IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. 2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE THIS DOCUMENT RELATES TO THE FOLLOWING BHR TRACK ACTIONS: ***Albritton v. Smith & Nephew, Inc.*, No. 1:17-cv-03677**

MEMORANDUM

Pending before the court is Smith & Nephew's motion for summary judgment in *William Albritton v. Smith & Nephew, Inc.*, No. 1:17-cv-03677. The motion has been fully briefed, and oral argument was heard on June 30, 2021. For the reasons that follow, the motion will be granted.

BACKGROUND

This case concerns alleged injuries suffered by plaintiff William Albritton as a result of his use of the Birmingham Hip Resurfacing Device ("BHR"), an artificial hip implant developed, designed, manufactured, and sold by defendant Smith & Nephew. As explained in the court's ruling on the motion to dismiss, the BHR replaces the hip joint with metal components—capping the femoral head with a metal covering and inserting a metal cup within the acetabular cup—to recreate the same ball and socket structure that occurs naturally. *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig. ("In re BHR")*, 300 F. Supp. 3d 732, 736 (D. Md. 2018). The friction between the metal components allegedly can cause metal debris to accumulate within the joint and blood stream of the patient. Metal debris from the device can then cause pain, metallosis, and other serious complications that may require corrective

surgery or revision to a different device. *Id.* In 2015, Smith & Nephew voluntarily recalled some BHR devices due to unreasonably high rates of failure in women and in men needing femoral head sizes 46 mm or smaller, including for complications due to metal debris. (ECF 2427, Ex. 2). Though Mr. Albritton is not one such patient, his BHR implant did require revision to a different implant. Mr. Albritton's theory of the case is that Smith & Nephew marketed the BHR as an excellent option for patients who, like him, had avascular necrosis ("AVN") by touting clinical results from hip implant surgeries which showed excellent success rates for the BHR in patients overall, with the knowledge that the device was contraindicated for some patients with AVN and the success rate of the device for patients with AVN was significantly lower than that for patients overall. He contends that by failing to incorporate this knowledge into its BHR marketing efforts and instead highlighting overall BHR revision rates, Smith & Nephew misleadingly represented to surgeons and to patients that the risk of revision for a patient like Mr. Albritton was lower than it actually was. Had Mr. Albritton not been so misled, he would not have agreed to the BHR implant.

I. Mr. Albritton's BHR and Revision Surgeries

Mr. Albritton is a 59-year old man who lives in Lithia, Florida. (ECF 2830-3, Albritton Dep. at 21). In 2008, Mr. Albritton began to experience significant pain in his right hip; he asked his doctor to refer him to an orthopedic surgeon, and he began to see Dr. Stephen Raterman regarding the pain in September 2008. (*Id.* at 70). Dr. Raterman ordered an MRI, which revealed that Mr. Albritton had AVN in the femoral heads of both his hips, and that the condition was "more pronounced" on the right hip. (ECF 2830-4, Raterman Dep. at 59). AVN is a condition where "the blood supply to the femoral head is interrupted and the underlying bone begins to weaken secondary to the lack of blood supply." (*Id.*). Dr. Raterman testified that he then gave Mr. Albritton

information on his surgical options, including hip resurfacing. (*Id.* at 61–62). Initially, Mr. Albritton wanted to avoid surgery because of his young age; accordingly, Dr. Raterman recommended changing Mr. Albritton's medication for the pain and told his patient to monitor the pain. (*Id.* at 61). The pain worsened, to the point that Mr. Albritton was missing work because of it. (ECF 2830-3, Albritton Dep. at 74–75). When his symptoms worsened, Mr. Albritton decided to consider surgery. (ECF 2760-4, Raterman Dep. at 63). In discussing Mr. Albritton's surgical options, Dr. Raterman testified that he "always was very cautious with AVN about guaranteeing anybody that I could ever do a resurfacing in the face of AVN" due to the high risk of fracture and high failure rate if there was not enough bone to support the implant. (*Id.* at 63–64).

Mr. Albritton relied on Dr. Raterman in deciding to have surgery and in selecting the device that would be used. (ECF 2830-3, Albritton Dep. at 79, 82, 147). Mr. Albritton did not know he was going to receive the BHR until Dr. Raterman told him what product he would be using. (*Id.* at 82). Mr. Albritton has testified that Dr. Raterman told him the BHR would last the rest of his life. (ECF 2830-3, Albritton Dep. at 81).[1] Mr. Albritton recalls being told that the BHR would last longer than other products because it was a metal-on-metal device and that resurfacing had the advantage of being less invasive. (*Id.* at 148). Mr. Albritton recalls being given a "booklet" of information regarding the BHR after Dr. Raterman recommended the product. (ECF 2830-3, Albritton Dep. at 147; ECF 2830-4, Raterman Dep. at 28). Mr. Albritton believes that this booklet was a document entitled "A Patient's Guide to the Birmingham Hip Resurfacing System." (ECF 2830-1, Albritton Aff. ¶¶ 7–8).

[1] Dr. Raterman disputes this, stating that he did not make any promises or guarantees to Mr. Albritton about how long his BHR would last. (ECF 2760-4 at 100–01, 105–06).

The Patient Guide includes AVN as one of "four primary diseases of the hip that may indicate the need for" the BHR, and advertises that a patient with AVN who, like Mr. Albritton, is active, under 60 years of age, and suffering from AVN is a "typical" BHR patient. (ECF 2830-1, Ex. A to Albritton Aff., "Patient's Guide" at 5, 22). The guide also touts an overall survivorship rate for the BHR of 98.4 percent over five years. (*Id.* at 22). The guide does not, however, discuss that the survivorship rates of the device are significantly lower for patients with AVN nor does it make clear that the BHR was contraindicated for some AVN patients. For example, the FDA-approved Instructions for Use ("IFU") for the BHR around the time of Mr. Albritton's surgery indicated that the BHR should not be used in "patients with . . . AVN with > 50% involvement of the femoral head[.]" (ECF 2830-2, FDA Label at 4). The IFU also discloses that the survivorship rate is 92.1 percent for patients with AVN over five years, compared with 98.4 percent for all patients over the same time period. (*Id.* at 15).

Mr. Albritton "looked over" the Patient Guide. (ECF 2830-3, Albritton Dep. at 167). He does not recall whether the guide had any information on how long the implant would be expected to last or whether it included any warnings. (*Id.*). Regardless, Mr. Albritton has said that he did not rely on any advertising in deciding whether to use the BHR. (*Id.* at 132–33). It is not clear from the record whether Dr. Raterman specifically discussed with Mr. Albritton that the BHR had a higher rate of revision for patients with AVN, though it appears that Dr. Raterman did discuss non-resurfacing surgical options with Mr. Albritton because of the possibility that his AVN was too extensive for the BHR implant. (ECF 2760-4, Raterman Dep. at 63–64). Mr. Albritton had a size 52 mm BHR implanted on April 6, 2009. (ECF 2760-4, Raterman Dep. at 68; ECF 2760-5, Shapiro (Albritton) Dep. at 210–11). Dr. Raterman's notes from the procedure document that he believed

there was enough bone left that he could move forward with the resurfacing. (ECF 2760-4, Raterman Dep. at 69).

In 2015, Mr. Albritton visited a different doctor, Dr. Phuc Vo, because he was experiencing hip pain. (ECF 2760-9, Vo Dep. at 42). Mr. Albritton had a revision surgery of the BHR on October 21, 2015. (*Id.* at 57). During the surgery, Dr. Vo "found that the femoral neck [had] a fracture" and loosening. (*Id.*). Dr. Vo did not see any indication of metallosis. (*Id.* at 58). Dr. Vo does not believe the fracture was caused by ongoing AVN. (*Id.* at 60). Mr. Albritton's medical causation expert, Dr. Shapiro, has opined that the loosening and femoral neck fracture was a sign of metal injury from the BHR's metal-on-metal components. (ECF 2760-13, Shapiro (Albritton) Rep. at 11–12).

II. Dr. Raterman's Understanding of the Risks of the BHR to Mr. Albritton

Dr. Raterman began performing the BHR surgery in 2006; he was among the first group of surgeons to use the device in the United States. (ECF 2760-4, Raterman Dep. at 20, 107). In 2005, he participated in a training in England to learn the BHR procedure. (*Id.* at 47). Because he was one of the "original" BHR surgeons in the United States, he often got questions from colleagues about the device, including questions concerning the IFU and the surgical technique booklet. (*Id.* at 100). Thus, he referred to those materials "constantly" and was familiar with them. (*Id.*). Otherwise, Dr. Raterman has said he gained knowledge regarding medical devices from journals, his own experience, the experiences of colleagues, podium discussions and meetings, registry data, and other papers. (ECF 2760-4, Raterman Dep. at 99–100, 123).

Dr. Raterman was aware before Mr. Albritton's surgery that patients with AVN were at an increased risk for needing a revision surgery of the BHR. (ECF 2760-4, Raterman Dep. at 112–13). Nonetheless, Dr. Raterman thought Mr. Albritton was an appropriate candidate for the BHR

because, in his opinion, there was not a better device at the time, "the actual amount of necrosis may be less than anticipated," and "after discussion of the pros and cons, [Mr. Albritton] preferred the resurfacing to the replacement." (*Id.* at 113). Out of caution, Dr. Raterman "asked specifically for a total hip standby" for Mr. Albritton's surgery in case the AVN was too advanced for the BHR. (*Id.*). Dr. Raterman does not believe that Smith & Nephew's sales representatives ever misrepresented the risks or results of the BHR to him. (*Id.* at 121–22).

PROCEDURAL HISTORY

On December 12, 2017, Mr. Albritton filed a complaint including eight counts against Smith & Nephew under Florida law: strict products liability (Count I), strict products liability for failure to warn (Count III), negligent failure to warn (Count IV), negligent misrepresentation (Count V), negligence *per se* (Count VI), breach of express warranties (Count VII), manufacturing defect (Count VIII), and punitive damages (Count IX). (ECF 485, Albritton Short Form Compl.). Smith & Nephew moved to dismiss all of the plaintiffs' claims in the BHR track, arguing they were either preempted or insufficiently pleaded. The court dismissed all strict products liability and strict products liability for failure to warn claims (Counts I and III) as expressly preempted and the manufacturing defect claim (Count VIII) for failure to state a claim. *In re BHR*, 300 F. Supp. 3d at 743, 746, 750. Following substantial fact and expert discovery, the Smith & Nephew filed this motion for summary judgment on May 25, 2021. (ECF 2760). The motions have been fully briefed (ECFs 2830, 2843) and oral argument was heard on June 30, 2021.

LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) provides that summary judgment should be granted "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) (emphases added). "A dispute is

genuine if 'a reasonable jury could return a verdict for the nonmoving party.'" *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012)). "A fact is material if it 'might affect the outcome of the suit under the governing law.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Accordingly, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment[.]" *Anderson*, 477 U.S. at 247–48. The court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (per curiam), and draw all reasonable inferences in that party's favor, *Scott v. Harris*, 550 U.S. 372, 378 (2007) (citations omitted); *see also Jacobs v. N.C. Admin. Office of the Courts*, 780 F.3d 562, 568–69 (4th Cir. 2015). At the same time, the court must "prevent factually unsupported claims and defenses from proceeding to trial." *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 526 (4th Cir. 2003) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993)).

DISCUSSION

Smith & Nephew reasserts some of its preemption defenses and argues that Mr. Albritton's claims, including claims for punitive damages, also fail either because Florida law does not recognize the legal theories under which he proceeds or because there is insufficient evidence to support one or more elements of each claim. The court will address in turn each remaining claim—negligent failure to warn, negligent misrepresentation, breach of express warranties, negligence *per se*, and negligent training—and will address any remaining preemption arguments in the context of each claim. The court will then address punitive damages. The court will conclude that Mr. Albritton's negligent failure to warn claim fails because he cannot satisfy the element of causation, and that his negligent training and negligence *per se* claims are preempted. The court

will further conclude that Smith & Nephew is entitled to summary judgment as to Mr. Albritton's negligent misrepresentation and breach of warranty claims because there is insufficient evidence in the record to create a genuine issue of material fact regarding whether Mr. Albritton relied on any misrepresentations or express warranties by Smith & Nephew.

I. Negligent Failure to Warn

Smith & Nephew contends that it should be granted summary judgment on the plaintiffs' negligent failure to warn claim because (1) the claim is preempted, as Florida law does not support a claim of failure to warn the FDA, and (2) Mr. Albritton cannot show that any failure to warn the FDA caused his injuries. As the court has explained previously, a negligent failure to warn claim based on a failure to warn the FDA may not be preempted to the extent that a state law duty to warn a third party may parallel federal requirements to report certain information to the FDA. (*See* ECF 2715, *Redick* Mem. at 15–16.). But it is unnecessary to determine whether Florida law recognizes such a duty, because Mr. Albritton cannot satisfy the difficult element of causation.

In order to prevail on a non-preempted failure to warn claim, Mr. Albritton must show that if Smith & Nephew had properly reported certain information to the FDA "as required under federal law, that information would have reached her doctors in time to prevent her injuries." *In re Smith & Nephew Birgmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.* ("*Daubert* Ruling"), MDL No. 2775, 2021 WL 781682, at *8 n.3 (D. Md. Mar. 1, 2021) (citing *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096–97 (N.D. Cal. 2016)); *see also Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 776 (5th Cir. 2011). As the plaintiffs appropriately have disavowed any arguments concerning discretionary actions the FDA may or may not have taken had it received certain ad hoc data and reports, *Daubert* Ruling, at *13, Mr. Albritton's theory of causation is limited to showing that information or data Smith & Nephew was required to provide to the FDA

would necessarily have been made public such that the higher revision rates would have been incorporated into materials Dr. Raterman read prior to Mr. Albritton's surgery. *See Hughes*, 631 F.3d at 776 n.12 (noting that the plaintiff's alternative theory of causation based on regulatory action the FDA might have taken was "entirely speculative" and thus failed as a matter of law). Mr. Albritton has identified no information that he claims Smith & Nephew should have disclosed to the FDA that, if publicized, would have reached Dr. Raterman in time to alter his decision to have the BHR implanted. Accordingly, because there is no genuine dispute of material fact as to whether any failure to inform the FDA of ad hoc data or other information caused Mr. Albritton's injuries, the court will award summary judgment to Smith & Nephew on the plaintiffs' failure to warn claim.

II. Negligent Misrepresentation

Under Florida law, to establish a claim for negligent misrepresentation, a plaintiff must show "(1) a misrepresentation of a material fact; (2) the representor made the representation without knowledge as to its truth or falsity, or under circumstances in which he ought to have known of its falsity; (3) the representor intended that the misrepresentation induce another to act on it; (4) injury must result to the party acting in justifiable reliance on the misrepresentation." *Souran v. Travelers Ins. Co.*, 982 F.2d 1497, 1503 (11th Cir. 1993) (cleaned up) (citing *Hoon v. Pate Constr. Co., Inc.*, 607 So.2d 423, 427 (Fla. Dist. Ct. App. 1992)). "A representation made with an honest belief in its truth may still be negligent, because of lack of reasonable care in ascertaining the facts, or in the manner of expression, or absence of the skill and competence required by a particular business or profession." *Id.* (quoting W. Page Keeton et al., Prosser and Keeton on The Law of Torts § 107, at 745 (5th ed. 1984)).

Smith & Nephew argues that summary judgment is warranted as to this claim because there is no evidence in the record that Smith & Nephew made any misrepresentation on which Mr. Albritton relied or which caused him injury. Smith & Nephew advances three points in support of this argument. First, Smith & Nephew argues that Mr. Albritton's claim must fail because his experts, namely Dr. Jeffrey Shapiro and Dr. Yadin David, testified that they did not believe Smith & Nephew made any misrepresentations with respect to the BHR for patients with head sizes 50 mm and larger. Second, it argues there is no evidence Mr. Albritton relied on any statement by Smith & Nephew that the company made directly to him in marketing materials. Third, Smith & Nephew contends there is no evidence it made any misrepresentations to Dr. Raterman regarding the risk of revision for patients with AVN on which Mr. Albritton could have relied. The court addresses each argument in turn.

First, Smith & Nephew correctly points out that Mr. Albritton's experts Dr. Shapiro and Dr. David have testified that they do not believe Smith & Nephew made any misrepresentations regarding the risk of revision for larger head sizes, including the 52 mm size Mr. Albritton received. (*See* ECF 2760-5, Shapiro (Albritton) Dep. at 211–12); ECF 2760-15, David Dep. at 227). The court does not believe these concessions are dispositive, as Mr. Albritton's claims are premised on alleged misrepresentations as to the risk of revision to him as a patient with AVN.

Second, the record indicates a sole instance of direct communication between Mr. Albritton and Smith & Nephew. Dr. Raterman gave Mr. Albritton a "booklet" regarding the BHR after recommending the product. (ECF 2830-3, Albritton Dep. at 147; ECF 2830-4, Raterman Dep. at 28). Mr. Albritton believes that this booklet was a document entitled "A Patient's Guide." (ECF 2830-1, Albritton Aff. ¶¶ 7–8). Mr. Albritton contends that the statements in the Patient Guide advertising a low overall revision risk for the BHR and touting its benefits for AVN misrepresented

and concealed the revision risk of the BHR for patients with AVN. While it may be that a reasonable juror could find the Patient Guide somewhat misleading as to the magnitude of the risk of revision for an AVN patient, there is no evidence in the record that Mr. Albritton relied on the Patient Guide in making the decision to have the BHR implanted. Though Mr. Albritton testified that he "looked over" the Patient Guide, he could not recall any warnings it contained and he has disclaimed that he relied on any advertisements from Smith & Nephew; rather, he testified that he relied on Dr. Raterman's opinion in selecting the device to be used for his resurfacing surgery. (ECF 2830-3, Albritton Dep. at 79; ECF 2760-3 at 132–33, 167). This heavily undercuts Mr. Albritton's argument that had the Patient Guide contained a more complete picture of the risks of the BHR to Mr. Albritton, that information would have altered Mr. Albritton's decision. The court is persuaded that the record does not contain any evidence that Mr. Albritton relied on a misrepresentation Smith & Nephew made to him directly.

Third, the court also agrees with Smith & Nephew that Mr. Albritton has failed to support a negligent misrepresentation claim based on information provided by Smith & Nephew to Dr. Raterman which might have influenced his recommendation to Mr. Albritton.[2] At the time of Mr. Albritton's surgery, Dr. Raterman was familiar with the BHR's IFU, which disclosed the known magnitude of the risk of revision for patients with AVN. (ECF 2760-4, Raterman Dep. at 100; ECF 2830-2, FDA Label at 15). Dr. Raterman was aware before Mr. Albritton's surgery that patients with AVN were at an increased risk for needing a revision surgery of the BHR. (ECF 2760-4,

[2] Smith & Nephew makes a related argument that any failure to more explicitly discuss revision rates for AVN patients in its patient brochures and with surgeons is only an omission that it had no duty to disclose under Florida law, citing *Behrman v. Allstate Ins. Co.*, 388 F. Supp. 2d 1346, 1352 (S.D. Fla. 2005). Because the court concludes that Mr. Albritton has failed to create a genuine dispute of material fact as to whether he or Dr. Raterman relied on any misrepresentation Smith & Nephew made, the court need not address this argument.

Raterman Dep. at 112–13; ECF 2760-5, Shapiro (Albritton) Dep. at 71–73). Dr. Raterman also testified that in learning about a device, he would get information from journals, his own personal experience, the experiences of his colleagues, podium discussions and meetings, and papers. (ECF 2760-4, Raterman Dep. at 99–100). He also reviews Australian registry data. (*Id.* at 122–23). Though he provides a pamphlet that "describes the difference between a total hip and a resurfacing hip" to his patients, he did not indicate that he viewed such a pamphlet or brochure as a source of information in his own decision-making. (ECF 2830-4, Raterman Dep. at 28). Nor has he testified that he relies on "Dear Doctor" letters or other Smith & Nephew marketing materials in making recommendations to patients.

Mr. Albritton contends that ad hoc reports from the Australian registry Smith & Nephew received following Mr. Albritton's surgery in 2009 showed an even greater magnitude of revision risk for patients with AVN. (ECF 2760-13, Shapiro (Albritton) Rep. at 9 (Dr. Raterman unaware of magnitude of risk of revision, risk disclosed in IFU was not accurate or specific enough)). In Mr. Albritton's view, the existence of those reports demonstrates that Smith & Nephew was increasingly aware of a greater risk to patients like him, but did not incorporate that risk in its marketing to surgeons or patients in favor of a marketing approach that presented overall revision rates which overstated the device's true success for AVN patients. There are two problems with this argument. First, it is not clear whether any ad hoc report Smith & Nephew received prior to Mr. Albritton's surgery disclosed a risk of revision for patients like Mr. Albritton with larger head sizes and AVN that was meaningfully greater than that already disclosed in the BHR's IFU. Dr. Shapiro's report refers to "at least one ad hoc report that quantified the revision rate of BHR patients with AVN of .98 revisions per 100 OCY" (meaning a revision rate of approximately 9.8 percent). (*Id.* at 9). This report is not included in the summary judgment record and Dr. Shapiro's

report does not include information regarding when Smith & Nephew received this report. Nor is there testimony by Dr. Raterman that the receipt of information showing that the revision rate for an AVN patient was closer to 9.8 percent, as opposed to the 7.9 percent revision rate disclosed in the IFU, (*see* ECF 2830-2, FDA Label at 15), would have changed his recommendations to Mr. Albritton. Second, while the court has acknowledged that evidence post-dating an individual plaintiff's implant may shed light on Smith & Nephew's knowledge of certain risks in the period prior to the implant, (*see* ECF 2827, *Redick & Mosca Motion in Limine* Mem. at 12), the existence of an ad hoc report with more granular data regarding the risks of the BHR to Mr. Albritton which may post-date his surgery does not assist the factfinder in identifying what Smith & Nephew knew before Mr. Albritton had the BHR implanted. The remaining dispute regarding whether Dr. Raterman informed Mr. Albritton of this risk does not create liability for Smith & Nephew as it does not concern any misrepresentation of fact that the company made.

In sum, Mr. Albritton has failed to create a genuine dispute of material fact as to whether he relied on any misrepresentation Smith & Nephew made. Mr. Albritton relied on Dr. Raterman, and there is no voluntary communication by Smith & Nephew which Dr. Raterman says he relied upon. Accordingly, the court will award summary judgment to Smith & Nephew on Mr. Albritton's negligent misrepresentation claim.

III. Breach of Express Warranty

Under Florida law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." Fla. Stat. § 672.313(1)(a). A claim for breach of express warranty pursuant to Fla. Stat. § 672.313(1)(a) requires proof of "(1) the sale of goods; (2) the express warranty; (3) breach of the warranty; (4) notice to seller of the breach; and

(5) the injuries sustained by the buyer as a result of the breach of the express warranty." *Jovine v. Abbott Lab'ys, Inc.*, 795 F. Supp. 2d 1331, 1339–40 (S.D. Fla. 2011) (citing *Dunham–Bush, Inc. v. Thermo–Air Serv., Inc.*, 351 So.2d 351, 353 (Fla. Dist. Ct. App. 1977) (footnotes omitted). Additionally, "[p]rivity is required in order to recover damages from the seller of a product for breach of express or implied warranties." *Douse v. Bos. Sci. Corp.*, 314 F. Supp. 3d 1251, 1261 (M.D. Fla. 2018) (citing cases).

Smith & Nephew argues summary judgment should be granted as to this claim because (1) the sole allegation in the plaintiffs' Master Amended Consolidated Complaint ("MACC") is preempted; (2) Mr. Albritton cannot establish privity between himself and Smith & Nephew; and (3) Mr. Albritton has failed to identify any express warranties made by Smith & Nephew on which he relied. The court will address each argument in turn.

First, Smith & Nephew cites paragraph 522 of the MACC, which alleges that "Smith & Nephew expressly warranted . . . directly to Plaintiffs that the [BHR] was safe and effective for use when it was not." (ECF 124, MACC ¶ 522). Smith & Nephew argues that this claim must fail because the Court has already dismissed as preempted any claim that requires proof that the BHR was unreasonably dangerous or unsafe. *See In re BHR*, 300 F. Supp. 3d at 743, 745. But the court also held at the motion to dismiss stage that the plaintiffs could pursue non-preempted breach of express warranty claims premised on false or misleading statements regarding the risks of the BHR relative to other products or other false or misleading off-label statements. *See id.* at 745. A claim that parallels an ongoing obligation under the BHR's PMA approval to disseminate truthful, accurate, and not misleading statements about the device is not preempted. *See id.*

Second, Smith & Nephew claims that privity does not exist between Mr. Albritton and Smith & Nephew because there is no evidence that Mr. Albritton purchased the BHR from Smith

& Nephew directly, citing *Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1193 (M.D. Fla. 2013) and *Douse*, 314 F. Supp. 3d at 1261. *Kaiser* and *Douse* together make clear that Florida law is not entirely settled on whether direct purchase is required to establish privity. *Compare Kaiser*, 944 F. Supp. 2d at 1193 ("[n]o privity exists, and a breach of warranty claims fails, where plaintiff did not purchase the product from the defendant") (citing *Cooper v. Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220, 1226 (M.D. Fla. 2009) *with Douse*, 314 F. Supp. 3d at 1261 (observing that there is disagreement among Florida courts regarding the "outer boundaries of privity" and whether those "outer boundaries of privity require substantial direct contacts [between the consumer and the manufacturer], . . . or mere product labeling . . .") (citing *Smith v. Wm. Wrigley Jr. Co.*, 663 F. Supp. 2d 1336, 1343 (S.D. Fla. 2009) and *Cedars of Lebanon Hosp. Corp. v. Euro. X-Ray Distrib. of Am., Inc.*, 444 So.2d 1068 (Fla. 3d DCA 1984)). It is not necessary, however, to resolve whether Mr. Albritton can establish privity with Smith & Nephew under one of these approaches, because he cannot show that he relied on any express warranty Smith & Nephew made.

As explained previously, the Patient Guide is the only communication in the record between Mr. Albritton and Smith & Nephew—Mr. Albritton has specifically denied that he relied on any advertisements by Smith & Nephew. (ECF 2760-3, Albritton Dep. at 132–33; ECF 2760-16, Albritton 1st Supp. Resp. to RFAs at 4, 5). And as for the only other guarantee Mr. Albritton contends he was given—that the BHR would last the rest of his life—Mr. Albritton does not attribute this statement to Smith & Nephew. Mr. Albritton testified that Dr. Raterman made this guarantee. (ECF 2830-3, Albritton Dep. at 81). Dr. Raterman disputes that he gave Mr. Albritton such an assurance and at any rate there is no evidence that, had he made such a statement, Smith

& Nephew was the source of his information. Accordingly, the court will award summary judgment to Smith & Nephew on Mr. Albritton's breach of express warranty claims.

IV. Remaining Negligence Claims

In his remaining common-law negligence claims, the plaintiffs seek to prove that Smith & Nephew was negligent in making false or misleading statements regarding the success rates of the BHR, in violation of Florida's misbranding statute, and that Dr. Raterman was negligently trained. Smith & Nephew argues that these claims are preempted and that the plaintiffs' evidence is insufficient to establish negligence. The court addresses each claim in turn.

a. Training

The court has previously held that any claim that Smith & Nephew had a duty to change its training program would add to or differ from the requirement to merely implement the program and is preempted, (*Redick* Mem. at 28–29), although to the extent the plaintiffs claim that misleading revision rates were touted as part of the training program, such evidence may support a non-preempted negligent misrepresentation or breach of express warranty claim. (*Id.*). Mr. Albritton's negligent training claim is not distinct from the Redicks' similar (and preempted) claim. Accordingly, the court will award summary judgment to Smith & Nephew on Mr. Albritton's negligent training claim.

b. Misbranding

Mr. Albritton also seeks to hold Smith & Nephew liable under a negligence *per se* theory, arguing that Smith & Nephew's marketing and trainings contained non-FDA approved statements, messages, and information that violate federal regulations and parallel Florida law, citing Fla. Stat. § 499.007. Section 499.007 provides that a drug or device is misbranded if its labeling is in any way false or misleading or if the label does not contain certain information prescribed by the statute

or does not place certain information prominently on the label. *Id.* The statute contains a number of additional limitations for the branding of drugs that are not applicable here. *Id.* This court has held that "misbranding" claims predicated on alleged false or misleading statements by Smith & Nephew outside of the FDA's approved labeling may survive a preemption challenge to the same extent as the plaintiffs' negligent misrepresentation and breach of warranty claims. *See In re BHR*, 300 F. Supp. 3d at 744 n.10. But a claim that Smith & Nephew had a duty to change its labeling, or a claim challenging the adequacy of the FDA-approved labeling, is preempted. *Id.* at 745; *see also Hughes*, 631 F.3d at 769 (holding that the plaintiff's products liability claim challenging the adequacy of FDA-approved labeling was preempted). Because Mr. Albritton would have to prove that the FDA-approved labeling that accompanied the BHR was misleading in order to prove that Smith & Nephew violated § 499.007, this negligence claim is preempted. Accordingly, the court will award summary judgment to Smith & Nephew as to this claim.

V. Punitive Damages

Under Florida law, "a demand for punitive damages is not a separate and distinct cause of action; rather it is auxiliary to, and dependent upon, the existence of an underlying claim." *Soffer v. R.J. Reynolds Tobacco Co.*, 187 So. 3d 1219, 1221 (Fla. 2016) (internal quotation marks omitted). Because none of Mr. Albritton's claims for liability survive summary judgment, his claim for punitive damages also must fail. Accordingly, Smith & Nephew's motion for summary judgment as to punitive damages will be granted.

CONCLUSION

For the foregoing reasons, Smith & Nephew's motion for summary judgment will be granted. A separate Order follows.

8/13/2021
Date

/S/
Catherine C. Blake
United States District Judge