

[2] The admissibility of Drewry's report and testimony is the subject of a pending motion in limine. *See* R. Doc. 156.

Defendants' "entire system of cleaning, sterilizing, and packaging is deficient/defective" rendering "every single product that Zimmer Biomet manufactures and puts into the field" defective. R. Doc. 156-2 at 21.

Even presuming the FDA's observations that Defendants failed to meet certain regulatory standards can satisfy Plaintiff's requirement to show what Defendants' specifications or performance standards were for the Device, the FDA warning letter and observation form do not support Plaintiff's argument that the specific Device with which he was implanted was defective in a manner that led to his infection with Enterobacter. As to the FDA observation form, R. Doc. 154-10, the inspection of Defendant's facility that produced this form was conducted between October 2, 2017, and October 16, 2017, almost two years after the Device was manufactured. *Id.* at 1; *see also* R. Doc. 72-2. Some of the observations note they are repeats from previous FDA inspections, which may have taken place closer to the time the Device was manufactured, but none of the observations contained in the form pertain to devices of the type at issue here, nor any of their component parts. *See* R. Doc. 154-10. Additionally, the form makes no mention of Enterobacter or bacterial endotoxin being located on any device manufactured by Defendants. *See* R. Doc. 154-10. At best, the form indicates the FDA observed regulatory violations at Defendants' facility unrelated to devices of the type implanted in Plaintiff and unrelated to contamination by Enterobacter or bacterial endotoxin. The FDA observation form thus does not render any more likely that the specific Device in this case was in fact defective as a result of contamination by Enterobacter or bacterial endotoxin, and therefore fails to create a genuine issue of material fact as to this issue. *See* Fed. R. Evid. 401; 402.

Similarly, the FDA warning letter pertains to an inspection performed between April 9, 2018, and April 24, 2018. *See* R. Doc. 154-9 at 2. The FDA warning letter does directly reference

two component parts of the Device: Product # XL-115464 and Product # 115310. *Id.* at 4–5. However, the FDA's observation as to Product # XL-115464 was that, over two years after the Device was manufactured, there were "inconsistencies in [Defendants'] assignment of *potential* severity ratings for hazards identified during design review[.]" *Id.* at 4 (emphasis added). That is, the FDA noted issues with the "design history file" for Product # XL-115464 in terms of how hazards with that product would be rated if they were identified. But those inconsistencies do not evidence that any iteration of Product # XL-115464, let alone the Device implanted in Plaintiff itself, was actually defective—as a result of contamination by Enterobacter or bacterial endotoxins or otherwise.

As for Product # 115310, the FDA warning letter states it observed an inspection of this component part during which it noted that mailboxes were not sterilized when transferred from an uncontrolled environment into the cleanroom in which the inspection was taking place. R. Doc. 154-9 at 5. This observation does not indicate the mailboxes were in fact contaminated, by Enterobacter or otherwise. Nor does it indicate any product under inspection was contaminated as a result of the unsterilized mailboxes. Additionally, this observation pertains to Product # 115310 only because that product happened to be under inspection by Defendants when the FDA observed Defendants' failure to sterilize the mailboxes. Thus, this observation does not indicate Defendants failed to sterilize Product # 115310 generally or released any defective iterations of that product, let alone that the particular Device at issue in this case was contaminated with Enterobacter or bacterial endotoxin. At most, this observation invites the prejudicial inference that *if* Defendants also failed to sterilize their mailboxes properly in 2016, and *if* those mailboxes were contaminated with Enterobacter or bacterial endotoxin, and *if* the Device came into contact with those

contaminated mailboxes, it is *possible* the Device was also contaminated by Enterobacter or bacterial endotoxin. This chain of speculative possibilities is inadequate to carry Plaintiff's burden.

In sum, Plaintiff seeks to use the FDA warning letter and observation form to show Defendants had issues with cleanliness and sterilization generally, with the hope that a jury will extrapolate therefrom to find the Device at issue here to have been contaminated with Enterobacter or bacterial endotoxin. This leap of logic is insufficient to pass the "narrow and demanding test that the *particular* product used by the plaintiff deviated from its intended design." *Fuller*, 513 F. Supp. 3d at 720 (emphasis original). Thus, Plaintiff cannot carry his burden to prove the Device had a manufacturing defect, and Defendants are entitled to summary judgment on this claim.

2. Design Defect

To prove a product is unreasonably dangerous in design, a plaintiff must show "at the time the product left its manufacturer's control: (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. The plaintiff must identify an alternate safer design because "[i]f there was no alternative way to make the product safer, the defendant could not have prevented plaintiff's injuries and therefore, the defendant is not liable under a design defect theory." *Couturier v. Bard Peripheral Vascular, Inc.*, 548 F. Supp. 3d 596, 608 (E.D. La. 2021). Here, Plaintiff asserts his "design theory is for Zimmer Biomet to follow their own and FDA's design protocols regarding cleaning, processing, and sterilizing medical devices." R. Doc. 93 at 12. However, an argument that a defendant did not follow its own design in manufacturing a certain product is a *manufacturing defect* claim, not a design defect claim, and

Plaintiff has also not presented any safer alternative design for the Device based on the FDA's design protocols, or otherwise. Thus, Plaintiff cannot carry his burden to show the Device was unreasonably dangerous in design, and Defendants are entitled to summary judgment on this claim. *See Celotex*, 477 U.S. at 322–23.

3. Inadequate Labeling

To prove a product is unreasonably dangerous due to inadequate warnings, a plaintiff must prove "at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." La. R.S. 9:2800.57. To carry this burden, a plaintiff must identify what warning was inadequate and propose an alternative adequate warning. *Reynolds v. Bordelon*, 2014-2371, p. 9 (La. 6/30/2015); 172 So.3d 607, 614. An "adequate warning" is defined as "a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made." La. R.S. 9:2800.54(D).

However, in cases involving prescription drugs or medical devices, under the learned intermediary theory, "the doctor acts as an informed intermediary between the drug company and the patient. Thus, a drug manufacturer has a duty to warn the prescribing doctor, rather than the patient, of potential risks associated with the use of the drug. This duty is fulfilled when the prescribing doctor is informed of the potential risks from the drug's reasonably anticipated use so that the physician may intelligently decide on its use with the particular patient." *Brown v. Glaxo, Inc.*, 99- 1531, p. 5 (La. App. 1 Cir. 11/15/00); 790 So. 2d 35, 38; *see also Marks v. OHMEDA,*

Inc., 2003- 1446, p. 11 (La. App. 3 Cir. 3/31/04); 871 So. 2d 1148, 1156-57 (applying the learned intermediary doctrine to medical devices). When the learned intermediary doctrine is applicable, in order to prevail on an inadequate warning claim under the LPLA, "[f]irst, 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." *Stahl v. Novartis Pharma Corp.*, 283 F.3d 254, 265-66 (5th Cir. 2002).

Here, Plaintiff contends "Zimmer Biomet failed to warn [Plaintiff's surgeon] about the issues with cleaning, processing, and sterilizing medical devices that the FDA noted in their inspections." R. Doc. 93 at 13. However, Defendants were not required to warn Plaintiff's surgeon about their alleged cleaning issues—they were required to warn Plaintiff's surgeon about the "dangers of harm" associated with the Device, not the underlying causes of those risks. *See Stahl*, 283 F.3d at 265–66. Here, presuming Defendants had issues with cleaning and sterilization of the Device, the risk associated with those issues is the possibility of infection; and, in fact, infection is exactly what Plaintiff alleges occurred. Because Plaintiff does not contest his surgeon was warned of infection as a possible risk associated with the implantation of the Device, Plaintiff cannot carry his burden to show his surgeon was inadequately warned of the risks associated with the Device. Therefore, Defendants are entitled to summary judgment on this claim.

4. Breach of Express Warranty

To prove a product is unreasonably dangerous because of non-conformity with an express warranty, a plaintiff must prove the product "does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused

because the express warranty was untrue." La. R.S. 9:2800.58. A plaintiff carries this burden by (1) identifying a specific express warranty made by the manufacturer that induced the plaintiff to use the product; (2) proving the warranty was untrue; and (3) showing the failure to conform to the express warranty caused the plaintiff's injuries. *See Reynolds*, 172 So. 3d at 615. Here, Plaintiff has not identified any express warranty made by Defendants. Plaintiff alleges only "that Zimmer Biomet failed to conform to the express warranty set out by the FDA and the Federal Rule of Regulations [sic] to provide a patient with a medical device and/or its component parts that are uncontaminated" and that it is "common sense for a patient to expect any medical device being implanted in them to be uncontaminated." R. Doc. 93 at 14–15. Even presuming these allegations are completely true, they still do not identify any express warranty *made by the manufacturer*, Defendants, with which the Device did not comply. Thus, Plaintiff cannot carry his burden to show the Device was unreasonably dangerous due to failure to conform with any express warranty, and Defendants are entitled to summary judgment on this claim. *See Celotex*, 477 U.S. at 322–23.

B. Redhibition

In Louisiana, "[t]he seller warrants the buyer against redhibitory defects, or vices, in the thing sold." La. Civ. Code art. 2520. "In order to establish a prima facie case [for redhibition], a buyer must show that a non-apparent defect existed at the time of sale." *Ezell v. Gen. Motors Corp.*, 446 So. 2d 954, 956 (La. App. 3 Cir. 1984). "The evidentiary burden is that the proof must be more probable than not." *Id.* The buyer "need not prove the underlying cause of the defect, but only that it existed." *Id.* "The term 'defect', as contemplated in Article 252, means a physical imperfection or deformity; or a lacking of necessary components or level of quality." *Id.* Thus, to sustain his redhibition claim, Plaintiff must adduce sufficient evidence to demonstrate that the

Device possessed a physical imperfection or deformity or lacked a level of quality at the time of sale.

In support of his claim that the Device has a redhibitory defect, Plaintiff relies on the FDA warning letter, the FDA observation form, and the testimony of his expert witnesses, Drewry and Dr. Jeffrey Semel to argue the Device was contaminated with Enterobacter or bacterial endotoxin. The Court, in its discussion of Plaintiff's manufacturing defect claim *supra*, has already rejected the testimony of Drewry and the FDA documents as competent evidence to show the Device was defective. Additionally, Dr. Semel's testimony on this issue suffers from the same deficiencies as Drewry's: Dr. Semel did no testing of the Device, and he relies on the FDA documents to support his opinion that the Device was "more likely than not" contaminated by Enterobacter. R. Doc. 157-3 at 30–31. Thus, Plaintiff has failed to make a sufficient showing on this essential element of his redhibition claim, and Defendants are entitled to judgment as a matter of law on this claim as well. *See Celotex*, 477 U.S. at 322–23.

IV. CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Defendant's Motion for Summary Judgment, R. Doc. 154, is **GRANTED**.

New Orleans, Louisiana, this 1st day of December, 2023.

Greg Gerard Guidry
United States District Judge