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: ***Phyliss Mosca v. Smith & Nephew, Inc.*, No. 1:18-cv-03520**

MEMORANDUM

Pending before the court are cross motions for summary judgment in BHR track action *Phyliss Mosca v. Smith & Nephew, Inc.*, No. 1:18-cv-03520. Ms. Mosca moves for summary judgment on her failure to warn, negligence, negligent misrepresentation, and breach of warranty claims. (ECF 2514). Ms. Mosca also seeks summary judgment on Smith & Nephew's affirmative defenses, including its defense of preemption. Smith & Nephew moves for summary judgment as to all of Ms. Mosca's claims. (ECF 2518). The motions have been fully briefed and oral argument was heard on April 14, 2021. For the reasons that follow, both motions will be granted in part, denied in part, and reserved in part.

BACKGROUND

This case concerns alleged injuries suffered by Ms. Mosca as a result of her 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, for reasons including complications due to metal debris. (ECF 2427, Ex. 28).[1] Ms. Mosca claims she was one such patient—her BHR implant required revision to a different implant due, in her surgeon's and expert's opinions, to symptoms caused by the accumulation of metal debris.

Ms. Mosca'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 which showed excellent and market-leading success rates for the BHR, while also requesting and receiving 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. Ms. Mosca refers to this information as "ad hoc data" or "ad hoc reports." Ms. Mosca further contends that the ad hoc data or reports were required to be disclosed to the FDA pursuant to several federal regulations and the BHR's PMA approval conditions. Had Smith & Nephew properly disclosed the ad hoc data to the FDA, Ms. Mosca contends that she would have been more fully informed of the magnitude of the

[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.

risk of the BHR before her surgery and would not have agreed to the BHR implant. Ms. Mosca also contends that by failing to incorporate its knowledge of the ad hoc data 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 Ms. Mosca was lower than it actually was. Had Ms. Mosca not been so misled, she would not have agreed to the BHR implant.

I. Ms. Mosca's BHR and Revision Surgeries

Ms. Mosca is a 55-year-old woman who lives in Forest Hill, Maryland. (ECF 2591-18, Ex. 17, Mosca Dep. at 7, 11). In or about 2003, Ms. Mosca began to experience pain in her right hip, which increased in severity over time. By 2007, the pain had "dramatically decreased her ability to do her normal activities," and was present while "walking standing, sitting, [and] lying down." (ECF 2518-10, Ex. H, 2007 Boucher Notes). That year, she began to see Dr. Henry Boucher regarding the pain. (*Id.*). Until that time, Ms. Mosca had been very physically active. (*Id.*). Dr. Boucher was able to treat Ms. Mosca's pain with non-surgical interventions for a few years but, by early 2010, the hip pain had worsened and was limiting Ms. Mosca's mobility. (ECF 2518-13, Ex. K, 2010 Dr. Boucher Notes). Dr. Boucher offered the option of two surgical interventions—a total hip replacement or a resurfacing. (ECF 2591-18, Ex. 17, Mosca Dep. at 147). Ms. Mosca recalls that Dr. Boucher explained that a resurfacing device came with the advantage of the ability to return to an active lifestyle. (*Id.*). Ms. Mosca decided to proceed with resurfacing, believing that it was the "best choice" for someone of her age and activity level. (*Id.* at 147–48). She did not research the BHR specifically prior to her implant surgery, nor does she recall receiving or reading any BHR-specific information or advertising. (*Id.* at 148–50).

Dr. Boucher's records indicate that he counseled Ms. Mosca on the risks, benefits, and alternatives of a BHR implant, including those posed by metal ion release associated with a metal-on-metal device. (ECF 2518-14, Ex. L, Post-Operative Notes).[2] Dr. Boucher testified that the probability and magnitude of the risk of revision of the BHR, as he understood it, is something he would have shared with Ms. Mosca and was an important component of obtaining Ms. Mosca's informed consent. (ECF 2514-3, Ex. 1, Boucher Dep. at 156–57, 175). Around the time of Ms. Mosca's implant surgery Dr. Boucher understood the failure rate of the BHR to be no more than five percent at ten years, (*id.* at 172), based on materials from Smith & Nephew, Smith & Nephew's 2006 training program, literature reviews, journals, conferences, and his review of publicly available American Registry information, (*id.* 156, 159–60, 163, 167–69, 172). He was also under the impression that the BHR was likely to last approximately fifteen years, and he would have shared that impression with Ms. Mosca. (*Id.* at 165–66). Dr. Boucher does not recall seeing data showing higher revision rates of the BHR for women compared to men. (*Id.* at 174–75). Had he seen the data showing higher revision rates for women, he would have shared those rates with Ms. Mosca. (*Id.* at 175). Failure rates for women reported in the Australian Registry at 9.5 percent at seven years, for example, would have been a "red flag" to Dr. Boucher, and he would have shared that information with a patient. (*Id.*). Ms. Mosca has said that had she known the failure rate of the BHR for women, she would not have agreed to the implant. (ECF 2514-19, Ex. 17, Mosca Suppl. Interrogatory Responses at 5, 31, 38).

Ms. Mosca had the BHR implanted on May 17, 2010. (ECF 2518-14, Ex. L, Post-Operative Notes). Nearly six years following the surgery, in April 2016, Ms. Mosca returned to Dr. Boucher

[2] Ms. Mosca does not recall being informed that the BHR was a metal-on-metal device. (ECF 2591-18, Ex. 17, Mosca Dep. at 150).

regarding "episodic" gluteal pain and thigh pain and a "clicking sensation in the low back/posterior hip." (ECF 2518-20, Ex. R, 2016 Boucher Notes). Ms. Mosca's blood work showed elevated cobalt and chromium ions. (ECF 2514-3, Ex. 1, Boucher Dep. at 15, 128, 132). Dr. Boucher's opinion was that the metal debris necessitated a revision surgery. (*Id.* at 134; ECF 2518-21, Ex. S, Operative Report). Ms. Mosca's expert, Dr. Shapiro, has opined that these elevated levels were indicative of metallosis which necessitated the revision surgery. (ECF 2518-31, Ex. CC, Shapiro (Mosca) Rep. at 19). On February 20, 2018, Ms. Mosca underwent revision surgery to a total hip arthroplasty ("THA") implant. (ECF 2518-21, Ex. S, Operative Report).

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

Between 2006 and 2010, Dr. Boucher attended at least three trainings or conferences regarding the BHR and was sent at least three marketing packets regarding the BHR—the training and materials all contained representations that the BHR's revision rates were between 1.5 and five percent overall, and those rates were not broken down by gender or head size.

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 2514-3, Ex. 1, Boucher 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).

In 2007, 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 2514-4, Ex. 2 at 1–3; ECF 2514-6, Ex. 4, Fifth Am. Def. Fact Sheet at 2; ECF 2514-3, Ex. 1, Boucher Dep. at 160). 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. (ECF 2514-4, Ex. 2 at 2). 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 between 7.4 and 16.4 percent. (*Id.* at 3).

In October 2007, Dr. Boucher attended a conference which included a talk focused on the 10-year anniversary of the BHR. (ECF 2514-3, Ex. 1, Boucher Dep. at 82; ECF 2514-6, Ex. 4 at 4). That presentation discussed Australian Registry data showing that the risk of revision for the BHR in females was twice that for males. (*Id.* at 86–87; ECF 2514-5, Ex. 3, Slides). This risk was not discussed, however, as one associated with the device; rather the explanation given was that female patients had a higher risk of fracture in the near-term following surgery. (ECF 2514-3, Ex. 1, Boucher Dep. at 86–87). In another BHR training Dr. Boucher attended in 2009, the elevated risk of revision for females was attributed to differences in post-operation management and surgical technique during a talk called "Is there a Gender Difference?" (*Id*. at 87–89, 160–61; ECF 2514-6, Ex. 4 at 4; ECF 2591-3, Ex. 2).

On May 1, 2009, Smith & Nephew sent to Dr. Boucher a letter providing information on the issue of "pseudo-tumors" in metal-on-metal hip resurfacing. (ECF 2514-4, Ex. 2 at 10–11; ECF 2514-6, Ex. 4 at 2). The letter notes a recent study in the Journal of Bone and Joint Surgery showing incidents of these tumors in female patients and argues that while the finding "could" be interpreted as a gender-specific higher susceptibility to metal ion hypersensitivity, previously published data in the 2007 Australian registry showed that the revision rate for any cause other than fracture, loosening, infection, and dislocation was only 0.32 percent overall and that the BHR had a 95 percent survivorship rate at seven years. (ECF 2514-4, Ex. 2 at 10).

Also in 2009, Smith & Nephew sent to Dr. Boucher a summary of the Australian Registry's 2009 annual report. (ECF 2514-8, Ex. 6). Though the mailer includes a cover letter to surgeons

that highlights favorable survivorship rates for males under fifty-five years of age, it also includes a table comparing the BHR's revision rates for *all* patients compared to those of its competitors. In this table, the BHR has lower revision rates, 3.6 percent at five years and 4.8 percent at seven years. In comparison, its competitors' rates are as high as 9.7 percent at five years and sixteen percent at seven years. (*Id.*).

III. Smith & Nephew's Knowledge of Revision Rates and Reporting to FDA

At least as of 2008, Smith & Nephew internal documents show a general awareness that peer-reviewed literature indicated that revision rates for the BHR were higher for females and patients with smaller head sizes than the overall revision rates for all patients. (ECF 2514-15, Ex. 13 at 3, 18). Nonetheless, Smith & Nephew remained committed to using overall revision rates published in annual registry reports in its marketing materials as part of a "simple 3 point messaging" plan which consisted of highlighting the BHR's "bone conserving" aspects, its "metallurgy," and its "clinical results." (*Id.* at 9). Around the time of Ms. Mosca's surgery, the company continued to urge its sales team to "be active and call on your surgeons to share the excellent results of BHR" by stressing that overall revision rates of the BHR were lower than its competitors. (ECF 2514-11, Ex. 9 at 3). This advice was in response to a British Hip Society and British Orthopedic Association alert regarding adverse patient reactions to metal debris caused by metal-on-metal hip implants. (*Id.* at 2).

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, Boucher Dep. at 162). In Australian Registry Ad Hoc Report 425, dated September 25, 2009, the

revision rate for females was 6.9 percent five years after implantation, and 9.1 percent seven years after implantation. For head sizes between 38 and 44 mm, the revision rates were even higher, at 10.5 percent five years after implantation and 13.5 percent seven years after implantation. (ECF 2514-16, Ex. 14 at 9–10). Smith & Nephew also received Australian Registry Ad Hoc Report 408, dated October 2009, which showed that for female patients younger than 65 implanted with a device with a head size less than 50 mm, the revision rate was 9.5 percent after seven years. (ECF 2514-17, Ex. 15 at 7).

Dr. Boucher has said that the revision rates for women and smaller head sizes contained within the ad hoc reports above would have been a "red flag" to him in terms of recommending the BHR to Ms. Mosca. (ECF 2514-3, Ex. 1, Boucher Dep. at 175).

IV. Regulatory Background

The FDA awarded premarket approval ("PMA") to the BHR as a Class III medical device in 2006. *In re BHR*, 300 F. Supp. 3d at 736.[3] The approval authorized Smith & Nephew to begin distribution of the BHR in the United States, subject to a number of conditions. Some of those conditions mandated that Smith & Nephew comply with various federal regulations.

Smith & Nephew was required to submit annual post-approval reports under 21 C.F.R. § 814.84, which must include a "[b]ibliography and summary of" information not previously submitted as part of the PMA "that is known to or reasonably should be known to the applicant[,]" including "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices[.]" (*See* ECF 2427, Ex. 9, at 9, citing 21 C.F.R. § 814.84).

[3] The court refers to its previous opinion for a further explanation of the PMA approval process. *See In re BHR*, 300 F. Supp. 3d at 736–37.

Smith & Nephew also was required to comply with the FDA's Medical Device Reporting ("MDR") Regulation, 21 C.F.R. § 803 *et seq.* (*See* ECF 2427, Ex. 9, at 10). The MDR regulation mandates that a manufacturer of a medical device must report to the FDA whenever it becomes aware of information, from any source, that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and the device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. 21 C.F.R. § 803.50(a). If an MDR reportable event "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health," a report to the FDA is due within five days of the manufacturer becoming aware of the need for remedial action. *Id* § 803.53. A "trend analysis" is one manner by which a manufacturer may become aware of such information, but the regulation does not require that such analysis accompany the five-day report; rather, the five-day report must include all information described in 21 C.F.R. § 803.52. *Id.* The FDA "may disclose to the public any report" submitted under the MDR regulations. 21 C.F.R. § 803.9(a).

The PMA also included four conditions requiring Smith & Nephew to submit certain data to the FDA every six months for the first two years following the PMA approval, and annually thereafter until completion of post-approval studies and the submission of a final report. (ECF 2427, Ex. 9 at 5). Condition No. 4 required Smith & Nephew "to provide an analysis of adverse events and complaints (including MDRs) received regarding the BHR system." (*Id.* at 6).

Smith & Nephew submitted annual PMA reports to the FDA in 2008, 2009, and 2010. (ECF 2516-19, Ex. Q; ECF 2516-20, Ex. R; ECF 2516-21, Ex. S; ECF 2516-22, Ex. T; ECF 2516-23, Ex. U). Smith & Nephew did not include the ad hoc reports discussed above or the data underlying them in the PMA reports. (*See, e.g.*, ECF 2515-22, Ex. 20, Tillman Dep. at 178–79).

PROCEDURAL HISTORY

On November 14, 2018, Ms. Mosca filed a complaint including eight 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), breach of express warranties (Count VII), manufacturing defect (Count VIII), and punitive damages (Count IX). (ECF 2518-3, Ex. A, Mosca 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 (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 parties filed cross motions for summary judgment on March 12, 2021. (ECF 2514, Mosca MSJ; ECF 2518, Smith & Nephew MSJ). The motions have been fully briefed (ECFs 2591, 2594, 2638, 2641) and oral argument was heard on April 14, 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*, 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

Ms. Mosca argues she is entitled to summary judgment on each of her claims as to liability, and on Smith & Nephew's thirty-eight affirmative defenses, including preemption. Smith & Nephew reasserts its preemption defenses and argues that Ms. Mosca's claims, including claims for punitive damages, also fail because Maryland law does not recognize the legal theories under which she proceeds, because one or more claims are barred by the statute of limitations, 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, negligence, and breach of express warranties—and will address any remaining preemption arguments in the context of each claim. The court will then address punitive damages and the balance of Smith & Nephew's affirmative defenses. The court will conclude, consistent with its prior rulings, that Ms.

Mosca's negligent misrepresentation and negligence claims predicated on alleged false or misleading statements by Smith & Nephew are not preempted. The court will further conclude that Smith & Nephew is entitled to summary judgment as to a negligent training claim because the claim is preempted; Smith & Nephew is entitled to summary judgment on Ms. Mosca's negligent failure to warn claim because she has failed to present an issue of material fact as to causation; and Smith & Nephew is entitled to summary judgment on Ms. Mosca's breach of express warranty claim because it is barred by the statute of limitations. Summary judgment will be denied to both parties with regard to Smith & Nephew's liability for negligent misrepresentation and negligence based on false or misleading statements. The court will reserve ruling on Smith & Nephew's motion as to punitive damages. Ms. Mosca's motion with respect to the remaining affirmative defenses will be granted in part, denied in part, and reserved in part.

I. Negligent Failure to Warn

Smith & Nephew contends that it should be granted summary judgment on Ms. Mosca's negligent failure to warn claim because (1) the claim is preempted, and (2) the plaintiffs cannot show that any failure to warn the FDA caused Ms. Mosca's injuries. Ms. Mosca argues she is entitled to summary judgment because (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 her 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 will not fully recount it here. *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). Briefly, the states are expressly preempted from establishing with respect to devices intended for human use any requirements which are different from or in addition to requirements imposed under the FDA's statutory framework governing PMA approval of medical devices. *See, e.g.*, *In re BHR*, 300 F. Supp. 3d at 742–43; *see also* 21 U.S.C. § 360k. And a state law is impliedly preempted "if the law exists 'solely' by virtue of the federal requirements and is not a 'traditional state tort law which [] predate[s] the federal enactments in question[].'" *Daubert* Ruling, 2021 WL 781682, at *2 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)). Thus, to survive a preemption challenge, "'a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption).'" *Id.* (quoting *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017)).

Pursuant to this court's prior rulings, the following of the plaintiffs' original claims are preempted:

- any strict liability claims;
- any claim that Smith & Nephew had a duty to change its labeling;
- any claim that Smith & Nephew had a duty to directly warn patients or the medical community (as opposed to a duty to warn the FDA);
- any claim that attempts to impose liability on Smith & Nephew for claiming the BHR was safe (as opposed to safer than competitor models);
- and any claim that attempts to impose liability on Smith & Nephew for any representation the FDA required Smith & Nephew to make.

In re BHR, 300 F. Supp. 3d at 743, 745, 747–48. But the plaintiffs' other claims, to the extent they parallel federal obligations, are not necessarily preempted. *See id.* 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, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013)).

But Smith & Nephew argues that Ms. Mosca'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, notwithstanding the court's noting in *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733 (D. Md. 2015) that Maryland's requirement that a manufacturer make "'reasonable efforts' to convey an effective warning" "would, in some circumstances, entail a warning to a third party such as the FDA." *Id.* at 742 (quoting *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 646 (Md. 1992)). Smith & Nephew cites the rejection of such a duty under the laws of many states other than Maryland. *See, e.g.*, *Conklin v. Medtronic, Inc*., 245 Ariz. 501, 507 (2018); *McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 575–78 (E.D.N.C. 2019); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016). As explained in the court's memorandum addressing cross-motions for summary judgment in BHR track action *Paula and Jace Redick v. Smith & Nephew, Inc.*, No. CCB-17-944, (ECF 2715, hereinafter "*Redick* Mem."), the cases Smith & Nephew cites on this point follow a line of federal case law that require plaintiffs alleging failure to warn claims against a medical device manufacturer to point to a specific and traditional state law duty to report information to the FDA (or at least to a regulatory body) in order to establish a parallel state law duty that survives preemption. (*Id.* at 15–16). As in *Redick*, the court declines to adopt similar reasoning, in favor of the reasoning of other courts which have held that, where state law imposes a duty to warn a third party, such as a medical practitioner, a failure to warn claim may be premised on the failure to comply with federal regulations mandating certain reports to the FDA. *See Hughes v. Boston Sci. Corp.*, 631 F. 3d 762, 769–70 (5th Cir. 2011); *Rosen v. St. Jude*

Med., Inc., 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014); *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017). It is, however, unnecessary to decide specifically whether Maryland recognizes such a duty in this circumstance, because Ms. Mosca cannot satisfy the difficult element of causation.

b. Causation

In order to show causation as to her failure to warn the FDA and negligence per se claims, Ms. Mosca 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 her doctors in time to prevent her injuries." *Daubert* Ruling, 2021 WL 781682, 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, Ms. Mosca'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 Ms. Mosca'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). As in *Redick*, Ms. Mosca has identified only one potential source where the data may have been publicized—the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. The FDA's MAUDE database is a repository of MDR reportable events. *See MAUDE—Manufacturer and User Facility Device Experience*, FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (last accessed July 13, 2021); *see also* 21 C.F.R. § 803.9(a) (providing for the disclosure of any MDR report).

Courts have recognized the viability of a theory of causation for a failure to warn claim whereby MDR reports are disseminated to the public through the MAUDE database, and those reports are then relied upon by doctors in assessing the safety of medical devices for their patients. *See, e.g.*, *Hughes*, 631 F.3d at 770 & n.5, 776; *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1232–33 (N.D. Cal. 2014); *Rosen*, 41 F. Supp. 3d at 187; *Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1286 (N.D. Ga. 2014). But the plaintiffs cannot complete this chain. While there is evidence that hip implant device data from the MAUDE database is commonly cited in journals Dr. Boucher may have read and in other medical education materials, (ECF 2591-35, Ex. 34 at 5; ECF 2591-36, Ex. 35 at 11; ECF 2591-37, Ex. 36 at 19), just as in *Redick*, there is insufficient evidence to support a jury's inference that the ad hoc data at issue here would have been published in the MAUDE database. *See, e.g.*, *Cline*, 17 F. Supp. 3d at 1286–87 (dismissing negligent failure to warn claim based on a failure to timely file MDRs because the FDA's disclosure of MDRs to the public is not guaranteed and the plaintiffs did not clearly allege that "the Defendant outright failed to file an MDR for these events; only that they were not timely filed"). (*See also Redick* Mem. at 18).

II. Negligent Misrepresentation

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 (2007) (internal quotation marks omitted).

Ms. Mosca contends that extra-labeling statements and marketing materials provided to Dr.

Boucher claiming that the BHR was different from or had a competitive advantage over other metal-on-metal hip implants because of its comparatively lower overall revision rates in international registries misrepresented the actual revision risk to female patients and patients needing smaller head sizes. She argues that Dr. Boucher relied on those representations in recommending the BHR to her and that she selected the device on his recommendation, resulting in injury to her. Had Smith & Nephew more accurately represented the magnitude of risk to Dr. Boucher, he would have shared that risk, which he described as a "red flag," with her, which would have altered her own calculus in deciding whether or not to agree to the implant. *See, e.g.*, *Kane v. Zimmer Biomet Holdings, Inc.*, No. CV RDB-17-2268, 2018 WL 4005216, at *5 (D. Md. Aug. 22, 2018).

Smith & Nephew argues that Ms. Mosca's claim fails for three reasons: (1) Smith & Nephew owed no duty to Ms. Mosca under Maryland law; (2) Smith & Nephew made no false statements of material fact; and (3) Ms. Mosca cannot show justifiable reliance or causation. The court will address these arguments in turn.

First, Smith & Nephew argues that "[u]nder FDA regulation and Maryland law, a device manufacturer owes no duty to provide information or warnings about a device to patients or consumers," 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). In *St. Jude*, the court dismissed a negligent misrepresentation claim brought against a medical device maker by the parents of a child after the child's pacemaker battery failed. The plaintiffs had been assured by their doctor that the device had a particular life expectancy, but the battery stopped working sooner than expected. *Id.* at *2. The complaint did not include any specific allegations of the content of what the device manufacturer communicated to the doctor with respect to the life expectancy of the device. *Id.* at

*5. The court observed that any duty owed by the manufacturer to present accurate information or warnings was to the child's doctor, as an extension of the learned intermediary doctrine—"the duty is owed to the prescribing physician, to allow the physician to provide casespecific information about the potential risks and benefits of proposed treatment to his or her patients." *Id.* Ms. Mosca's claim, however, is not based on an alleged duty to present accurate information directly to her. Her theory is that Smith & Nephew had a duty to provide Dr. Boucher with truthful, non-misleading information about the BHR, which would then inform Dr. Boucher's recommendations. *St. Jude* support this theory of liability, as do other Maryland cases. *See id.* at *5; *McCormick v. Medtronic, Inc.*, 219 Md. App. 485, 528 (2014); *Kane*, 2018 WL 4005216, at *5 (under learned intermediary doctrine, relevant inquiry is whether the treating physician relied on misrepresentation); *McCoy v. Biomet Orthopedics, LLC*, No. CV ELH-12-1436, 2021 WL 252556, at *27 (D. Md. Jan. 25, 2021) (causation-in-fact in negligence claim against hip implant manufacturer depended on whether plaintiff's treating physician would have acted differently if he had received different information from the manufacturer).

Second, Smith & Nephew argues there is no evidence it made any false statements of material fact. "[A]s other courts in this District have recognized, 'Maryland law distinguishes between statements that relate to material facts—which may give rise to cognizable claims—and vague generalities, statements of opinion, or puffery—which are deemed non-cognizable.'" *Kiddie Acad. Domestic Franchising, LLC v. Wonder World Learning, LLC*, No. CV ELH-17-3420, 2020 WL 4338891, at *21 (D. Md. July 27, 2020) (citing cases). Omissions may "give[] rise to a negligent misrepresentation claim . . . where the defendant was not silent but affirmatively represented only part of the truth." *Id.* at *24 (internal quotation marks omitted). *See also Lubore v. RPM Assocs., Inc.*, 109 Md. App. 312, 341–42 (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.").

Ms. Mosca has presented evidence that Smith & Nephew made certain representations during Dr. Boucher's training and in marketing materials that the BHR had lower revision rates overall than its competitors, specifically rates between 1.5 and five percent, citing British and Australian registry data. (*See* ECF 2514-3, Ex.1, Boucher Dep. at 169–72; ECF 2515-4, Ex. 2). These statements are not ones of opinion and are distinguishable from those in cases Smith & Nephew cites in which a defendant's statements were too vague or general to give rise to a cognizable misrepresentation claim. For example, in *Kiddie Academy*, the defendant induced the plaintiff to enter into a franchisor-franchisee agreement by making vague representations as to the ease of entering into the agreement, including statements that the franchisor's curriculum "was as good [as] or better than its best competitor" and potential franchisees needed no experience, without facts to support those assertions. 2020 WL 4338891, at *21. And in *Baney Corp v. Agilysys NV, LLC*, 773 F. Supp. 2d 593, 608–09 (D. Md. 2011) the defendant asserted only that its system was "easy to use and perfect for a multi-property environment." *Id.*

Under Maryland law, once Smith & Nephew made specific representations comparing its revision rates to those of its competitors, it undertook a duty to make truthful and non-misleading disclosures as to its revision rates. *See Lubore*, 109 Md. App. at 342 (negligent misrepresentation claim viable where defendant "not silent, but rather affirmatively represented only part of the truth"). For female patients and patients needing smaller head sizes, Smith & Nephew learned its revision rates were much worse than the rates it touted in its marketing materials and were not meaningfully distinct from its competitors for those populations. (*See, e.g.*, ECF 2514-16, Ex. 14;

ECF 2514-17, Ex. 15). Ms. Mosca's claim that it was misleading to continue to refer to an overall comparison in light of that knowledge is a cognizable theory of negligent misrepresentation under Maryland law and is a question for the jury.[4]

Third, Smith & Nephew contends that Ms. Mosca cannot prove that she relied on any misrepresentations made to Dr. Boucher. Ms. Mosca's evidence that Dr. Boucher relied on Smith & Nephew's representations of revision rates consists primarily of evidence that he was informed of revision rates between one and three percent during his 2006 training and thereafter Smith & Nephew sent him marketing materials containing public Australian registry data that publicized similar revision rates for all patients and were not broken down by gender. (ECF 2514-3, Ex.1, Boucher Dep. at 154–56; ECF 2514-8, Ex. 6 at 2; ECF 2591-3, Ex. 2 at 2).[5] Boucher attended at least two additional meetings and/or trainings at which the performance of the BHR and its revision rates were discussed (ECF 2514-3, Ex. 1, Boucher Dep. at 86–89, 160–61; ECF 2514-4, Ex. 6 at 4; ECF 2591-3, Ex. 2 at 3; ECF 2514-5, Ex. 3). The agenda for one such conference, in 2009,

[4] The court rejects the plaintiffs' contention that Smith & Nephew's marketing was misleading as a matter of law. The cases cited in support of this argument simply acknowledge that a court may determine a statement misleading as a matter of law, but do not address facts similar to those in this case. *See In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202, 1259–60 (S.D. Cal. 2010) (on claims of violations of federal securities law, the court found a statement misleading as a matter of law, but because it concerned a "tangential" issue, it was insufficient to create a triable issue of fact); *Janda v. Riley-Meggs Indus., Inc.*, 764 F. Supp. 1223, 1228 (E.D. Mich. 1991) (concerning misleading statements under the Lanham Act); *McMahon v. LVNV Funding, LLC*, 301 F. Supp. 3d 866, 877–78 (N.D. Ill. 2018) (concluding letter misleading under the FDCPA). Smith & Nephew has pointed to evidence in the record from which a reasonable jury could conclude that the BHR was at least the "best of the worst" in terms of the performance of resurfacing devices for patients like Ms. Mosca and thus that the comparison of its overall revision rates with its competitors was not misleading. (ECF 2593-2, Ex. A, Shapiro Dep. at 320).

[5] There is evidence Boucher received information in 2007 and 2010 showing a higher risk of revision for females, but it appears he believed it was a risk in the short term, due to potentially higher fracture rates rather than metallosis. (ECF 2514-3, Ex. 1, Boucher Dep. at 86–87, 91, 161, 192–94).

includes talks that discuss revision rates and the long-term viability of the device similar to that discussed in 2006 and available in the public registry data. (ECF 2591-3, Ex. 2 at 3 (noting total survivorship of 94.7 percent after 10 years)). Another talk at the same conference appears to have attributed gender differences to fracture risks and errors in technique. (ECF 2591-3, Ex. 2 at 3). Subsequent to these trainings, materials, and conferences, and at the time of Ms. Mosca's surgery, Dr. Boucher believed BHR to perform better than other metal-on-metal devices. (ECF 2514-3, Ex. 1, Boucher Dep. at 166). Dr. Boucher testified that had he known of the gender-specific revision rates from the Australian registry data, he would have considered that data a "red flag" with regard to whether to recommend the device to Mosca and would have shared that data with Mosca. (*Id.* at 161–62, 175). Ms. Mosca in turn affirmed in answers to interrogatories that disclosure of higher revision rates would have altered her decision. (ECF 2514-19, Ex. 17, Mosca Suppl. Interrogatory Responses at 5, 31, 38).

At the same time, Smith & Nephew appears to be correct that Dr. Boucher never specifically testified he recommended the BHR to Ms. Mosca based solely on company advertising materials. (ECF 2514-3, Ex.1, Boucher Dep. at 51). And Smith & Nephew presents evidence that Boucher was aware of the magnitude of risk to Ms. Mosca based on his own experience of implanting the BHR, in which he saw a 10 percent revision rate, and that he educated himself on the product through non-Smith & Nephew specific conferences and literature. (ECF 2514-3, Boucher Dep. 16–18, 37–38, 87–88). This evidence is not dispositive. Dr. Boucher's testimony regarding his own patient population includes his estimate of revision rates for his patients from 2006 to 2017; therefore, it does not definitively show what he understood at the time of Ms. Mosca's surgery. Furthermore, Dr. Boucher does not recall many of the details of the other conferences and literature to which Smith & Nephew points. A jury hearing this evidence and Ms.

Mosca's evidence of Smith & Nephew's marketing to and training of Dr. Boucher could draw the inference that the primary way Dr. Boucher formed an opinion about revision rates for the BHR was through marketing materials and trainings. (*Id.* at 38). Thus, this case is distinct from *Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 105–06 (D. Md. 2020), on which Smith & Nephew primarily relies. In that case, the plaintiff could not show that her doctor relied on any misrepresentations by a device manufacturer that inflated survivorship rates and downplayed the risks of the device where the doctor specifically disavowed that he relied on companies to give him information, stating: "I make my own decisions. I research it in peer-reviewed literature. I, by and large, don't rely on representatives of companies to give me information" *Id.* at 106. There was no other evidence that the doctor relied on the manufacturer's statements in selecting the device. *Id.* Ms. Mosca's case is closer to *In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 127 F. Supp. 3d 1306, 1362–64 (N.D. Ga. 2015) in which the court denied a device manufacturer's motion for summary judgment on a negligent misrepresentation claim where the plaintiff's physician believed that the plaintiff was a good candidate for a hip implant based in part on information given by the manufacturer's representatives. *Id.* at 1364.

III. Remaining Negligence Claims

In her remaining common-law negligence claims, Ms. Mosca seeks to prove that Smith & Nephew was negligent in (1) failing to report adverse events to the FDA; (2) making off-label statements during Dr. Boucher's training relating to the magnitude of risk of revision in the BHR, in violation of training requirements under the PMA; and (3) making false or misleading statements regarding the success rates of the BHR, in violation of Maryland misbranding and false advertising statutes. 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. Failure to Report Adverse Events

Ms. Mosca contends that a failure to report adverse events to the FDA, in violation of the PMA, constitutes negligence *per se*. 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 Ms. Mosca seeks to prove through evidence of a violation of a statute. Nonetheless, this claim suffers from the same causal deficiencies as her failure to warn claim, discussed above. There are no material facts to support a jury finding that had Smith & Nephew disclosed ad hoc data and reports from international registries to the FDA, the data would have been publicized such that it would have informed Dr. Boucher's risk assessment of the BHR implant for Ms. Mosca. Accordingly, summary judgment will be awarded to Smith & Nephew on this claim.

b. Negligent 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 FDA's requirement to implement the program and is preempted. *Redick* Mem. at 28–29. But to the extent plaintiffs in this MDL claim that misleading revision rates were touted as part of the training program, such evidence may support a non-preempted negligent misrepresentation or a breach of express warranty claim. *Id.* Ms. Mosca'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 Ms. Mosca's negligent training claim.

c. Misbranding

Ms. Mosca also seeks to hold Smith & Nephew liable under a separate 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, citing Md. Code Ann., Health-Gen. §§ 21-256, 21-217(b)(1).

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. Mosca 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. Ms. Mosca represents that she intends to offer essentially the same evidence underlying her negligent misrepresentation claim to support a theory that Smith & Nephew violated this statute. Accordingly, her negligence claim survives to the same extent as her negligent misrepresentation claim.

IV. Breach of Warranty

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

Mosca's initial BHR implant took place in 2010 and her lawsuit was initiated in 2018. 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) (emphasis added). Ms. Mosca contends her 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 and Ms. Mosca's testimony regarding how long they expected the BHR device to last. Dr. Boucher acknowledged that when he appeared on NPR's 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, Boucher Dep. at 164–65). That assertion was not as to the BHR specifically and there is no other evidence regarding whether his estimation of that number resulted from representations made by Smith & Nephew. Ms. Mosca recalls Dr. Boucher telling her he was pretty

certain the BHR would last 15 or 20 years and that she did her own research to gain the understanding that the BHR could last up to 25 years. (ECF 2591-18, Ex. 17, Mosca Dep. 157–58). That testimony is not evidence that those representations came from Smith & Nephew. Where nothing in the record suggests that Smith & Nephew was the source of an assertion the BHR would last fifteen years, it would be improper to permit the jury to infer that Smith & Nephew made such a warranty to Ms. Mosca. *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. Punitive Damages

"In a non-intentional tort action, the trier of facts may not award punitive damages unless the plaintiff has established that the defendant's conduct was characterized by evil motive, intent to injure, ill will, or fraud, i.e., 'actual malice.'" *Zenobia*, 325 Md. at 460. In products liability cases, the equivalent of "actual malice" is "actual knowledge of the defect and deliberate disregard of the consequences." *Id.* at 462. "[T]he test requires a bad faith decision by the defendant to market a product, knowing of the defect and danger, in conscious or deliberate disregard of the threat to the safety of the consumer." *Id.* at 463. Actual malice must be established by clear and convincing evidence. *Id.* at 469.

Smith & Nephew argues that compliance with federal law precludes a finding of actual malice and that plaintiffs cannot present any evidence of actual malice. Neither argument persuades the court to preclude punitive damages at this time. First, as explained previously, whether Smith & Nephew violated post-PMA federal requirements to present truthful and non-misleading information remains in dispute. Second, Ms. Mosca argues that evidence showing Smith & Nephew concealed ad hoc reports from the FDA while at the same time marketing the

BHR as having low revision rates overall could support a jury finding that Smith & Nephew acted with an intent to injure, with an evil motive, or with intent to defraud. The court believes it may be more apparent in the context of trial whether such evidence is sufficient to submit an issue of punitive damages to the jury, and also notes that Smith & Nephew has made a related motion to bifurcate the trial on the issue of punitive damages (ECF 2596). For now, the court will defer ruling on the issue of punitive damages.

VI. Smith & Nephew's Affirmative Defenses

Ms. Mosca moves for summary judgment on all of the affirmative defenses Smith & Nephew invoked in its answer to the Master Amended Consolidated Complaint. (ECF 663). Smith & Nephew concedes that it does not intend to assert the majority of these defenses. The court accordingly will deny as moot Ms. Mosca's motion as to defenses Smith & Nephew has disclaimed.[6] [7]

The court also will deny as moot the plaintiffs' motion regarding defenses that pertain only to claims which are not proceeding to trial. Smith & Nephew asserts the following defenses only in connection with Ms. Mosca's failure to warn claim: Smith & Nephew had no post-sale duty to warn the plaintiffs (First Affirmative Defense); Dr. Boucher was aware of the risks of the BHR

[6] These defenses include: comparative fault of the plaintiffs and others (Third and Fourth Affirmative Defenses); superseding cause (Fifth Affirmative Defense); laches (Ninth Affirmative Defenses); contracts (Twelfth Affirmative Defense); unintended use (Thirteenth Affirmative Defense); lack of privity (Sixteenth Affirmative Defense); primary jurisdiction (Twenty-Second Affirmative Defense); waiver and/or estoppel (Twenty-Third Affirmative Defense); disclaimers bar claims for breach of express warranty (Twenty-Fourth Affirmative Defense); condition of warranties (Twenty-Sixth Affirmative Defense); failure to follow warnings accompanying the product (Twenty-Eighth Affirmative Defense); misuse of product (Twenty-Ninth Affirmative Defense).

[7] Ms. Mosca's motion as to Smith & Nephew's federal preemption defense (Tenth Affirmative Defense) is addressed elsewhere in this memorandum, above.

(Nineteenth Affirmative Defense); applying the learned intermediary doctrine, any duty to warn Ms. Mosca was discharged by providing adequate warnings to surgeons (Twentieth Affirmative Defense); no additional warnings were required, as the BHR was not unreasonably dangerous (Twenty-First Affirmative Defense); and the BHR was manufactured in accordance with the state of the art (Thirty-Sixth Affirmative Defense). (*See* ECF 663 at 1, 114–15, 119). As explained above, Smith & Nephew is entitled to judgment on Ms. Mosca's failure to warn claim because any claim based on a failure to warn surgeons or Ms. Mosca directly is preempted and Ms. Mosca cannot meet the causation element of a failure to warn claim based on a failure to warn the FDA.

And because Ms. Mosca's breach of express warranty claim is barred by the statute of limitations, the court will deny as moot Ms. Mosca's motion as to the following defenses which are applicably only to that claim: statute of limitations (Eighth Affirmative Defense); no reliance on warranties (Seventeenth Affirmative Defense); express warranties were true (Eighteenth Affirmative Defense); and failure to provide timely notice (Twenty-Fifth Affirmative Defense). (*See id.* at 112, 114, 116).

The court will now address the remaining disputed affirmative defenses.

a. Failure to Mitigate Damages (Sixth Affirmative Defense)

Smith & Nephew claims that the plaintiffs have failed to mitigate damages (Sixth Affirmative Defense). In Maryland, an injured person has a duty to "use ordinary care to alleviate the effects of the injury or breach." *Cave v. Elliott*, 190 Md. App. 65, 96 (2010). Smith & Nephew contends summary judgment as to this defense is premature as Ms. Mosca has not provided evidence of damages at all, and that evidence is uniquely in her hands. But the plaintiffs have produced evidence of damages in this matter. (*See* ECF 2518-5, Ex. C, Fifth Am. Pl. Fact Sheet at Section VIII). Though Smith & Nephew has so far failed to proffer evidence that would support a

defense of failure to mitigate, this issue is better addressed in connection with jury instructions in the context of trial. Accordingly, the court will defer ruling on Ms. Mosca's motion as to this affirmative defense.

b. Contributory Negligence and Failure to Exercise Ordinary Care (Eleventh and Twenty-Seventh Affirmative Defenses)

Several of Smith & Nephew's affirmative defenses focus on allegations that Ms. Mosca's injuries were caused by her own negligence. Ms. Mosca argues summary judgment is appropriate because there is no record evidence to support any of these defenses.

As to their claim that Ms. Mosca was contributorily negligent (Eleventh Affirmative Defense) and failed to exercise ordinary care on her own behalf (Twenty-Seventh Affirmative Defense), Smith & Nephew points to evidence in the record that Ms. Mosca chose to take chromium supplements from 2011 to 2014. (ECF 2518-31, Ex. CC, Shapiro (Mosca) Rep. at 9, 11–12; ECF 2518-22, Ex. T. Hungerford Rep. at 3).

However, as explained in the court's memorandum addressing the plaintiffs' motion to exclude Dr. Hungerford's testimony, Dr. Hungerford never opines that chromium supplements were a cause of Ms. Mosca's hip implant failure. (*See* ECF 2717 at 28). And Smith & Nephew has conceded that his opinion is not intended to suggest as much; it is intended only to counter Dr. Shapiro's opinion that Ms. Mosca's BHR is the only factor that led to her elevated chromium levels. (*Id.*). Smith & Nephew has failed to identify any evidence that would support an inference that chromium supplements caused Ms. Mosca's injuries.

Smith & Nephew further contends that Ms. Mosca failed to exercise ordinary care (Twenty-Seventh Affirmative Defense) because she failed to heed Dr. Boucher's warnings of the risks of the BHR. Any discrepancy between Ms. Mosca's and Dr. Boucher's recollections regarding the warnings Ms. Mosca was given goes to the weight and credibility of her testimony

but does not create an affirmative defense for Smith & Nephew. Smith & Nephew can hardly argue that Ms. Mosca's decision to get the BHR implant despite warnings was negligent and at the same time maintain, as it has throughout this litigation, that the BHR was safe.

Accordingly, the court will grant the plaintiffs' motion as to Smith & Nephew's Eleventh and Twenty-Seventh Affirmative Defenses.

c. Defenses Related to Damages (Thirtieth through Thirty-Fifth Affirmative Defenses)

Smith & Nephew raises four affirmative defenses that assert that an award of punitive damages in this case would be either unconstitutional or void for vagueness (Thirtieth through Thirty-Third Affirmative Defenses). It would be premature to reach such issues of law before a jury has made a punitive damages award. Accordingly, Ms. Mosca's motion for summary judgment as to these defenses will be deferred.

Smith & Nephew also claims Ms. Mosca is not entitled to recover for economic damages that were not actually incurred and that any recovery must be reduced by the amount provided by any collateral source (Thirty-Fourth Affirmative Defense) or any lost earnings provided by her employer that were not required to be paid (Thirty-Fifth Affirmative Defense). Where no damages have yet been specifically requested from the jury nor awarded, it is premature to address issues related to a reduction in damages. Accordingly, Ms. Mosca's motion as to these defenses will be deferred.

d. Failure to State a Claim (Thirty-Seventh Affirmative Defense)

Smith & Nephew claims that the Complaint fails to state a claim upon which relief can be granted. To the extent that the court previously found that Ms. Mosca stated claims for relief as to negligent misrepresentation and negligence and concludes here that Smith & Nephew is not entitled to judgment as to those claims and to the extent that the court has dismissed or awarded

judgment to Smith & Nephew on the plaintiffs' remaining claims, the motion for summary judgment as to this defense is denied as moot.

e. Remaining Affirmative Defenses

The remaining affirmative defenses (Second, Seventh, Fourteenth, and Fifteenth Affirmative Defenses), including assumption of the risk and proximate causation, involve issues of disputed material facts. A decision on Smith & Nephew's ability to present those defenses will be deferred.

CONCLUSION

For the foregoing reasons, the cross motions for summary judgment will be granted in part, reserved in part, and denied in part. Consistent with the court's prior rulings, Ms. Mosca's negligent misrepresentation and negligence claims based on false or misleading statements are not preempted. Ms. Mosca's motion for summary judgment is granted as to Smith & Nephew's Eleventh and Twenty-Seventh Affirmative Defenses. The court will deny or reserve ruling on the balance of Ms. Mosca's motion. The court will grant Smith & Nephew's motion for summary judgment as to the breach of warranty claim, negligent training claim, negligent failure to warn claim, and negligence claims based on a failure to report adverse events to the FDA, a failure to adequately train surgeons, or a violation of Md. Code. Ann., Health-Gen. § 21-217(b). The court will deny or reserve ruling on the balance of Smith & Nephew's motion. A separate Order follows.

7/19/2021
Date

/S/
Catherine C. Blake
United States District Judge