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: ***Aubrey W. Sedgwick v. Smith & Nephew, Inc.*, No. 1:17-cv-01344**

MEMORANDUM

Pending before the court are cross motions for summary judgment in BHR track action *Aubrey W. Sedgwick v. Smith & Nephew, Inc.*, No. 1:17-cv-01344. Mr. Sedgwick seeks summary judgment on Smith & Nephew's affirmative defenses, including its defense of preemption. (ECF 2757). Smith & Nephew moves for summary judgment as to all of Mr. Sedgwick's remaining claims for negligent failure to warn, negligence *per se*, negligent training, breach of express warranty, negligent misrepresentation, and punitive damages. (ECF 2756). The motions have been fully briefed and oral argument was heard on July 15, 2021. For the reasons that follow, Smith & Nephew's motion will be granted, and Mr. Sedgwick's motion will be denied.

BACKGROUND

This case concerns alleged injuries suffered by the plaintiff Aubrey Sedgwick ("Mr. Sedgwick") 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. 28).[1] Mr. Sedgwick claims he was one such patient—his BHR implant required revision to a different implant due, in the opinion of one of his experts, to symptoms caused by the accumulation of metal debris. (ECF 2756-19, Ex. Q, Shapiro (Sedgwick) Rep. at 2, 13).

Mr. Sedgwick's theory of the case is that Smith & Nephew marketed the BHR by touting publicly available reports from international registries containing clinical results from hip implant surgeries, reports that showed excellent and market-leading success rates for the BHR overall. Meanwhile, Mr. Sedgwick contends, Smith & Nephew also requested and received from some of those same registries reports with more granular data regarding revision surgeries by gender, age, and product head size that showed significantly worse success rates for the BHR in women and patients with smaller head sizes. Mr. Sedgwick refers to this information as "ad hoc data" or "ad hoc reports." Though Smith & Nephew did not receive any of these ad hoc reports before Mr. Sedgwick's surgery, he contends that the company was aware that its use of overall revision risks may have been misleading, that the *availability* of ad hoc data was known to Smith & Nephew at

[1] The exhibits associated with ECF 2427 and referenced herein were provided to the court, but due to a technical error have not yet been uploaded to the public docket.

the time it marketed the BHR to Mr. Sedgwick's doctor, and that this is evidence that Smith & Nephew's decision to market the BHR using only more general data was negligent. He contends that Smith & Nephew's marketing misled Dr. Boucher, and had he not been so misled, this would have altered Mr. Sedgwick's decision to agree to the BHR implant.

I. Mr. Sedgwick's BHR and Revision Surgeries

Mr. Sedgwick is a 63-year-old man who lives in Middle River, Maryland. (ECF 2831-3, Ex. 2, Sedgwick Dep. at 4). In or about 2005, Mr. Sedgwick began to experience pain in his left hip and groin area, which increased in severity over time. By 2007, the pain was "constant" and limited Mr. Sedgwick's mobility. (*Id.* at 63–65. 70, 74). That year, he began to see Dr. Henry Boucher regarding the pain. (*Id.* at 66). Dr. Boucher informed Mr. Sedgwick that his hip was badly arthritic and recommended surgery to alleviate the pain. (*Id.* at 69, 83–84). He recommended a resurfacing surgery using the BHR because Mr. Sedgwick was "pretty active and fairly still kind of young" and the procedure would require less rehabilitation than a total hip replacement (*Id.* at 84, 85). Mr. Sedgwick does not recall Dr. Boucher strongly suggesting a total hip replacement as an alternative to the BHR—"What I do recall mostly is how much he talked about the BHR and how good that would be and how he recommended that." (*Id.*). Dr. Boucher explained that the BHR was a metal-on-metal device, and gave Mr. Sedgwick brochures on the product, which Mr. Sedgwick read, but he does not specifically recall their contents. (*Id.* at 55–58, 85, 87–88). Mr. Sedgwick may have "pulled something up on-line" regarding the BHR before his surgery, but he is not sure and does not recall any specifics of that research. (*Id.*). Mr. Sedgwick does not recall Dr. Boucher discussing any risk of the device loosening or a risk of metal ion release. (*Id.* at 86). While Mr. Sedgwick recalls hearing someone mention that the BHR would last 20 years, he could not recall the source of this information; he does not believe Dr. Boucher was the source. (*Id.* at

92). Mr. Sedgwick relied on Dr. Boucher to choose the best device available in his opinion. (*Id.* at 93).

Dr. Boucher's records indicate that he counseled Mr. Sedgwick on the risks, benefits, and alternatives of a BHR implant, including those posed by metal ion release associated with a metal-on-metal device and loosening of the device. (ECF 2756-10, Ex. H, Post-Operative Notes).

Mr. Sedgwick had the BHR, size 46 mm, implanted on September 12, 2007. (ECF 2756-8, Ex. F, Operation Notes). In 2014, Mr. Sedgwick returned to Dr. Boucher because an "intense" pain had returned to his left hip, to the point that he could not put weight on his left hip. (ECF 2831-3, Ex. 2, Sedgwick Dep. at 102–03, 107–08). Dr. Boucher's evaluation at that time was that the femoral component of the BHR had shifted and the femoral neck had shortened. (ECF 2756-12, Ex. J, May 1, 2014 Boucher Notes). Dr. Boucher informed Mr. Sedgwick that the BHR would have to be replaced and converted to a total hip replacement. (*Id.*; ECF 2831-3, Ex. 2, Sedgwick Dep. at 111). At that time, Dr. Boucher believed that the device's failure was "likely due to a bone quality issue since he did have cystic change of the femoral head with bone grafting at the time of surgery." (ECF 2756-12, Ex. J, May 1, 2014 Boucher Notes; ECF 2831-2, Ex. 1, Aug. 7, 2020 Boucher Dep. at 58–60). Mr. Sedgwick's medical causation expert, Dr. Shapiro, has opined that adverse tissue reaction in Mr. Sedgwick's pathology reports is a sign of metal injury from the BHR's metal-on-metal components. (ECF 2756-19, Ex. Q, Shapiro (Sedgwick) Rep. at 13). Neither Dr. Shapiro nor Smith & Nephew's medical causation expert, Dr. Hungerford, have criticized Dr. Boucher's surgical technique or his treatment of Mr. Sedgwick. (*Id.*; ECF 2757-7, Ex. 5, Hungerford Dep. at 57).

I. Smith & Nephew's Training and Marketing Directed at Dr. Boucher

In a 2006 training that Dr. Boucher attended, Smith & Nephew represented that the BHR performed better than its competitors' products because it was manufactured without heat treatment. (ECF 2757-5, Ex. 3, Boucher (Mosca) Dep. at 154–55). Dr. Boucher also was informed that the five-year revision rate of the BHR was one to three percent overall. (*Id.* at 156). Dr. Marc Hungerford, who attended a similar training shortly after Dr. Boucher, recalls that the training contained a discussion of a higher risk of femoral neck fracture for patients with smaller device sizes. (ECF 2757-7, Ex. 5, Feb. 12, 2021 Hungerford Dep. at 51). Around the time of Mr. Sedgwick's implant surgery Dr. Boucher understood the failure rate of the BHR to be between one and three percent over ten years, based on materials from Smith & Nephew and Smith & Nephew's 2006 training program, and that this performance outpaced other products, including for men around Mr. Sedgwick's age. (ECF 2757-5, Ex. 3, Boucher (Mosca) Dep. at 155–61; ECF 2757-6, Ex. 4, Australian Registry Resurfacing Results 2007). The FDA-approved "Important Medical Information," or label, for the BHR at the time of Mr. Sedgwick's surgery publicizes similar rates of revision between one and three percent. (ECF 2824-9, Ex. H., 2005 BHR Label at 13, 15).

In November 2007, after Mr. Sedgwick's surgery, Smith & Nephew sent to Dr. Boucher a summary of the Australian Orthopaedic Association's National Joint Replacement Registry ("Australian Registry")'s 2007 annual report. (ECF 2757-6, Ex. 4, Dear Dr. Letter at 3; ECF 2842 at 9, Sedgwick Reply (conceding the marketing piece was sent after Sedgwick's surgery)). The mailer includes a table showing an overall revision rate for the BHR of 2.5 percent, compared with revision rates of other resurfacing devices, all of which show revision rates between four and 8.4 percent. (*Id.*). Another table shows the overall revision rate for the BHR over time. Smith & Nephew advertised that, at five years, the Australian Registry reported a revision rate of 3.7 percent for the BHR, compared with competitor rates of 7.4 to 16.4 percent. (*Id.*).

II. Smith & Nephew's Knowledge of Revision Rates

In 2001, Derek McMinn's company, Midland Medical Technologies, the predecessor developer of the BHR to Smith & Nephew, was aware that they did not yet have ten years of survival data for the BHR and that this was a "major problem with the analysis of the BHR survival data" at the time. (ECF 2757-8, Ex. 6, 2001 NICE Submission, at 40). The company predicted that the BHR would have a revision rate of ten percent over ten years (*Id.* at 49). In 2006, Smith & Nephew's research department believed the company's data on Treacy and McMinn patients did not contain every observed revision in those patient populations, potentially raising the inference that the risk of revision of the BHR was higher than previously thought. (ECF 2757-12, Ex. 10, Feb. 8, 2006 Tildesley Email). Dr. Boucher does not recall being informed that the BHR had a projected ten-year failure rate of ten percent. (ECF 2831-5, Ex. 4, Jul. 24, 2020 Boucher Dep. at 9–10). Had he been so informed, he would have shared those rates with Mr. Sedgwick. (*Id.* at 10). He did not, however, testify that revision rates of such magnitude would have altered his recommendation to Mr. Sedgwick.

As for Smith & Nephew's knowledge that smaller femoral head sizes carried an increased risk of revision, a Smith & Nephew expert has testified that the "medical community" was aware of that increased risk at least as of 2004. (ECF 2514-20, Ex. 18, Mont Dep. at 105–06). At least as of 2008, Smith & Nephew internal documents show a general awareness that peer-reviewed literature showed that revision rates for the BHR were higher for females and patients with smaller head sizes than overall clinical results of the device. (ECF 2514-15, Ex. 13 at 4). Nonetheless, Smith & Nephew remained committed to using overall revision rates in annual registry reports in its marketing materials as part of a "simple 3 point messaging" which consisted of highlighting the BHR's "bone conserving" aspects, its "metallurgy," and its "clinical results." (*Id.* at 9).

Beginning in 2009, Smith & Nephew began to request and receive from the Australian and UK registries ad hoc reports that showed higher revision rates in the BHR for women and patients with smaller head sizes. These ad hoc reports would not have been publicly available to doctors, and Dr. Boucher was unaware that Smith & Nephew could request such data. (ECF 2514-3, Ex. 1 Feb. 7, 2020 Boucher Dep. at 162). Smith & Nephew was aware prior to 2009 that it had the ability to request such data. (ECF 2757-13, Ex. 11, Nov. 2007 Australian Registry response to Smith & Nephew request for data on reasons for revision by device). In 2010, Smith & Nephew revised the BHR label to include as risk factors for revision the fact of being a female patient or the receipt of a smaller head size (equal to or under 44mm). (ECF 2593-4, Ex. C, 2010 BHR Label at 4).

Smith & Nephew's understanding of the advantages of its as-cast design also may have evolved over the years. In an internal presentation circulated in 2009 or later, the company cited data showing that its revision rate was five percent at eight years compared with a similar, but heat-treated, device which had a sixteen percent revision rate at seven years. (ECF 2757-10, Ex. 8 at 15). By 2015, Smith & Nephew had received data that its overall revision rate at the seven-year mark for its recalled devices was similar to that of a heat-treated device, with a revision rate of 17.2 percent. (ECF 2757-11, Ex. 9 at 1).

Mr. Sedgwick has said, in interrogatory responses, that had Dr. Boucher told him of a revision risk of ten percent, he would not have gotten the BHR. (ECF 2757-14, Ex. 12, Sedgwick Suppl. Interrogatory Responses at 21–22). Smith & Nephew's knowledge of revision risk was not discussed with Mr. Sedgwick in his deposition, but Mr. Sedgwick expressed that he was not warned of the risks of metallosis before his BHR surgery and that he would not have had the device implanted had he known those risks. (ECF 2757-3, Ex. 1, Sedgwick Dep. at 85, 86, 90, 167). Mr.

Sedgwick also testified that he relied on Dr. Boucher's recommendation in selecting a resurfacing device. (*Id.* at 93).

PROCEDURAL HISTORY

On May 16, 2017, Mr. Sedgwick filed a complaint against Smith & Nephew under Maryland law. *Sedgwick v. Smith & Nephew, Inc.*, 1:17-cv-01344, ECF 1 (D. Md. May 16, 2017). On August 23, 2017, Mr. Sedgwick filed a short form complaint including nine counts against Smith & Nephew under Maryland law: strict products liability (Count I), negligence (Count II), 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 162, Sedgwick 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 as expressly preempted (Counts I and III) and the manufacturing defect claim for failure to state a claim. *In re BHR*, 300 F. Supp. 3d at 743, 746, 750. Following substantial fact and expert discovery, the parties filed cross motions for summary judgment on May 25, 2021. (ECF 2756, Smith & Nephew MSJ; ECF 2757, Sedgwick MSJ). The motions have been fully briefed (ECFs 2824, 2831, 2842, 2846) 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. "When faced with cross-motions for summary judgment, the court must review each motion separately on its own merits 'to determine whether either of the parties deserves judgment as a matter of law.'" *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003) (quoting *Phillip Morris Inc. v. Harshbarger*, 122 F.3d 58, 62 n.4 (1st Cir. 1997). For each individual motion, the court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 572 U.S. 650, 657 (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 its preemption defenses and argues that Mr. Sedgwick's claims, including claims for punitive damages, also fail because they are barred by the statute of limitations, because Maryland 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. Mr. Sedgwick opposes Smith & Nephew's motion and argues he is entitled to summary judgment on Smith & Nephew's affirmative defenses. The court will first address Smith & Nephew's statute of

limitations defense and will then address in turn each remaining claim—negligent failure to warn, negligent misrepresentation, breach of express warranties, and negligence. The court will then address punitive damages. The court will conclude that Smith & Nephew is entitled to summary judgment on all of Mr. Sedgwick's remaining claims.

I. Statute of Limitations

In Maryland, personal injury claims are subject to a three-year statute of limitations. Md. Code. Ann., Cts. & Jud. Proc. § 5-101. Maryland uses a fact-specific discovery rule to assess when claims accrue. In a products liability action, the statute of limitations begins to run when "the plaintiff knows or through the exercise of due diligence should know of the injury, its probable cause, and either manufacturer wrongdoing or product defect." *Pennwalt Corp. v. Nasios*, 314 Md. 433, 452 (1988).

Smith & Nephew argues that Mr. Sedgwick was on notice that he had a potential claim against Smith & Nephew by May 1, 2014, when Dr. Boucher informed Mr. Sedgwick that the femoral component of his BHR had loosened, and he would need revision surgery. Based on this information, Mr. Sedgwick understood that "the BHR was no longer safe to be in his body." (ECF 2846-2, Ex. A, Sedgwick Responses to 1st Set of RFAs at 12). Had Mr. Sedgwick conducted a reasonable investigation at that time, he would have discovered that other BHR patients had sued Smith & Nephew for product defects. Mr. Sedgwick argues that the record is clear he was not aware at the time he was told of the need for revision, or even at the time of revision, that a defect in the BHR or conduct by Smith & Nephew was the cause of his injury. He contends that his claims began to accrue either in September 2015, when Smith & Nephew withdrew the device size implanted in Mr. Sedgwick because of a higher risk of revision than had previously been represented to Dr. Boucher, or on June 9, 2014, the date of his revision surgery.

In its previous ruling regarding statutes of limitation in BHR track cases, the court observed that this inquiry "cannot be resolved simply by looking to the date on which a plaintiff had a revision surgery[.] . . . Revision surgery, alone, only tells a plaintiff that she is suffering from complications as a result of her implant procedures, but is silent as to the cause of that complication. Without more information, a reasonably conscientious patient could not deduce whether the cause of her injury is her doctor's malpractice, something unique to her own medical history, an unfortunate but accepted ill-effect of the BHR device, or a true product defect." (ECF 1190, hereinafter "BHR SOL Mem.", at 5–6). Likewise, Dr. Boucher's statement to Mr. Sedgwick on May 1, 2014 that he would need a revision surgery due to the femoral component loosening could not have indicated to Mr. Sedgwick the *cause* of that complication. (ECF 2756-12, Ex. J, May 1, 2014 Boucher Notes). The knowledge that the BHR was not "safe to be in his body" (ECF 2846-2, Ex. A at 12) is similarly ambiguous as to the cause of that danger. Moreover, at the time, Dr. Boucher believed that the device's failure was "likely due to a bone quality issue since [Mr. Sedgwick] did have cystic change of the femoral head with bone grafting at the time of surgery." (ECF 2756-12, Ex. J, May 1, 2014 Boucher Notes; ECF 2831-2, Ex. 1, Aug. 7, 2020 Boucher Dep. at 58–59). Thus, by May 1, 2014, based on Dr. Boucher's opinion, it was reasonable for Mr. Sedgwick to believe that the failure of his BHR was "something unique to [his] own medical history," and not due to Smith & Nephew's conduct. BHR SOL Mem. at 5–6.

Mr. Sedgwick filed his claim within three years of the date of his revision surgery on June 9, 2014, and certainly within three years of when Smith & Nephew withdrew the BHR in his head size from the market in 2015. Smith & Nephew has not met its burden to demonstrate that Mr. Sedgwick reasonably should have known at an earlier date that Smith & Nephew's conduct was the cause of his revision.

II. Negligent Failure to Warn

Smith & Nephew contends that it should be granted summary judgment on Mr. Sedgwick's negligent failure to warn claim because (1) the claim is preempted, as Maryland law does not support a claim of failure to warn the FDA, and (2) Mr. Sedgwick cannot show that any failure to warn the FDA caused his injuries. Mr. Sedgwick argues that (1) Smith & Nephew's preemption defense fails as a matter of law, (2) Smith & Nephew was negligent in failing to share ad hoc data from international registries with the FDA, and (3) that failure indisputably caused his injuries. The court will address the parties' preemption arguments and then the issue of causation

a. Preemption

The court has explained in prior decisions in this case the legal framework of preemption under the Medical Device Amendments to the Food, Drug and Cosmetic Act and its application to the plaintiffs' failure to warn claims. *See, e.g.*, *In re BHR*, 300 F. Supp. 3d at 741–43, 746–47; *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.* ("*Daubert* Ruling"), No. 1:17-MD-2775, 2021 WL 781682, at *2 (D. Md. Mar. 1, 2021); (ECF 2715, hereinafter "*Redick* Mem."; ECF 2905, hereinafter "*Mosca* Mem."). Briefly, to the extent that Mr. Sedgwick attempts to premise his negligent failure to warn claim on statements it alleges Smith & Nephew failed to make to Dr. Boucher, such a claim is preempted. *In re BHR*, 300 F. Supp. 3d at 743, 745, 747–48. (*See also Mosca* Mem. at 13–14). But his other claims, to the extent they parallel federal obligations, are not necessarily preempted. *In re BHR*, 300 F. Supp. 3d at 743–44. One such claim is a failure to warn claim that seeks to hold Smith & Nephew liable for a failure to report ad hoc data from international registries to the FDA, in violation of the PMA and various federal regulations. The court's prior preemption ruling held that such claims predicated on an "alleged failure to report specific information to the FDA are not expressly preempted." *In re BHR*,

300 F. Supp. 3d at 745 (citing *Stengel v. Medtronic*, 704 F.3d 1224, 1233 (9th Cir. 2013)). (*See also Mosca* Mem. at 13–14).

But Smith & Nephew argues that Mr. Sedgwick's failure to warn the FDA claim is impliedly preempted because there is no traditional duty under Maryland law for a manufacturer to warn the FDA. As explained in the court's memorandum addressing cross motions for summary judgment in BHR track action *Phyliss Mosca v. Smith & Nephew*, Inc., No. CCB-18-3520, it is unnecessary to decide specifically whether Maryland recognizes such a duty in this circumstance, because Mr. Sedgwick cannot satisfy the difficult element of causation. (*Mosca* Mem. at 14–15).

b. Causation

In order to show causation as to his failure to warn the FDA claim, Mr. Sedgwick must show that if Smith & Nephew had "properly reported the adverse events to the FDA as required under federal law, that information would have reached [his] doctors in time to prevent [his] injuries." "*Daubert* Ruling", at *8 n.3 (citing *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096–97 (N.D. Cal. 2016)); *see also Hughes*, 631 F.3d at 776. 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. Sedgwick'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. Boucher read prior to Mr. Sedgwick'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. Sedgwick has identified no information that he claims Smith & Nephew should have disclosed to the FDA that, if publicized, would have reached Dr. Boucher

in time to alter his decision to have the BHR implanted. He simply "adopts entirely" the arguments in the *Mosca* briefing related to causation—those arguments were predicated on the failure to disclose to the FDA ad hoc data and reports that Smith & Nephew received *after* Sedgwick's surgery, and at any rate were insufficient even for Ms. Mosca to show causation. (*See Mosca* Mem. at 15–16). 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. Sedgwick's injuries, the court will award summary judgment to Smith & Nephew on his failure to warn claim.

III. Negligent Misrepresentation

a. Preemption

Mr. Sedgwick seeks summary judgment on Smith & Nephew's defense of preemption. This court's prior preemption ruling makes clear that Smith & Nephew had an ongoing obligation under the PMA approval to disseminate truthful, accurate, and not misleading statements about the device that parallels obligations under the plaintiff's state law actions for negligent misrepresentation. *See In re BHR*, 300 F. Supp. 3d at 745. "A claim which challenges a representation the FDA blessed in the approval process is preempted, while a claim challenging a warranty above and beyond any guarantee that was explicitly or implicitly approved by the FDA is not preempted." *Daubert* Ruling, at * 6 (citing *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017). Maryland courts also have held that misrepresentations a device manufacturer makes in voluntary communications to the medical profession or the public are not preempted by 21 U.S.C. § 360k(a). *McCormick v. Medtronic, Inc.*, 219 Md. App. 485, 519 (2014). Smith & Nephew's argument in response is based on the faulty premise that only false statements, and not omissions, are actionable as negligent misrepresentations, and thus that Mr. Sedgwick's claims are preempted to the extent that Mr. Sedgwick's negligent misrepresentation claims are based only on

omissions. *See Lubore v. RPM Assocs., Inc.*, 109 Md. App. 312, 341 (1996) ("[A] fragmentary representation can be rendered misleading by virtue of material facts not disclosed. As a consequence, it reasonably may be said that appellees negligently misrepresented the truth by affirmatively representing only a fragment of the entire picture."). To the extent Mr. Sedgwick's claims are based on voluntary statements made to surgeons which were not FDA-approved, they are not preempted.

b. Liability

Under Maryland law, Mr. Sedgwick must prove the following elements to recover on his negligent misrepresentation claim:

> (1) the defendant, owing a duty of care to the plaintiff, negligently asserts a false statement; "(2) the defendant intends that his statement will be acted upon by the plaintiff; "(3) the defendant has knowledge that the plaintiff will probably rely on the statement, which, if erroneous, will cause loss or injury; "(4) the plaintiff, justifiably, takes action in reliance on the statement; and "(5) the plaintiff suffers damage proximately caused by the defendant's negligence.
>
> *Lloyd v. Gen. Motors Corp.*, 397 Md. 108, 136, 916 A.2d 257, 273 (2007).

Mr. Sedgwick asserts that Smith & Nephew made several false or misleading statements either to him or to Dr. Boucher prior to his implant which he contends omitted relevant information regarding the performance of Mr. Sedgwick's BHR. The court will first address those alleged misrepresentations made to Mr. Sedgwick and then turn to those allegedly made to Dr. Boucher.

Mr. Sedgwick points to one piece of information from Smith & Nephew that he personally reviewed. Mr. Sedgwick recalls seeing a brochure from Smith & Nephew prior to his implant surgery. At his deposition, he testified that a Smith & Nephew document entitled "A Patient's Guide" may have been that brochure, stating "some of it looks familiar" but he could not say specifically. (ECF 2831-3, Ex. 2, Sedgwick Dep. at 56–58, discussing ECF 2831-4, Ex. 3, "A Patient's Guide"). Any representations made in this brochure cannot form the basis of a negligent

misrepresentation claim because Mr. Sedgwick has failed to create a genuine issue of material fact as to whether he relied on it. Mr. Sedgwick could not recall specifically whether he saw the Patient Guide, could not recall its contents and, at any rate, testified that he relied on Dr. Boucher, not any statements by Smith & Nephew in selecting the BHR. (ECF 2831-3, Ex. 2, Sedgwick Dep. at 56–58 (discussing ECF 2831-4, Ex. 3, "A Patient's Guide"), 93 (reliance on Dr. Boucher)).[2]

As for representations made to Dr. Boucher, Mr. Sedgwick relies on four alleged misrepresentations made to Dr. Boucher in marketing or during his training which he contends omitted relevant information regarding the performance of Mr. Sedgwick's BHR:

1. During Dr. Boucher's training, Smith & Nephew represented that the BHR had design advantages over other metal-on-metal devices, including the use of as-cast metal instead of "heat-treated" metal, that produced a lower revision rate. (ECF 2757-5, Ex. 3, Feb. 7, 2020 Boucher Dep. at 154–55).
2. During Dr. Boucher's training, Smith & Nephew represented that the five-year revision rate of the BHR was one to three percent overall and that this rate applied to patients like Mr. Sedgwick. (*Id.* at 156).
3. During Dr. Boucher's training, Smith & Nephew represented that any increased risk of revision to patients with a smaller device size, like Mr. Sedgwick, was related to the risk of early fracture, not metal wear or other medium- to long-term risks. (ECF 2757-7, Ex. 5, Feb. 12, 2021 Hungerford Dep. at 51; 7/30/21 Tr. at 51).

[2] Smith & Nephew additionally argues that it owed no duty to provide information or warnings directly to Mr. Sedgwick; rather any duty to disclose truthful and non-misleading information was to Dr. Boucher, citing *Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div.*, No. CIV. CCB-12-1746, 2013 WL 1104427, at *5 (D. Md. Mar. 13, 2013). Because the court concludes that there is no evidence Mr. Sedgwick relied on any information Smith & Nephew provided to him directly, the court need not address this argument.

4. Smith & Nephew sent a "Dear Dr." letter to Dr. Boucher which represented that the BHR's performance was as good as or better than non-metal total hip replacements for certain patient populations, including younger men Mr. Sedgwick's age. (ECF 2757-6, Ex. 4, Dear Dr. Letter).

As an initial matter, the Dear Dr. letter sent to Dr. Boucher cannot support a misrepresentation claim, as it was sent in November 2007, after Mr. Sedgwick's surgery (ECF 2757-6, Ex. 4, Dear Dr. Letter at 3). As for the other alleged misrepresentations, Smith & Nephew argues that these statements were either (1) consistent with the FDA label at the time of Mr. Sedgwick's surgery, and thus the court's preemption ruling shields them from liability regarding those statements, or (2) not false or misleading because Smith & Nephew knew them to be true or believed them to be true at the time of Mr. Sedgwick's surgery. The court agrees with Smith & Nephew.

Representations that the five-year revision rate of the BHR was one to three percent overall were consistent with information contained within the BHR's FDA label at the time of Mr. Sedgwick's surgery. (ECF 2824-9, Ex. H., 2005 BHR Label, at 13, 15). Moreover, there is no evidence that this representation did not reflect Smith & Nephew's knowledge of the BHR's overall revision rates up until the point of the surgery. Mr. Sedgwick does not appear to dispute this, but argues that Smith & Nephew had reason to be aware, or should have investigated further, that the overall revision rates it used to market the BHR to Dr. Boucher overstated the success of the product, particularly for smaller head sizes like the one used for Mr. Sedgwick. For example, Midland Medical Technologies predicted in 2001 that the BHR would have a revision rate of ten percent at ten years, but this information was not included in voluntary communications to Dr. Boucher nor was it provided to the FDA during the PMA approval process. (ECF 2757-8, Ex. 6,

2001 NICE Submission, at 40). And by 2004, the "medical community" at large may have been increasingly aware that smaller femoral head sizes carried an increased risk of revision. (ECF 2514-20, Ex. 18, Mont Dep. at 105–06). Both pieces of information predate the FDA's PMA approval of the device. Mr. Sedgwick argues that the projected ten percent failure rate and other debates in the medical community show that it was impossible to verify, and therefore negligent to disseminate, the one to three percent revision rate. This strikes the court as a preempted attempt to undermine the FHA's PMA approval process and the FDA-approved BHR label which contained and "blessed" those revision rates. *See Daubert* Ruling, at * 6 (citing *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017).

As for representations regarding the benefits of the BHR's "as cast" metallurgy and the relationship between an increased risk of revision to patients with a smaller device and early fracture, there is no evidence Smith & Nephew had additional information that contradicted those assertions before Mr. Sedgwick's surgery. Smith & Nephew did not begin to receive ad hoc reports from Australian and UK registries showing longer-term higher rates of revision for patients with smaller head sizes until 2009, and it was not until 2015 that Smith & Nephew received data that undercut its assertions that the BHR's "as-cast" metallurgy was responsible for a revision rate that was lower than its heat-treated competitors. (ECF 2757-11, Ex. 9). Again, Mr. Sedgwick does not dispute this, but argues that Smith & Nephew cannot prove as a matter of law the inverse—that all of the above statements were true.[3]

[3] Smith & Nephew's contention that Mr. Sedgwick has conceded the truth of the above statements is not persuasive. Smith & Nephew cites testimony by Dr. Shapiro that the BHR did have better outcomes than other resurfacing systems (ECF 2756-17, Ex. O, Shapiro (Sept. 11, 2020) Dep. at 273; ECF 2756-18, Ex. P, Shapiro (Redick) Dep. at 320). But in this testimony, Dr. Shapiro appears to be discussing the BHR's overall performance relative to other resurfacing devices, not its performance in relevant subpopulations.

There is some minimal evidence in the record that Smith & Nephew had reason to be aware that the overall revision rates it used to market the BHR to Dr. Boucher overstated the success of the product, particularly for smaller head sizes like the one used for Mr. Sedgwick. For example, in 2006, Smith & Nephew's research department believed the company's data on Treacy and McMinn patients did not contain every observed revision in those patient populations, raising the inference that the risk of revision of the BHR may have been higher than previously thought. (ECF 2757-12, Ex. 10, Feb. 8, 2006 Tildesley Email). Smith & Nephew was aware at least as of the fall of 2007 that it had the ability to request more specific data. (ECF 2757-13, Ex. 11, Nov. 2007 Australian Registry response to Smith & Nephew request for data on reasons for revision by device).[4]

At best, Mr. Sedgwick has presented evidence to support an inference that Smith & Nephew had a general awareness of the possibility it was overstating the success of the BHR in comparison to its competitors and that it failed to investigate and present those impressions to surgeons like Dr. Boucher. Mr. Sedgwick claims such conduct can give rise to liability because it reveals Smith & Nephew made the above statements without reasonable care as to their veracity, citing *Appel v. Hupfield*, 198 Md. 374 (1951), *Galvagna v. Bank of America NA*, No. CV GLR-16-1696, 2016 WL 7474586, at *5 (D. Md. Dec. 29, 2016), and *Univ. Nursing Home, Inc. v. R.B. Brown & Assocs., Inc.*, 67 Md. App. 48 (1986). *Appel* addresses the elements of fraudulent misrepresentation in Maryland. In *Appel*, a real estate broker made a representation to the plaintiffs

[4] Mr. Sedgwick also seeks to use the 2011"ii4sm" report, an internal Smith & Nephew audit, to show that Smith & Nephew lacked a "systematic approach to safety science" and that the company ultimately did not know what the actual risk of revision was for the BHR in patients. (ECF 2842-10, Ex. 9). But the report does not include specific information regarding the company's knowledge of revision rates for the BHR. Accordingly, the report is irrelevant and not helpful to any of Mr. Sedgwick's claims.

that he could sell their house within a specific period of time. The court affirmed judgment for the broker because the record did not demonstrate that he had no intention of selling the house within that timeframe or otherwise believed he would be unable to do so. 198 Md. at 382–83. In *Galvagna*, the court dismissed the plaintiff's fraudulent misrepresentation claim where he did not plead any facts that suggested the defendant's representation was false or made with reckless indifference to its truth. 2016 WL 7474586, at *5. And in *R.B. Brown & Assocs.*, the Court of Special Appeals held that a plaintiff could maintain an action for negligent misrepresentation against an insurance agent after the agent made representations that business interruption insurance purchased would fully cover fire damage and then failed to include provisions in the policy that would live up to that representation. 67 Md. App. at 69.

The factual relevance of these cases to Mr. Sedgwick's case is not immediately apparent but all three seem to indicate that some awareness that a representation is misleading or fails to include relevant information at the time it is made is required to show that the defendant acted negligently, that is, without reasonable care. Other Maryland cases are in accord. *See, e.g.*, *Lubore v. RPM Assocs., Inc.*, 109 Md. App. 312, 341 (1996) ("Oft-quoted respected authorities recognize that a party may be liable for failing to exercise reasonable care to ensure that a partial disclosure is not rendered misleading by virtue of undisclosed information *known to be material*.") (emphasis added) (citing Restatement (Second) of Torts § 551(2)). Ultimately, Mr. Sedgwick's theory depends on imposing a duty on Smith & Nephew to seek out additional information and disclose it to surgeons. But the court has held that any claim that Smith & Nephew had a duty to warn the medical community is preempted. *See In re* BHR, 300 F. Supp. 3d at 745. And the duty to make "truthful, accurate, and not misleading" statements, *see id.*, requires only that Smith & Nephew not create a misleading impression by failing to disclose other known information. *See Lubore*,

109 Md. App. at 341. The record is clear that the information provided to Dr. Boucher during his 2006 training was consistent with Smith & Nephew's knowledge at the time the statements were made. Thus, those representations cannot support a negligent misrepresentation claim.

Finally, the court also is persuaded that Mr. Sedgwick cannot prove he relied on any misrepresentations made to Dr. Boucher. The parties agree that in order for Mr. Sedgwick to prove reliance, he must show that Dr. Boucher himself relied on a misrepresentation by Smith & Nephew in making his recommendation of the BHR to Mr. Sedgwick. *See* ECF 2831, Sedgwick Opp. at 25; ECF 2756-1, S&N Mot. at 22, citing *Kane v. Zimmer*, No. RDB-17-2268, 2018 WL 4005216, at *5 (D. Md. Aug. 22, 2018) (holding plaintiff can state a claim for negligent misrepresentation against medical device manufacturer based on their physician's reliance on alleged misrepresentations of the manufacturer).

Both parties largely rely on Dr. Boucher's testimony in the *Mosca* case as to what materials he did or would rely on in recommending a treatment option to a patient. Dr. Boucher testified that he relies on a combination of trainings, peer-reviewed literature, registry data, conferences, and, to a certain extent, information from manufacturers, in making treatment recommendations. (ECF 2757-5, Ex. 3, Feb. 7, 2020 Boucher Dep. at 35–38, 50–51, 112–13). With respect to the BHR, however, it appears that the majority of his information regarding the success of the product came from the 2006 Smith & Nephew sponsored training, as no voluntary communications were sent to Dr. Boucher between his training and Mr. Sedgwick's implant surgery. Though Dr. Boucher explained that he keeps up with literature generally and attends other conferences, it is not clear any of these sources included information regarding the BHR. So, it is plausible that the primary way he would have formed an opinion about revision rates for the BHR was through the Smith & Nephew training.

But on this record, and even if the statements made to Dr. Boucher about during his 2006 training could form the basis of a negligent misrepresenation claim, Mr. Sedgwick has not shown that additional information provided during the training from Smith & Nephew would have changed Dr. Boucher's recommendation to Mr. Sedgwick. The only piece of information Dr. Boucher has said he would like to have known is that the BHR had a projected ten-year failure rate of ten percent. (ECF 2831-5, Ex. 4, Jul. 24, 2020 Boucher Dep. at 9–10). Had he been so informed, he would have shared those rates with Mr. Sedgwick. (*Id.* at 10). He did not, however, testify that this information would have altered his recommendation to Mr. Sedgwick. And while Mr. Sedgwick has said that had Dr. Boucher told him of this revision risk, he would not have gotten the BHR, (ECF 2757-14, Ex. 12, Sedgwick Suppl. Interrogatory Responses at 21–22), his deposition testimony is to the contrary—he testified that he simply relied on Dr. Boucher's recommendations in selecting a resurfacing device. (ECF 2831-3, Ex. 2, Sedgwick Dep. at 93). *Cf. Barwick v. Celotex Corp.*, 736 F.2d 946, 959–60 (4th Cir. 1984) (affidavit conflicting with prior deposition testimony insufficient to create a genuine issue of material fact).

IV. Breach of Express Warranty

Smith & Nephew argues Mr. Sedgwick's breach of express warranty claim fails because it is (1) barred by the statute of limitations; (2) Mr. Sedgwick did not see, hear, or rely on any express warranties Smith & Nephew made.

Mr. Sedgwick's initial BHR implant took place in 2007 and his lawsuit was initiated in 2017. Generally, "under Maryland commercial law, the statute of limitations for breach of warranty claims is four years from the time of receipt." *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000) (citing Md. Code. Ann., Comm. Law I § 2–725 (1997)). But the Maryland Commercial Code contains an exception: "where a warranty explicitly extends to future

performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered." Md. Code. Ann., Comm. Law § 2–725(2). Mr. Sedgwick contends his claim falls within this exception because Smith & Nephew warranted that the BHR implant would last a specific period of time, about fifteen years. *See Joswick v. Chesapeake Mobile Homes, Inc.*, 362 Md. 261, 273–74 (2001) (recognizing that the exception in § 2-725(2) applies where a seller affirms that a good will have a certain quality or be free from certain defects for a stated period of time).

The alleged "fifteen-year" warranty comes from Dr. Boucher's testimony in the *Mosca* case regarding how long he expected the BHR device to last. Dr. Boucher acknowledged that when he appeared on the Diane Rehm show, he represented that an artificial hip placement generally lasts 15 years; he likely gave the same indication to Ms. Mosca before her surgery. (ECF 2514-3, Ex. 1, Feb. 7, 2020 Boucher Dep. at 164–65). That assertion was not specific to the BHR and there is no other evidence regarding whether his estimation of that number resulted from representations from Smith & Nephew. While Mr. Sedgwick recalls hearing someone mention that the BHR would last twenty years, he could not recall the source of this information; he does not believe Dr. Boucher was the source. (ECF 2831-3, Ex. 1, Sedgwick Dep. at 92). And the only material from Smith & Nephew Mr. Sedgwick claims to have seen specifically disclaims that the BHR will last a particular period of time: "It is impossible to say how long your implant will last because so many factors play into the lifespan of an implant." (ECF 2831-4, Ex. 3, "A Patient's Guide" at 22). Where nothing in the record suggests that Smith & Nephew was the source of an assertion the BHR would last twenty years, it would be impermissible to permit the jury to infer that Smith & Nephew made such a warranty to Mr. Sedgwick. *See Barwick v. Celotex Corp.*, 736 F.2d 946, 963

(4th Cir. 1984) ("Genuine issues of material fact cannot be based on mere speculation or the building of one inference upon another.").

V. Remaining Negligence Claims

a. Negligent Training Failure to Train

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. In this case, Mr. Sedgwick'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. Sedgwick's negligent training claim.

b. Misbranding

Mr. Sedgwick also seeks to hold Smith & Nephew liable under a negligence *per se* theory—Smith & Nephew's marketing and trainings contained non-FDA approved statements, messages, and information that violate federal regulations and parallel Maryland law. Under Maryland law, the breach of a statutory duty is evidence of negligence, but it does not constitute a separate action for negligence *per se*. *Bray v. Marriott Int'l*, 158 F. Supp. 3d 441, 445 (D. Md. 2016). The court construes this claim as one of common law negligence which Mr. Sedgwick seeks to prove through evidence of a violation of the statute.

Mr. Sedgwick cites Md. Code Ann., Health-Gen. §§ 21-256, 21-217(b)(1) as regulations Smith & Nephew violated through misleading marketing and extra-labeling statements. Section 21-217(b) deems a device "misbranded" if its labeling is false or misleading or if its labeling does not conform to certain requirements of the provision. *See* Md. Code. Ann., Health-Gen. § 21-217(b). 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. 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). Thus, in order to prove that Smith & Nephew violated this misbranding provision, Ms. Sedgwick would have to show that the FDA-approved labeling that accompanied the product was misleading, a claim which is preempted.

Section 21-256 prohibits the dissemination of a "false advertisement" for food, drugs, devices, and cosmetics. *See* Md. Code. Ann., Health-Gen. § 21-256. An advertisement is false "if it is false or misleading in any way." *Id.* § 21-247. Mr. Sedgwick represents that he intends to offer essentially the same evidence underlying his negligent misrepresentation and breach of warranty claims to support a theory that Smith & Nephew violated this statute. Accordingly, his negligence claim cannot survive, as it is coextensive with his negligent misrepresentation claim.

VI. Punitive Damages

Under Maryland law, "[t]here is no separate cause of action for punitive damages apart from an underlying cause of action upon which punitive damages can be grounded." *Biggs v. Eaglewood Mortg., LLC*, 582 F. Supp. 2d 707, 711 (D. Md. 2008) (citing *Exxon Corp. v. Yarema*, 69 Md. App. 124, 138 (1986). Because none of Mr. Sedgwick's claims for liability survive summary judgment, his claim for punitive damages also must fail.[5] Accordingly, Smith & Nephew's motion for summary judgment as to punitive damages will be granted.

[5] Additionally, because the court will award summary judgment to Smith & Nephew on all claims, it is unnecessary to address Mr. Sedgwick's motion for summary judgment as to Smith & Nephew's affirmative defenses.

CONCLUSION

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

8/19/2021
Date

/S/
Catherine C. Blake
United States District Judge