IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF MISSISSIPPI

WESTERN DIVISION

STEPHANIE KNOTH **PLAINTIFF**

VS. **CAUSE ACTION NO.: 5:18-CV-49-DCB-MTP**

DR. STEPHEN P. KEITH, ET AL. **DEFENDANTS**

ORDER

This matter is before the Court on Apollo Endosurgery US, Inc., ("Apollo")'s Motion for Summary Judgment. [ECF No. 126]. Having read the Motion, the responsive submissions of the parties, the record, applicable statutory and case law, and being otherwise fully informed of the premises, the Court denies the Motion for Summary Judgment.

Background

This is a medical malpractice and products liability dispute, arising from the implant of an ORBERA® gastric balloon manufactured by Apollo. On November 29, 2016, Dr. Stephen Keith implanted the ORBERA® balloon in Ms. Knoth ("Plaintiff"). Soon after, Plaintiff experienced nausea and vomiting. On December 2, 2016, Dr. Keith opted to reposition the balloon and remove three to four liters of

fluid from Plaintiff's stomach. After the Plaintiff continued to experience complications, Dr. Keith removed the balloon on December 9, 2016.

On May 4, 2018, Knoth, representing herself pro se, filed this lawsuit against Apollo and other defendants. [ECF No. 1]. In October 2018, Plaintiff retained counsel and sought leave to amend her Complaint to plead state-law claims that "parallel" federal law, agreeing that her original state-law claims were preempted. [ECF No. 11 and ECF No. 23]. This Court granted her leave to amend the Complaint, and she did so. [ECF No. 29 and ECF No. 30]. Apollo moved to dismiss Plaintiff's claims against it, pursuant to FED. R. CIV. P. 12(b)(6). [ECF No. 46]. This Court granted the motion in part. [ECF No. 67]. Apollo now brings a Motion for Summary Judgment on the only two remaining parallel state claims: (1) manufacturing defect and (2) breach of express warranty. The Court incorporates in this Order a lengthy description of the background and underlying facts in this action, discussed in its previous orders. [ECF No. 29 and ECF No. 67].

Summary Judgment Standard

Summary judgment is appropriate, pursuant to Rule 56 of the Federal Rules of Civil Procedure, "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The evidence must be reviewed in a light most favorable to the nonmoving party. See Sierra Club, Inc. v. Sandy Creek Energy Assocs., L.P., 627 F.3d 134, 138 (5th Cir. 2010) (internal citation omitted). An issue of material fact is genuine if a reasonable jury could return a verdict for the non-movant. Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986). Summary judgment must be rendered when the nonmovant "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

Discussion

1. Manufacturing Defect

To prevail in a products liability case, Mississippi law requires plaintiff to prove at the time the product left control of the manufacturer or seller that "[t]he product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications . . . ." Miss. Code Ann. § 11-1-63(a)(i)(1); Leverette v. Louisville Ladder Co., 183 F.3d 339, 341 (5th Cir. 1999). "In order to survive summary judgment, a plaintiff must present expert testimony that the product is defective, and that the defect was a medical cause of the

plaintiff's injuries." Harris v. Stryker Spine, 39 F. Supp. 3d 846, 850 (S.D. Miss. 2014).

Dr. Hollis's expert opinion does not address the specific ORBERA® balloon that was implanted in and removed from Plaintiff, inasmuch as Dr. Keith, the physician who removed the ORBERA® balloon from Plaintiff, disposed of it. [ECF No. 142] at 3; [ECF No. 142-2] at 29 (111:6-17). Notwithstanding the absence of this evidence, Dr. Hollis was able to opine that:

> . . . The Mallory-Weiss tear in the lower esophagus, and the tear in the upper stomach, were both caused by vomiting for an extended period-of-time which was caused by the balloon.
> . . .
> The Apollo Balloon implant more likely than not, significantly contributed to the pathology experienced by Ms. Knoth (Plaintiff), specifically the tear in her stomach, the tear in her esophagus and the aspirational pneumonia and respiratory failure of the lungs and the sepsis related to the gastric content leaking through the stomach tear. Furthermore, it is my opinion that for Ms. Knoth, the placement of the Apollo balloon was significantly more likely to have produced these pathologies than an endoscopic procedure alone.

[ECF No. 126-4] at 6-7.

Apollo's internal investigation report [ECF No. 145], a standard fill-in-the-blank form document, confirms that relevant information suggested that the device caused Plaintiff's injuries and that the ORBERA® balloon was not available for analysis:

> Death/Injury NOT Caused by Device No
> . . .
> Does information suggest serious injury? Yes
> Info suggests Device Caused Injury? Yes
> Info suggests Device Malfunctioned [left blank]
> . . .
> The device will not be returned for analysis.
> . . .
> Assessment of the device involved in this complaint was not possible. . . .

Id. at 5, 8-9.

Claiming spoliation of evidence, Plaintiff argues that summary judgment is not appropriate because Dr. Keith, whom Apollo marketed as an ORBERA® specialist and who was acting as an agent with apparent authority for Apollo, destroyed the very piece of evidence that is critical to Plaintiff's manufacturing defect claim. [ECF No. 137] at 2-8. Apollo counters that there is no spoliation of evidence because Dr. Keith was not Apollo's agent, he did not satisfy the federal law standard of acting in bad faith or with bad conduct, King v. Illinois Cent. R.R., 337 F.3d 550, 555-56 (5th Cir. 2003), and he had no duty to preserve the evidence. Guzman v. Jones, 804 F.3d 707, 713 (5th Cir. 2015) (a party's duty to preserve evidence comes into being when the party has notice that the evidence is relevant to the litigation or should have known that the evidence may be relevant).

In order to attribute the destruction of the evidence to Apollo, Plaintiff must show that Dr. Keith, the spoliator, was acting as an agent under Apollo's apparent authority. To do so, Plaintiff

must show: (1) acts or conduct by the principal indicating the agent's authority; (2) reasonable reliance by a third party upon those acts or conduct; and (3) detrimental change in position by the third party as a result of such reliance. Barnes, Broom, Dallas & McLeod, PLLC v. Estate of Cappaert, 991 So. 2d 1209, 1212 (Miss. 2008).

The first prong of the apparent authority test is the most problematic.[1] To meet the first prong, Plaintiff claims that: the patient brochure, television commercials and the ORBERA® website listed Dr. Keith as an ORBERA® specialist; she saw a standing life-sized poster that included images of Dr. Keith pictured with the ORBERA® gastric balloon; and it was apparent to her that Dr. Keith was deeply intertwined with the ORBERA® gastric balloon system. [ECF No. 136-1] at 1.

Questions of apparent authority are questions of fact, and typically are for the jury to determine. Wood v. Holiday Inns, Inc., 508 F.2d 167, 176 (5th Cir. 1975); Sys. Inv. Corp. v. Montview Acceptance Corp., 355 F.2d 463 (10th Cir. 1966); Frank Sullivan Co. v. Midwest Sheet Metal Works, 335 F.2d 33 (8th Cir. 1964); Lind v. Schenley Indus., Inc., 278 F.2d 79 (3d Cir. 1960).

[1] The second and third prongs are satisfied given Plaintiff's reliance on Dr. Keith as an ORBERA® specialist and her resulting injuries.

Courts have held that the concept of apparent authority is based upon manifestations by the alleged principal to third persons, and the reasonable belief by those persons that the alleged agent is authorized to bind the principal. Wood, 508 F.2d at 176; Gizzi v. Texaco, Inc., 437 F.2d 308, 309 (3d Cir. 1971); Johnson v. Shenandoah Life Ins. Co., 281 So.2d 636, 640 (Ala. 1973). "The manifestations of the principal may be made directly to the third person, or may be made to the community, by signs or advertising." Gizzi, 437 F.2d at 309. Apollo's advertising of the ORBERA® device creates a factual issue regarding Dr. Keith's apparent authority.

Apollo further argues that, even if Dr. Keith was acting as Apollo's agent, there was no spoliation because (1) he did not act in bad faith, and (2) he had no duty to preserve the evidence given that: (i) he had no notice that the evidence was relevant to any litigation, and (ii) there was no reason that he should have known the evidence was relevant. Guzman, 804 F.3d at 713. Apollo relies on Dr. Keith's deposition testimony as proof that Dr. Keith did not act in bad faith.[2] [ECF No. 142] at 3, 6-7.

[2] In his deposition, Dr. Keith testified:

Q. . . . -- why did you feel like this should not have gone to pathology when you removed the balloon?
A. I didn't see any benefit clinically in doing so. The balloon was intact at the time I removed it and obviously it was a damaged balloon with perforation when I took it out. So I don't see any valuable information being achieved by a pathologist looking at it.

The Fifth Circuit standard encompasses not only "bad faith" but also "bad conduct." King, 337 F.3d at 556; Consol. Aluminum Corp. v. Alcoa, Inc., 244 F.R.D. 335, 340 (M.D. La. 2006). Dr. Keith disposed of evidence that is at the core of Plaintiff's manufacturing defect claim. He did so after being the surgeon in charge of a procedure which placed his patient in ICU with a diagnosis of septic shock, gastric perforation, acute peritonitis, bilateral aspiration pneumonia, and a Mallory-Weiss tear. [ECF No. 126-4] at 3-4. Apollo's internal investigation report affirms that the reported information suggests serious injury and that the device caused Plaintiff's injury. [ECF No. 145] at 5. On these facts, it would not be unreasonable for a jury to conclude that Dr. Keith should have known that the balloon would be relevant evidence in a subsequent investigation. Regarding Dr. Keith's deposition testimony that he did not see any need to return the balloon to Apollo, see note 1, supra, and accompanying text, Apollo's mandatory FDA report states: "The reporter of the event was asked to return the product for analysis. To date, Apollo has not received the device." [ECF 136-6] at 3. Furthermore, Dr. Keith knowingly had a duty to send the ORBERA® balloon to pathology under the hospital's policy. [ECF No. 136-9] at 3. The Court thus finds

---

Q. Did you have any duty to deliver the balloon to Apollo for inspection?
A. I didn't see any need for that, either.

[ECF No. 142-2] at 29 (111:6-17).

that there are enough material facts in dispute for the manufacturing defect claim to survive summary judgment.

2. Breach of Express Warranties

An "express warranty," as referenced in the Mississippi Products Liability Act ("MPLA") Miss. Code Ann. § 11-1-63, is defined as "any affirmation of fact or promise which concerns the product and becomes part of the basis for the purchase of such a product." Forbes v. Gen. Motors Corp., 935 So. 2d 869, 876 (Miss. 2006). To prevail on a claim for breach of express warranty, plaintiff must prove by a preponderance of the evidence that at the time the product left the control of the manufacturer "[t]he product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product." Miss. Code Ann. § 11-1-63(a)(i)(4).

Plaintiff claims that she relied to her detriment on the ORBERA® brochure that Dr. Keith gave her and the 2016 ORBERA® website, which allegedly contained representations that were not approved by the FDA. [ECF No. 137] at 10-14; 21-22. Plaintiff cites to Wildman v. Medtronic, Inc., 874 F.3d 862, 870 (5th Cir. 2017), in which the Fifth Circuit considered whether a warranty on Medtronic's website was consistent with assessments made during the FDA approval process (in which case the lawsuit would be

preempted), or whether the warranty went beyond what the FDA approved. Id. at 869. Finding that the website statement went beyond the FDA's approval and was therefore not preempted, the Fifth Circuit reversed the district court's Rule 12 dismissal and remanded the case. Id. at 870-71.

Also relying on Wildman, Apollo claims that Plaintiff has failed to prove that any statements in either the ORBERA® website or brochure are false or misleading. [ECF No. 142] at 7; Wildman, 874 F.3d at 870 (Medtronic may make representations that are not approved by the FDA but faces state law liability if they are proven false). Apollo further argues that Plaintiff cannot base her express warranty claim on risks that were omitted from the list of warnings in the brochure, Young v. Bristol Myers Squibb Co., No. 4:16-CV-00108-DMB-JMV, 2017 WL 706320, at *n.10 (N.D. Miss. Feb. 22, 2017), and that, at most, the statements criticized by Plaintiff are "puffery", which is not actionable. Presidio Enterprises, Inc. v. Warner Bros. Distrib. Corp., 784 F.2d 674, 682 (5th Cir. 1986).

Plaintiff has introduced the expert opinion of Joshua S. Sharlin, Ph.D. [ECF No. 136-12], who concludes that the ORBERA® brochure and the 2016 ORBERA® website were not reviewed or approved by the FDA and opines that express warranties for the device were breached. Id. at 3, 17-20. Apollo vigorously disputes Dr.

Sharlin's conclusions. [ECF No. 127] at 7-8, 14. This dispute creates a triable issue of material fact. Apollo's "puffery" defense [ECF No 142], is also a jury issue. In re TETRA Techs., Inc. Sec. Litig., No. 4:08-CV-0965, 2009 WL 6325540, at *4 (S.D. Tex. July 9, 2009), order clarified, No. CIV.A. 4:08-CV-0965, 2009 WL 6326865 (S.D. Tex. Aug. 10, 2009) (jury determined that statements were material and not, as the defendant alleged, immaterial puffery); see also Pizza Hut, Inc. v. Papa John's Int'l, Inc., 227 F.3d 489, 499–501 (5th Cir. 2000). Because issues of material fact remain, summary judgment is not appropriate.

Conclusion

Accordingly,

IT IS HEREBY ORDERED that Apollo's Motion for Summary Judgment is DENIED.

SO ORDERED this the 9th day of December 2020.

/s/ David Bramlette
UNITED STATES DISTRICT JUDGE