IN THE UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF GEORGIA
AUGUSTA DIVISION

OTIS MOORE and DOROTHY R. MOORE,	*	
Plaintiffs,	*	
v.	*	
	*	1:14-cv-62
WRIGHT MEDICAL TECHNOLOGY, INC.,	*	
Defendant.	*	

O R D E R

Plaintiffs Otis and Dorothy Moore filed this case against Defendant Wright Medical Technology, Inc. seeking damages arising out of the failure of the PROFEMUR® titanium modular long neck component of Otis Moore's hip implant, which Defendant designed and manufactured. Plaintiffs' Complaint advanced numerous legal claims against Defendant, and Defendant now seeks summary judgment in its favor on the following claims and theories:

- Product Liability based on Design Defect;
- Product Liability based on Manufacturing Defect;
- Product Liability based on Failure to Warn;
- Negligence *Per Se*;
- Loss of Consortium; and
- Punitive Damages

(Def.'s Mot. Summ. J., Doc. 49.)[1] The Court **GRANTS IN PART** and **DENIES IN PART** Defendant's motion.

I. BACKGROUND

Wright Medical Technology, Inc. is the manufacturer of the PROFEMUR® Hip System, which includes as a component part the PROFEMUR® titanium modular long neck. The PROFEMUR® neck is a line of modular necks, which has a modular connection where the neck connects to the stem component. The PROFEMUR® model was introduced in 2002 for the U.S. market. Defendant, however, had produced modular neck components in Europe since 1985. A 2003 clinical follow-up sheet advertising the PROFEMUR® modular neck referred to the 50,000 modular necks implanted between 1985 and 2002 and claimed that "[n]one of the necks has experienced a clinical failure since their inception." (Pls.' Opp. Br., Doc. 95, Ex. 10 at 8-9.) However, a dozen neck fractures were reported pre-2002. Later, with respect to the 2002 PROFEMUR® modular neck model, Defendant received notice of neck fractures in April and May 2005. Later still, Defendant received information concerning significant numbers of fractures, which Defendant warned surgeons about in subsequent letters.

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[1] Plaintiffs' Complaint also alleges a negligence claim that is distinct from their negligence *per se* claim. Defendant has not moved for summary judgment on the negligence claim. Additionally, Defendant filed three Daubert motions to exclude Plaintiffs' experts' testimony, which the Court addresses in a separate order.

The 2002 PROFEMUR® Hip System includes Instructions For Use ("IFU") that detail some of the considerations and risks associated with the hip implant. The IFU included the following "factors," among others, that "can be critical to the eventual success of the procedure":

> **Patient's Weight.** An overweight or obese patient can produce high loads on the prosthesis which can lead to failure of the prosthesis
>
> **Patient's occupation or activity.** If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.

(Pls.' Opp. Br., Doc. 95, Ex. 1 at 1-2.) The IFU also includes "absolute contraindications," which specifically mention "obesity where obesity is defined as three times normal body weight." (Id. at 2-3.)

In September 2005, Plaintiff Otis Moore met with Dr. R. Scott Corpe, an orthopedic surgeon and Associate Professor at the Medical College of Georgia, regarding hip pain. Since his residency in 1981, Dr. Corpe has been experienced with modularity hip replacement systems. He understood that hip replacement systems and their component parts include the risk of failures, material interactions, and corrosion and fretting at each modular junction. Dr. Corpe also authored surgical

guides for Defendant, including one for the PROFEMUR® hip stem that he implanted in Otis Moore. In 2005, however, Dr. Corpe had no information that Defendant's PROFEMUR® hip system had a greater risk of mechanical failure by fracture of its component parts than other hip systems, or that it was not appropriate for heavier patients or those who wanted to engage in high levels of activity.

During the course of his consultation with Otis Moore, Dr. Corpe determined that Moore suffered from end-stage degenerative joint disease in his right hip. Moore indicated that the pain was so great that he wanted his hip replaced and further informed Dr. Corpe that he caddied for professional golfers and that a full golf bag can weigh as much as sixty pounds. Dr. Corpe cautioned Moore that the bag's additional weight and the amount of walking associated with his job could adversely affect the success of his a hip replacement. Nevertheless, Dr. Corpe agreed to perform the surgery.

In his initial consultation, Dr. Corpe described Moore as "muscular in his build" and "not obese." (Doc. 49 at 31.) A week before the operation, Moore weighed 230.8 lbs. and was 72.01 inches tall. Moore did not qualify as obese under Defendant's IFU, which defined obesity as three times normal body weight.

On November 15, 2005, Dr. Corpe performed a right hip total arthroplasty, implanting the PROFEMUR® total hip system,

including the relevant titanium modular long neck. Over six years later, on March 13, 2012, Otis Moore's artificial hip failed, causing severe pain. Moore sought a consultation with Dr. Corpe who determined that the modular neck had fractured. Dr. Corpe performed a revision surgery to remove the fractured neck component.

At the time of Moore's initial implant surgery on November 15, 2005, only two of Defendant's 2002 PROFEMUR® modular necks had fractured. Dr. Corpe was unaware of these fractures when he agreed to implant the modular neck in Otis Moore and, more generally, was unaware of the fractures that occurred in Defendant's other modular neck models between 1985 and 2002. In late 2008, after he did learn of fractures in PROFEMUR® modular necks, Dr. Corpe switched to using models with smaller heads and non-metal bearings before discontinuing using the PROFEMUR® modular neck entirely around 2010.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate only if "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). Facts are "material" if they could affect the outcome of the suit under the governing substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The Court must view the facts in the light most favorable to the non-moving

party, Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986), and must draw "all justifiable inferences in [its] favor." U.S. v. Four Parcels of Real Prop., 941 F.2d 1428, 1437 (11th Cir. 1991) (en banc) (internal punctuation and citations omitted).

The moving party has the initial burden of showing the Court, by reference to materials on file, the basis for the motion. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). How to carry this burden depends on who bears the burden of proof at trial. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993). When the non-movant has the burden of proof at trial, the movant may carry the initial burden in one of two ways: by negating an essential element of the non-movant's case or by showing that there is no evidence to prove a fact necessary to the non-movant's case. See Clark v. Coats & Clark, Inc., 929 F.2d 604, 606-08 (11th Cir. 1991) (explaining Adickes v. S.H. Kress & Co., 398 U.S. 144 (1970) and Celotex, 477 U.S. 317). Before the Court can evaluate the non-movant's response in opposition, it must first consider whether the movant has met its initial burden of showing that there are no genuine issues of material fact and that it is entitled to judgment as a matter of law. Jones v. City of Columbus, 120 F.3d 248, 254 (11th Cir. 1997) (per curiam). A mere conclusory statement that the non-movant cannot meet the burden at trial is insufficient. Clark, 929 F.2d at 608.

If—and only if—the movant carries its initial burden, the non-movant may avoid summary judgment only by "demonstrat[ing] that there is indeed a material issue of fact that precludes summary judgment." Id. When the non-movant bears the burden of proof at trial, the non-movant must tailor its response to the method by which the movant carried its initial burden. If the movant presents evidence affirmatively negating a material fact, the non-movant "must respond with evidence sufficient to withstand a directed verdict motion at trial on the material fact sought to be negated." Fitzpatrick, 2 F.3d at 1116. If the movant shows an absence of evidence on a material fact, the non-movant must either show that the record contains evidence that was "overlooked or ignored" by the movant or "come forward with additional evidence sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency." Id. at 1117. The non-movant cannot carry its burden by relying on the pleadings or by repeating conclusory allegations contained in the complaint. See Morris v. Ross, 663 F.2d 1032, 1033-34 (11th Cir. 1981). Rather, the non-movant must respond with affidavits or as otherwise provided by Federal Rule of Civil Procedure 56.

In this action, the Clerk of the Court gave Plaintiffs notice of Defendant's motion for summary judgment and informed them of the summary judgment rules, the right to file affidavits or other materials in opposition, and the consequences of

default. (Doc. 52.) The notice requirements of Griffith v. Wainwright, 772 F.2d 822, 825 (11th Cir. 1985) (per curiam), therefore, are satisfied and the motion is ripe for review.

III. ANALYSIS

Plaintiff Otis Moore asserts the followings three causes of action: (1) strict product liability; (2) negligence; (3) negligence *per se*. (Compl., Doc. 1 at 39-43.) In more detail, Otis Moore alleges three different theories of product liability: design defect, manufacturing defect, and failure to warn. (Id. at 39-41.) Further still, the Complaint includes a damages section that requests Plaintiff Dorothy Moore's loss of consortium damages and punitive damages against Defendant. (Id. at 44.) Defendant's motion breaks Plaintiffs' requests into individual claims for relief and requests summary judgment on each.

A. Design Defect

Defendant seeks summary judgment on Otis Moore's design defect theory on the grounds that, "should the Court grant [Defendant's] Daubert motions regarding Plaintiffs' experts, then summary judgment is also warranted as to all claims." (Def.'s Mot. Summ. J. at 5). The Court agrees with Defendant that proving a design defect in this case requires the use of expert testimony. See Meade v. Ford Motor Co., No. 1:09-cv-1833-TWT, 2011 WL 4402539, at *2 (N.D. Ga. 2011) ("Because the

alleged design defect . . . is not one that can be understood by the reasonable juror, expert testimony is required." (internal quotations omitted)). Having denied the bulk of Defendant's Daubert motions, the Court finds that, in the light most favorable to Plaintiffs, the expert evidence supports Otis Moore's design defect theory of product liability. The Court, therefore, **DENIES** Defendant's motion with respect to the design defect theory.

B. Manufacturing Defect

Defendant's motion for summary judgment seeks the dismissal of Otis Moore's manufacturing defect theory of liability. (Def.'s Mot. Summ. J. at 12.) Under Georgia law,

> [t]o establish defendant's strict liability, plaintiffs must prove that defendant is the manufacturer of the property, that the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended (i.e., defective), and that its condition when sold was the proximate cause of the injury sustained.

Chicago Hardware & Fixture Co. v. Letterman, 510 S.E.2d 875, 877-78 (Ga. Ct. App. 1999) (footnote omitted).

In their response brief, Plaintiffs admit that Defendant's "manufacturing records indicate that at the time of manufacture the subject device conformed to [Defendant's] dimensional and surface-finish specifications." (Pls.' Opp. Br., Doc. 95 at 15.) Nevertheless, Plaintiffs assert that the manufacturing defect claim should proceed because Dr. Corpe supposedly

testified that the device's failure was caused by either a design or a manufacturing defect. In reply, Defendant argues that Dr. Corpe's testimony is insufficient to create a material factual dispute. (Doc. 85 at 3 (citing Anderson, 577 U.S. at 252 ("[t]he mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient" to avoid summary judgment))).

The Court agrees with Defendant. Plaintiffs' reliance on Dr. Corpe's off-hand remark about the possibility of manufacturing defects in Defendant's products cannot sustain Otis Moore's manufacturing defect theory of liability because no reasonable juror could conclude based solely on that testimony that Moore's hip implant was defectively manufactured.[2] Simply put, Dr. Corpe's testimony is not "evidence sufficient to

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[2] A review of the testimony in question makes clear that Dr. Corpe is speaking about the possibility of manufacturing defects in hip implants generally and not with respect to Otis Moore's implant. The full exchange in deposition was as follows:

> Q: With respect to implant challenges, "whether Total Joint Arthroplasty implants can be realistically guaranteed for five years, guaranteed for five years, let alone 20 years, is also questionable. Catastrophic implant failures can mechanically occur in the absence of a design or manufacturing flaw.
>
> A: I would have to say that I agree with everything in that until the last statement, because I don't understand that last statement.
>
> Q: Okay.
>
> A: There has to be some reason that it failed, but to say that it's not a design or a manufacturing flaw, how else does it fail then?

withstand a directed verdict motion at trial on the material fact sought to be negated." Fitzpatrick, 2 F.3d at 1116. The Court, therefore, **GRANTS** summary judgment with respect to Otis Moore's manufacturing defect theory.

C. Failure to Warn

Under Georgia law, to prove a product-liability claim based on a failure-to-warn theory, a plaintiff "must show the defendant had a duty to warn, the defendant breached that duty and the breach was the proximate cause of the plaintiff's injury." Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1362-62 (N.D. Ga. 1999) (citations omitted). A duty to warn arises "when the manufacturer knows or reasonably should know of a danger arising from product use." Id. Breach may be proved in two ways: by failing to adequately communicate the warning to the ultimate user or by failing to provide an adequate warning of the product's potential risks. Watkins v. Ford, 190 F.3d 1213, 1219, (11th Cir. 1999). "Under the learned intermediary doctrine, [Defendant] was not required to directly warn [Moore] of the risks of the [PROFEMUR® titanium modular long neck] because Dr. Corpe was a learned intermediary between the manufacturer and ultimate consumer; [Defendant] could have adequately communicated the warning by only warning Dr. Corpe." Mims v. Wright Med. Tech., Inc., No. 1:11-cv-213-TWT, 2012 WL 1681810, at *4 (N.D. Ga. 2012).

Defendant seeks summary judgment on this claim for two reasons. First, Defendant contends that its warnings were adequate as a matter of law because Defendant warned of the risk of weight and activity, and Dr. Corpe knew of the relevant risks, namely that PROFEMUR® modular necks, like any hip implant, could fail and that weight and activity, in particular, is a cause of failure. Second, Defendant argues that Plaintiffs cannot prove causation because Dr. Corpe continued to implant PROFEMUR® necks after he learned of fractures.

Plaintiffs' failure-to-warn theory rests on an allegation that the information given to Dr. Corpe was inadequate to warn him that PROFEMUR® titanium modular long necks should not be used in someone weighing 230.8 lbs. To begin, Defendant's own IFU supports Plaintiffs' claim. In particular, Defendant's IFU's only contraindication regarding weight included a definition of "obesity" as three times normal body weight. (Pls.' Opp. Br., Ex. 1 at 2-3.) Consistent with that definition, Dr. Corpe testified that, though he knew weight can affect the success or failure of a hip implant, Otis Moore's weight did not meet the contraindication contained in the IFU and that he was the "appropriate patient population" for the modular neck. (Corpe Depo., Doc. 67 at 102-05.) And Dr. Corpe's initial evaluation of Moore indicated he was "muscular in build" and "not obese." (Outpatient Note, Def.'s Mot. Summ. J., Ex. 4 at 49.) Elsewhere, the IFU mentions that a patient's

weight "can lead to failure of the prosthesis," but describes this as a "major consideration when the patient is small boned and small sized prosthesis must be used." (Hip System IFU, Pls.' Opp. Br., Ex. 1 at 1.) Dr. Corpe further testified that Defendant never warned that "heavier weight" or "high levels of activities" produced an increased risk of failure in a patient or that a modular neck possessed an increased risk compared to fixed necks. (Corpe Depo. at 102-05.)

The inadequacy of Defendant's warning is also supported by Plaintiffs' expert reports. Dr. Sonny Bal, Plaintiffs' orthopedic surgeon expert, gave the opinion that if Defendant "had any notice of prior failures by factures of any model of these modular necks . . . an orthopedic surgeon would reasonably expect" that Defendant would correct the problem or give a clear warning if a correction was not possible. (Bal Report, Doc. 51 at 25.) And the expert report of Mari S. Truman, Plaintiffs' engineering expert, states, among other opinions, that "[t]he warning pages supplied by [Defendant] for this device (in 2003) were insufficient concerning weight and/or activity restrictions to prevent implant overload, failure and patient injury." (Truman Report, Doc. 91, Ex. 2 at 66.) In short, Plaintiffs' evidence, including the IFU, Dr. Corpe's evaluation and testimony, and Plaintiffs' experts, raises a factual dispute over whether Defendant adequately warned Dr. Corpe.

With respect to causation, Defendant argues that there is no evidence that an additional warning would have changed Dr. Corpe's conduct. Defendant notes that Plaintiffs "obtained no testimony that Dr. Corpe would have acted differently with different warnings." (Def.'s Mot. Summ. J. at 11.) Moreover, argues Defendant, Dr. Corpe continued to implant PROFEMUR® modular necks until 2010, after he learned that his own patients suffered fractures. (Id.) In Defendant's view, Dr. Corpe's conduct after learning of fractures demonstrates that he would have implanted the PROFEMUR® titanium modular long neck in Moore even with an adequate warning.

Defendant's selective reading of Dr. Corpe's testimony does not provide a full picture of his response to learning of fractures in PROFEMUR® modular necks. Read in the light most favorable to Plaintiffs, and with all inferences drawn in their favor, Dr. Corpe testified that once he learned about PROFEMUR® neck failures he discontinued his use of the titanium modular long necks and then all of Defendant's modular necks. Defense counsel asked Dr. Corpe whether, even after learning of some fractures, he continued to use PROFEMUR® modular necks until 2010, and Dr. Corpe confirmed that was the case. But, crucially, Dr. Corpe clarified that he stopped using the models with "large heads against metal bearings," and he had not experienced any fractured necks "that were not articulated against a metal liner . . . or a short neck," though he admitted

the decision to stop was not made immediately after the first fracture in his patients. (Doc. 67, Ex. 1 at 69.) The Court is not aware of any legal authority that requires Dr. Corpe to immediately stop implanting all PROFEMUR® modular neck models for Plaintiffs to prove causation. His testimony was that once he learned of fractures he stopped using models "with large heads against metal bearings," the model implanted in Otis Moore. Even if Dr. Corpe's cessation of PROFEMUR® modular neck implants was not immediate, a jury could draw the inference that because he stopped implanting the long beck model once he was adequately apprised of the device's risks, he therefore would not have implanted the device in Moore. Because Plaintiffs' evidence raises a disputed material fact regarding adequacy of Defendant's warnings and causation, the Court **DENIES** Defendant's motion for summary judgment on Otis Moore's failure-to-warn theory.

D. Negligence *Per Se* Claim

Defendant's motion also seeks summary judgment in its favor with respect to Otis Moore's negligence *per se* claim. (Def.'s Mot. Summ. J. at 12-13.) In response, Otis Moore has chosen to abandon that claim. (Doc. 95 at 16.) The Court therefore **GRANTS** summary judgment on Moore's negligence *per se* claim in favor of Defendant.

E. Dorothy Moore's Loss-of-Consortium Claim

Because the Court has not dismissed all of Plaintiff Otis Moore's claims, Plaintiff Dorothy Moore may maintain her derivative loss-of-consortium claim. See Pattee v. Georgia Ports Authority, 477 F. Supp. 2d 1272, 1276-77 (S.D. Ga. 2007) (discussing derivative nature of the loss-of-consortium claim). Thus, the Court **DENIES** Defendant's motion for summary judgment on Dorothy Moore's loss-of-consortium claim.

F. Punitive Damages Claim

Under Georgia law, Plaintiffs may recover punitive damages where "defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A. § 51-12-5.1(b). Plaintiffs are required to prove this conduct by clear and convincing evidence. Id. Further, in a product-liability case, "punitive damages are typically not appropriate where the manufacturer has complied with regulatory standards." Mims, No. 1:11-cv-213-TWT, 2012 WL 1681810, at *5 (N.D. Ga. 2012) (citing Stone Man, Inc. v. Green, 435 S.E.2d 205, 206 (Ga. 1993); Welch v. General Motors Corp., 949 F.Supp. 843 (N.D. Ga. 1996)). But, if Plaintiffs present "other evidence showing culpable behavior," then "nothing in Stone Man precludes an award of punitive damages." General Motors Corp. v. Moseley, 447 S.E.2d 302, 311 (Ga. Ct. App. 1994)

abrogated on other grounds by Webster v. Boyett, 496 S.E.2d 459 (Ga. 1998). Defendant argues that Plaintiff has no evidence that Defendant acted with the required mental state of "willful misconduct, malice, fraud, wantonness, oppression" to harm Plaintiff, and, further, that the FDA cleared the sale of the PROFEMUR® modular neck.

As an initial matter, Plaintiffs argue that the Court should defer ruling on the punitive damages claim at summary judgment because whether punitive damages can be proven is a question "best left for the Court to make when it hears and sees all of the evidence that will be submitted in this case at trial." (Pls.' Opp. Br. at 17.) But, under Georgia law, punitive damages claims may be decided at summary judgment "when a plaintiff fails to establish a question of fact that a defendant's conduct was either willful or consciously indifferent to the consequences . . . ." Duling v. Domino's Pizza, LLC, No. 1:13-CV-01570-LMM, 2015 WL 3407602, at *5 (N.D. Ga. Jan. 14, 2015)(citing Taylor v. Powertel, Inc., 551 S.E.2d 765, 769 (Ga. Ct. App. 2001).

Without citing any legal authority, Plaintiffs respond by generally referencing the "evidence of [Defendant's] misconduct." (Doc. 95 at 16.) At bottom, Plaintiffs' allegation is that Defendant published materials in which it claimed to have never experienced modular neck fractures since 1985, even though Defendant knew those statements were false.

As discussed above, in the light most favorable to Plaintiffs, the evidence supports a viable failure-to-warn theory. However, Plaintiffs have failed to point to any evidence that Defendant did so with "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A. § 51-12-5.1(b). Additionally, the FDA cleared Defendant's product for sale. See Mims, 2012 WL 1681810, at *5 (dismissing plaintiffs' punitive damages claim on similar evidence as presented in this case).

Given Defendant's compliance with federal regulations and Plaintiffs' failure to point to evidence of willful and wanton misconduct, the Court **GRANTS** Defendant's motion for summary judgment on Plaintiffs' punitive damages claim.

IV. CONCLUSION

As discussed, the Court **GRANTS IN PART** and **DENIES IN PART** Defendant's motion for summary judgment. Plaintiffs design defect, failure-to-warn, negligence, and loss-of-consortium claims shall proceed to trial.

ORDER ENTERED at Augusta, Georgia, this 31ST day of March, 2016.

HONORABLE J. RANDAL HALL
UNITED STATES DISTRICT JUDGE
SOUTHERN DISTRICT OF GEORGIA