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: ***Paula & Jace Redick v. Smith & Nephew, Inc.*, No. 1:17-cv-00944**

MEMORANDUM

Pending before the court are cross motions for summary judgment in BHR track action *Paula & Jace Redick v. Smith & Nephew, Inc.*, No. 1:17-cv-00944. The plaintiffs move for summary judgment on their failure to warn, negligent training, negligence *per se*, negligent misrepresentation, and breach of warranty claims (ECF 2515). The plaintiffs also seek summary judgment on Smith & Nephew's affirmative defenses, including its defense of preemption. Smith & Nephew moves for summary judgment as to all of the plaintiffs' claims. (ECF 2516). 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 plaintiffs Paula and Jace Redick as a result of Ms. Redick's 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] The plaintiffs claim Ms. Redick was one such patient—her BHR implant required revision to a different implant due, in her surgeon's opinion, to symptoms caused by the accumulation of metal debris.

The plaintiffs' 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. The plaintiffs refer to this information as "ad hoc data" or "ad hoc reports." The plaintiffs further contend 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. Had Smith & Nephew properly disclosed the ad hoc data to the FDA, the plaintiffs contend that Ms. Redick would have been more fully informed of the magnitude of the risk of the BHR before her surgery, and would not have agreed to the BHR

[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.

implant. The plaintiffs also contend 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. Redick was lower than it actually was. Had Ms. Redick not been so misled, she would not have agreed to the BHR implant.

I. Ms. Redick's BHR and Revision Surgeries

Ms. Redick is a 59-year-old woman who lives in Jacksonville, North Carolina. (ECF 2515-19, Ex. 17, P. Redick Dep. at 28–29, 30). In 2010, Ms. Redick began to experience an ache in her groin area, sometimes occurring while she played racquetball or after a long bike ride. (*Id.* at 65). That year, or in early 2011, she began to see Dr. Jack Bowling regarding the pain. (*Id.* at 67). After a couple of years of non-surgical interventions and pain medications, Ms. Redick's hip pain became unmanageable and was greatly affecting her daily life. (*Id.* at 68–75). Dr. Bowling recommended the BHR, stating Ms. Redick was an "excellent" candidate given her age and her activity level at that time. (*Id.* at 76). Ms. Redick relied heavily on Dr. Bowling's recommendation in selecting the BHR. (*Id.* at 99, 148, 169). She recalls reading a brochure regarding the BHR, but cannot remember anything from it specifically, and remembers reading online that the BHR was an "outstanding product" that would help her resume her activities. (*Id.* at 95–97).

Dr. Bowling recommended the BHR to Ms. Redick based in part on his understanding that "the failure rates . . . were equal to or below that what we would have typically seen with a hip replacement in her age group and activity level[.]" (ECF 2515-3, Ex. 1, Bowling Dep. at 113). At that time, he understood the failure rate of the BHR to be between two and five percent, (*id.* at 115, 119), based on materials from Smith & Nephew, Smith & Nephew's 2006 training program, literature reviews, journals, annual meetings of several surgeon societies, educational meetings

available through Smith & Nephew, and his own review of publicly available UK and Australian Registry data, (*id.* at 46, 53–54, 62, 67). Dr. Bowling does not recall seeing data showing higher revision rates of the BHR for women compared to men. (*Id.* at 79–81).

Dr. Bowling testified that he informed Ms. Redick of his understanding of the BHR's revision rates, including those he read in registries. (*Id.* at 49, 106; ECF 2593-12, Ex. K, Medical Records). He also informed her of the risk of metallosis.[2] Had he seen the data showing higher revision rates for women, he would have shared those rates with Ms. Redick. (ECF 2515-3, Ex. 1, Bowling Dep. at 81, 85–86, 209). Ms. Redick has said that had she known the failure rate of the BHR for women, she would not have agreed to the implant. (ECF 2515-19, Ex. 17, P. Redick Dep. at 164).

Ms. Redick had the BHR implanted on March 20, 2012. (*Id.* at 99). Nearly four years following the surgery, in January 2016, Ms. Redick returned to Dr. Bowling regarding joint stiffness and pain in her groin area. (*Id.* at 104). Ms. Redick's blood work showed elevated cobalt and chromium ions, indicating metallosis. (ECF 2515-3, Ex. 1, Bowling Dep. at 152–55). Dr. Bowling's opinion was that the metal debris was causing Ms. Redick's pain and creating bone resorption. (*Id.* at 151, 157). On September 12, 2016, Ms. Redick underwent revision surgery to a total hip arthroplasty ("THA") implant. (ECF 2515-19, Ex. 17, P. Redick Dep. at 123).

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

Between 2006 and 2012, Dr. Bowling attended a training regarding the BHR and was sent at least four marketing packets regarding the BHR—the training and materials all contained

[2] Ms. Redick does not recall being informed of any risk of metallosis, and has said that she did not know the BHR was metal and would not have consented to the BHR had she known it was a metal device. (ECF 2515-19, Ex. 17, P. Redick Dep. at 98, 114–16).

representations that 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. Bowling attended, Smith & Nephew represented that the BHR, unlike its competitors' products, was manufactured without heat treatment, which meant the device retained more carbide particles important for resistance to wear. (ECF 2515-3, Ex. 1, Bowling Dep. at 25).[3] He was also informed that the five-year revision rate of the BHR was 1.5 to two percent overall. This was not broken down by gender. (*Id.* at 46). Smith & Nephew's discussion of gender as it related to the BHR was limited to relative contraindication for pregnant women, because it was unknown what potential consequences a metal on metal product could create for a fetus. (*Id.* at 28).

In 2007, Smith & Nephew sent to Dr. Bowling a summary of the Australian Orthopaedic Association's National Joint Replacement Registry ("Australian Registry")'s 2007 annual report. (ECF 2515-4, Ex. 2, at 27; ECF 2515-5, Ex. 3, Third Am. Def. Fact Sheet at 2). 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 2515-4, Ex. 2, at 27). 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.* at 28).

On May 1, 2009, Smith & Nephew sent to Dr. Bowling a letter providing information on the issue of "pseudo-tumors" in metal on metal hip resurfacing. (ECF 2515-4, Ex. 2, at 34; ECF

[3] Smith & Nephew also described the cup of the BHR as having less contact between the two metal surfaces of the device, so "[t]he ball would kind of float a little bit on the socket and not rub as much, so there would be less contact between the two metal surfaces." (ECF 2515-3, Ex. 1, Bowling Dep. 25–26).

2515-5, Ex. 3 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 2515-4, Ex. 2, at 34).

In a March 29, 2011, letter to surgeons, including Dr. Bowling, Smith & Nephew advertised that surgeons should share with patients a clinical study of the BHR based on data from Oswestry Registry, showing a 95.4% survivorship rate for the BHR over ten years for patients overall. (ECF 2515-4, Ex. 2, at 40, 43; ECF 2515-5, Ex. 3 at 2).

A March 9, 2012, letter to surgeons, including Dr. Bowling, responded to a British Medical Journal article that discussed possible risks of metal on metal hip implants. (ECF 2515-4, Ex. 2, at 44–45; ECF 2515-5, Ex. 3 at 2). The letter attempts to undermine the article in part by arguing that the article did not differentiate between metal on metal hip implants. It goes on to say that "[a]ll available, long-term evidence unequivocally confirms that the BHR Hip is a safe and effective system[,]" citing a McMinn study showing survival rates of 96 percent 13 years after surgery and the publicly available 2011 Australian Registry Annual Report showing a 93.7 percent survival rate for the BHR at ten years. (ECF 2515-4, Ex. 2, at 45).

In late 2010, Smith & Nephew finalized changes to the BHR label mandated by the FDA which included a warning that female patients and patients receiving a 44mm or smaller head size had a greater risk of revision than other patients. (ECF 2644-5, Ex. D). Dr. Bowling was not aware of this change. (ECF 2515-3, Ex. 1, Bowling Dep. at 190–91).

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 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 2515-9, Ex. 7, 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).

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. (ECF 2515-11, Ex. 9; ECF 2515-3, Ex. 1, Bowling Dep. at 78). 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 2515-11, Ex. 9, at 9–10). Smith & Nephew also received Australian Registry Ad Hoc Report 581, dated November 2010 (ECF 2515-12, Ex. 10), 2011 and 2012 data from the NJR British Registry (ECF 2515-13, Ex. 11; ECF 2515-14, Ex. 12), Australian Registry Ad Hoc Report 827, dated January 2012 (ECF 2515-15, Ex. 13), and Australian Registry Ad Hoc Report 858, dated March 2012 (ECF 2515-16, Ex. 14). Those reports all show BHR revision rates for females above five percent and as high as 21.95 percent and for head sizes at or under 44mm, rates of at least eight percent and as high as 13.2 percent. (ECF 2515-

12, Ex. 10; ECF 2515-13, Ex. 11; ECF 2515-14, Ex. 12; ECF 2515-15, Ex. 13; ECF 2515-16, Ex. 14).

At least one Smith & Nephew employee, Peter Heeckt, proposed including at least the revision data for smaller head sizes and by gender from Ad Hoc Report 581 on the BHR's label and in Smith & Nephew's BHR training. (ECF 2515-12, Ex. 10, Nov. 19, 2010, P. Heeckt Email). While the Australian Registry declined his request for permission to share the data specifically, the registry's director, Stephen Graves, wrote that Smith & Nephew could point to the publicly available data on all resurfacing procedures that showed the BHR performed in a "similar manner." (ECF 2515-10, Ex. 8, Graves Ltr.).[4]

As of May 8, 2012, Smith & Nephew's own internal complaint data regarding the BHR was "almost entirely revision surgeries" and trends within those complaints showed that revisions for females and smaller head sizes were "prevalent." (ECF 2515-17, Ex. 15). Smith & Nephew employee Dave Telling suggested using the complaint data to "warn users of this increased risk of adverse event," through a further revised FDA-label, though it is not clear from the record whether further disclosure or labeling changes occurred. (*Id.*). Dr. Bowling has said that the revision rates for women and smaller head sizes contained within the ad hoc reports above would have been a

[4] What Mr. Graves meant by saying that Smith & Nephew could report to surgeons that the BHR performs in a "similar manner" to other resurfacing procedures reflected in the 2010 Annual Report is somewhat ambiguous, as it is not clear from the record what data was included in the 2010 Annual Report. To the extent that the plaintiff's expert Mari Truman noted that the BHR revision rates for subpopulations in Ad Hoc Report 581, including for females and smaller head sizes, were similar to market-wide revision rates for those same populations in the 2010 Annual Report (*see* ECF 2593-5, Truman Dep. at 213–19), there is some support for an inference that the 2010 Annual Report would have reflected market-wide revision rates for females and smaller head sizes that, like Ad Hoc Report 581, exceeded five percent.

"yellow light" to him in terms of recommending the BHR to Ms. Redick. (ECF 2515-3, Ex. 1, Bowling Dep. at 98).

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.[5] 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).

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

[5] 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.

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, 2010, 2011, and 2012. (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 179).

PROCEDURAL HISTORY

On August 23, 2017, the plaintiffs filed a complaint including nine counts against Smith & Nephew under North Carolina 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 VII), and punitive damages (Count IX). (ECF 161, Redick 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 March 12, 2021. (ECF 2515, Redick MSJ; ECF 2516, Smith & Nephew MSJ). The motions have been fully briefed (ECFs 2592, 2593, 2638, 2642) 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

The plaintiffs argue they are entitled to summary judgment on each of their claims as to liability, and on Smith & Nephew's thirty-eight affirmative defenses, including preemption. Smith & Nephew reasserts its preemption defenses and argues that the plaintiffs' claims, including claims for punitive damages, also fail either because North Carolina law does not recognize the legal theories under which the plaintiffs proceed 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 *per se*, negligent training, and breach of express warranties—and will address the parties' 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 the plaintiffs' negligent misrepresentation, breach of express warranty, and negligence *per se* 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 the plaintiffs' negligent failure to warn and some of their negligence *per se* claims because the plaintiffs have failed to present an issue of material fact as to one or more elements of those claims; summary judgment will be denied to both parties with regard to Smith & Nephew's liability for negligent misrepresentation and breach of express warranty; a ruling on summary judgment will be reserved with regard to the plaintiffs' negligence *per se* claim based on false or misleading

statements and as to punitive damages; and the plaintiffs' 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 the plaintiffs' negligent failure to warn claim because (1) the claim is preempted, as North Carolina law does not support a claim of failure to warn the FDA, and (2) the plaintiffs cannot show that any failure to warn the FDA caused Ms. Redick's injuries. The plaintiffs argue they are 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 Ms. Redick's 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*, 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*, 704 F.3d 1224, 1233 (9th Cir. 2013)).

But Smith & Nephew argues the plaintiffs' failure to warn the FDA claim is impliedly preempted because there is no traditional duty under North Carolina law for a manufacturer to warn the FDA, citing *McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570 (E.D.N.C. 2019). In *McNeil*, the plaintiffs brought negligence claims against the manufacturer of a knee-implant device based on a theory of a duty to provide the FDA with "adverse reaction" and "device defect" reports. *Id.* at 575. The district court rejected this theory, holding that "North

Carolina law does not recognize a parallel duty on manufacturers to report to the FDA[.]" *Id.* The court cited North Carolina cases which recognize a duty to warn users of products, not third parties, and relied on *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577–79 (Ariz. 2018), in which the Arizona Supreme Court held that Arizona did not recognize a duty to warn third parties beyond prescribers and other health care providers. *McNeil*, 384 F. Supp. 3d at 575–77.

McNeil and *Conklin* follow a developing line of federal case law that requires 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. *See, e.g.*, *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 201 (E.D.N.Y. 2015). This court declines to adopt similar reasoning, as the notion that a state law duty must be exactly identical to federal requirements in order to "parallel" them appears to be inconsistent with the United States Supreme Court's discussion of parallel claims in *Medtronic v. Lohr*, 518 U.S. 470 (1996). In *Lohr*, the Court held that the MDA did not preempt various Florida common law claims, including a failure to warn claim. *Id.* at 501–02. The Court reasoned that the MDA was not intended to preempt "State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices or to unfair trade practices in which the requirements are not limited to devices[,]" *id.* at 499 (alterations omitted), particularly not where the state requirement threatened no "specific federal interest," *id.* at 500. A general state common-law duty to warn "of the risks involved" in the use "of potentially dangerous items" is not directed only to medical devices and does not "impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.* at 501–02. Other courts adopting this reasoning 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). While the scope of the warnings required cannot be greater than the reports that must be filed with the FDA, a failure to warn claim extending only to a failure to file those reports does not impose an additional or different requirement on the manufacturer. Such a claim is "limited to an assertion that the defendant violated a relevant federal statute or regulation" and is thus "'parallel' to federal requirements[.]" *Hughes*, 631 F. 3d at 769.

While the court concludes that a state law duty to warn a third party may parallel federal requirements to report certain information to the FDA, in this case it is unnecessary to determine whether North Carolina recognizes such a duty, because the plaintiffs cannot satisfy the difficult element of causation.

b. Causation

In order to prevail on a non-preempted failure to warn claim, the plaintiffs 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 the ad hoc data and reports, *Daubert* Ruling, at *13, their theory of causation is limited to showing that ad hoc data provided to the FDA would necessarily have been made public such that the higher revision rates would have been incorporated into the literature Dr.

Bowling read prior to Ms. Redick'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).

The plaintiffs have 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 May 17, 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. Bowling read, (ECF 2592-12, Ex. 11 at 10, 18, 20, 28), 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").

Though several experts in the case, including Smith & Nephew expert Donna-Bea Tillman, arguably have opined that ad hoc data obtained from an international registry may constitute an "analysis of adverse events" required to be reported under PMA Condition No. 4 or "unpublished reports of data" from studies involving the device under 21 C.F.R. § 814.84(b)(2), (ECF 2515-22, Ex. 20, Tillman Dep. at 107–08, 111–15, 142, 176; ECF 2427, Ex. 5, Spears Rep. at 11–19; ECF 2427, Ex. 6, David Rep. at 17), no witness has opined that an aggregated report of revision data is an MDR reportable event or a "trend analysis" that would have alerted Smith & Nephew that it was required to make a 5-day report under 21 C.F.R. § 803.53 as the plaintiffs suggest. The plaintiffs' regulatory expert Larry Spears opined that the FDA would have expected a manufacturer that received the ad hoc data at issue to investigate it further to determine whether or how many reported revisions constituted MDR reportable events, but he could not determine whether Smith & Nephew had failed to do so. (ECF 2427, Ex. 109, Spears Dep. at 109, 114, 118–19). *See Cline*, 17 F. Supp. 3d at 1286. Nor is there evidence that had Smith & Nephew included the ad hoc data in its annual PMA reports, the FDA would have identified the data as MDR reportable and publicized it in the MAUDE database.[6] Accordingly, because there is no genuine dispute of material fact as to whether any failure to inform the FDA of the ad hoc data caused Ms. Redick's injuries, the court will award summary judgment to Smith & Nephew on the plaintiffs' failure to warn claim.

[6] Indeed, there is some evidence to the contrary, as it appears that the office within the FDA responsible for reviewing annual PMA reports is not the same office that reviews MDR reports submitted by manufacturers, (ECF 2515-22, Ex. 20, Tillman Dep. at 360, 362; ECF 2427, Ex. 31, Spears Dep. at 41). Any arguments about the likelihood of information sharing between them would veer into impermissible speculation regarding actions the FDA may or may not have taken. *See Daubert* Ruling, 2021 WL 781682, at *13.

II. Negligent Misrepresentation

Under North Carolina law, to establish a claim for negligent misrepresentation, a plaintiff must show she "[1] justifiably relies [2] to h[er] detriment [3] on information prepared without reasonable care [4] by one who owed the relying party a duty of care." *Raritan River Steel v. Cherry, Bekaert & Holland*, 322 N.C. 200, 206 (1998). The plaintiffs contend that extra-labeling statements and marketing materials provided to Dr. Bowling 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. They argue that Dr. Bowling relied on those representations in recommending the BHR to Ms. Redick, who selected the device on his recommendation, resulting in injury to her. Had Smith & Nephew more accurately represented the magnitude of risk to Dr. Bowling, he would have shared that risk, which he described as a "yellow light," with Ms. Redick, which would have altered Ms. Redick's own calculus in deciding whether or not to agree to the implant. *See Smith v. Ethicon*, No. 1:20-CV-212, 2020 WL 3256926, at *3 (W.D.N.C. June 16, 2020).

Smith & Nephew argues the court should grant it summary judgment as to the plaintiffs' negligent misrepresentation claim because North Carolina does not recognize negligent misrepresentation by omission and because the plaintiffs cannot prove that Ms. Redick or Dr. Bowling justifiably relied on any representations by Smith & Nephew.[7] The plaintiffs contend

[7] Smith & Nephew also contended, briefly, at oral argument, that the plaintiffs' negligent misrepresentation claims based on a failure to provide ad hoc registry data to surgeons are preempted because any obligation to provide additional data to surgeons or the public is preempted. (Apr. 14, 2021 Tr. at 18). But the 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 plaintiffs' state law actions for negligent misrepresentation. *See In re BHR*, 300 F. Supp. 3d at 745.

their claim is viable under North Carolina law and that there is at least enough evidence in the record to support submitting the claim to a jury.

a. Negligent Misrepresentation Based on Omissions

Because the plaintiffs do not contend that the overall revision rates for the BHR, as published in the Australian and British Registries and as advertised by Smith & Nephew, were inaccurate, their negligent misrepresentation claim depends on the theory that its use of those rates was misleading to surgeons, because they failed to present the full picture to surgeons using the ad hoc registry data. That data would have shown that for patients like Ms. Redick, the true revision rates were significantly worse, and were not meaningfully different from revision rates for competitors. The plaintiffs argue that the failure to incorporate that knowledge into Smith & Nephew's marketing was misleading.

Smith & Nephew responds that the failure to reveal registry data is only a negligent omission that is not actionable under North Carolina law, citing *Breeden v. Richmond Cmty. Coll.*, 171 F.R.D. 189, 202 (M.D.N.C. 1997). In *Breeden*, the plaintiff claimed that his contract to teach at the defendant-community college was not renewed due to racial discrimination and also brought fraudulent and negligent misrepresentation claims, arguing that the college had concealed the availability of other positions and the fact that his position was temporary and contingent on funding. *Id.* at 195, 197–98. The court held that the plaintiff was required and failed to plead the fraudulent and negligent misrepresentation claims with particularity under Rule 9(b). *Id.* at 195–96, 202. After concluding that the plaintiff did not satisfy the pleading standard, the court went on to note that dismissal would be with prejudice because the plaintiff "has alleged a negligent omission, not a negligent misrepresentation claim." *Id.* at 202. In using the term "a negligent omission," the court was referring to a claim, like Breeden's, in which the defendant had no duty

to disclose information to the plaintiff and remained silent, providing no information at all. *See id.* (citing *Mason v. Burkett*, 756 F. Supp. 679, 682 (D. Conn. 1991)). The opinion elsewhere acknowledges that, like fraudulent misrepresentation, negligent misrepresentation may be "based upon some confusion or delusion of a party such as by some misrepresentation, *omission*, misapprehension or misunderstanding" where the defendant had a duty to speak or, if speech was voluntary, to make full and fair disclosures. *Id.* at 196, 202 (emphasis added). Thus, *Breeden* did not hold that omissions may never support a claim for negligent misrepresentation, but is consistent with other North Carolina precedent which makes clear that once a party makes a representation, "it has a duty to reveal other pertinent information, the absence of which would make the original statement misleading." *Jones v. Am. Tobacco Co.*, 908 F.2d 967 (Table), *5 (4th Cir. 1990) (citing *Childress v. Nordman*, 238 N.C. 708, 713 (1953)); *see also Ragsdale v. Kennedy*, 286 N.C. 130, 139 (1974) ("[E]ven though a vendor may have no duty to speak under the circumstances, nevertheless if he does assume to speak he must make a full and fair disclosure as to the matters he discusses.").

Here, unlike in *Breeden*, the plaintiffs have presented evidence that Smith & Nephew made certain representations during Dr. Bowling's training and in marketing materials that the BHR specifically had lower revision rates overall than its competitors, rates between 1.5 and 5 percent, citing British and Australian registry data. (*See* ECF 2515-3, Ex. 1, Bowling Dep. at 46, 51, 52; ECF 2515-4, Ex. 2). Thus, under North Carolina law, once Smith & Nephew made those representations, it undertook a duty to make truthful and non-misleading disclosures as to its revision rates in comparison to its competitors. *See Ragsdale*, 286 N.C. at 139. 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 2515-11, Ex. 9, Ad Hoc Report 425; ECF 2515-12, Ex. 10, Ad Hoc Report 581; ECF 2515-13, Ex. 11). The plaintiffs' 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 North Carolina law and is a question for the jury.[8]

b. Justifiable Reliance

"The question of whether a party's reliance was justifiable for purposes of a negligent-misrepresentation claim is 'one for the jury, unless the facts are so clear as to permit only one conclusion.'" *Cummings v. Carroll*, 270 N.C. App. 204, 224, (2020), *review allowed*, 376 N.C. 525 (2020) (quoting *Marcus Bros. Textiles, Inc. v. Price Waterhouse, L.L.P.*, 350 N.C. 214, 225, (1999)). Smith & Nephew argues the plaintiffs cannot show reliance on any representations Smith & Nephew made concerning the BHR's success rates, for three reasons. First, it argues there is no evidence Ms. Redick relied on any statement by Smith & Nephew that the company made directly to her. Second, Smith & Nephew contends any comparisons it made to its competitors were nonactionable "puffery." Third, Smith & Nephew argues the publicly available information

[8] 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. Redick 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). Similarly, the FDA label for the BHR in use at the time of Ms. Redick's surgery disclosed that female patients and patients needing smaller head sizes were at greater risk of revision, though it did not disclose the magnitude of the risk compared to the risk of revision overall. (ECF 2644-5, Ex. D, BHR IFU).

regarding the performance of all resurfacing devices for female patients and patients needing smaller head sizes made it unreasonable for Dr. Bowling to conclude that the BHR's performance for the same population was significantly better. The court addresses each argument in turn.

In North Carolina, representations do not necessarily have to be made directly to a plaintiff in order for her to show justifiable reliance. In *Rowan Cnty. Bd. of Educ. v. U.S. Gypsum Co*., 332 N.C. 1 (1992), the North Carolina Supreme Court held that a jury could reasonably find that a plaintiff justifiably relied on a manufacturer's representations about asbestos removal where the plaintiff did not read the relevant materials advertising the product, but relied on its agent architect, who did review that literature and based his recommendations in part on those advertisements. *Id.* at 21. The plaintiffs argue that, like the plaintiff in *Rowan*, Ms. Redick justifiably relied on Dr. Bowling's recommendation of the BHR, and Dr. Bowling in turn relied in part on Smith & Nephew's assertions regarding the BHR's revision rates and design advantages over its competitors. Smith & Nephew argues that *Rowan* requires the plaintiffs to demonstrate a traditional agency relationship between Ms. Redick and Dr. Bowling, citing *Hospira Inc. v. Alphagary Corp.*, 194 N.C. App. 695 (2009). *Hospira* rejected a medical device company's claim that it relied, through a third-party intermediary, on a supplier's misrepresentation of the nature of certain materials used to manufacture the device, distinguishing *Rowan* on the basis that the plaintiff disavowed any agency relationship between itself and the third-party and that by the time the defendant's representations reached the plaintiff, the third party had altered them. *Id.* at 699–701.

In this case, the record does not demonstrate that Dr. Bowling altered the information regarding the BHR that he received from Smith & Nephew; further, there exists a relationship between doctor and patient that, similar to an agency relationship, would justify Ms. Redick's

reliance on Dr. Bowling's knowledge. A number of courts have recognized that under the learned intermediary doctrine, "where a patient relies on a physician for treatment or advice as to [a] . . . device, justifiable reliance by the physician on misrepresentations or concealment by the manufacturer of that device constitutes justifiable reliance by the patient." *Tetuan v. A.H. Robins Co.*, 241 Kan. 441, 464 (1987); *see also In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 127 F. Supp. 3d 1306, 1362–63 (N.D. Ga. 2015) (citing cases). This is because a manufacturer's duties to warn of risks associated with a device and by extension, make truthful and non-misleading statements, are to the medical community and the plaintiff's treating physician. *See, e.g.*, *In re Wright*, 127 F. Supp. 3d at 1362–63 (citing *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 835 (Utah 1984)); *Kane v. Zimmer Biomet Holdings, Inc.*, No. CV RDB-17-2268, 2018 WL 4005216, at *5 (D. Md. Aug. 22, 2018). Thus, that Ms. Redick relied heavily on Dr. Bowling's recommendation in selecting the BHR, (ECF 2515-19, Ex. 17, P. Redick Dep. at 99, 148, 169), and does not remember any specific representations from the one BHR brochure she read, (*id.* at 95–97), is not fatal to her negligent misrepresentation claim. The plaintiffs have presented evidence that Dr. Bowling recommended the BHR to Ms. Redick based in part on his understanding that the BHR's revision rates were superior to those of other products, (ECF 2515-3, Ex. 1, Bowling Dep. at 113), and that his understanding of its failure rate, between two and five percent, was based in part on materials from Smith & Nephew and Smith & Nephew's 2006 training program, (*id.* at 46, 53–54, 62, 67, 81, 87, 115). The court is persuaded that a jury could reasonably infer that Dr. Bowling at least partially relied on Smith & Nephew's representations as to the revision rates of the BHR in recommending the device to Ms. Redick.

Nor is Smith & Nephew entitled to summary judgment on the basis that its comparisons between the BHR and its competitors were mere "puffery" and thus could not reasonably be relied

upon. In order to be actionable under North Carolina law, a representation generally must be "definite and specific," *Rowan*, 332 N.C. at 17 (quoting *Johnson v. Owens*, 263 N.C. 754, 756 (1965)); *see also Solum v. Certainteed Corp.*, 147 F. Supp. 3d 404, 412 (E.D.N.C. 2015) (in predicting the North Carolina Supreme Court's interpretation of reasonable reliance under the state's Unfair and Deceptive Trade Practices Act, holding that "[g]eneral statements of comparison or superiority are puffery and are not actionable as a matter of law"), but more general assertions of success or superiority may be sufficient to submit the issue of reliance to the jury where a defendant has a "peculiar knowledge of the facts," *Ragsdale*, 286 N.C. at 139. For example, in *Ragsdale*, the Supreme Court of North Carolina concluded that a jury could reasonably infer fraud where a president of a business described his company as a "gold mine" though he knew that it had lost money in recent months, because the party receiving the representation could not obtain the same facts, but understood that the president would have relevant information about the company's profitability. *Id.* And in *Rowan*, an asbestos manufacturer's promotion of its product's "exceptional bonding ability" without mention of known performance issues in environments containing dust was specific enough to constitute a false representation or concealment of a material fact on which the plaintiff could rely. 332 N.C. at 17–18. Smith & Nephew's representations as to the BHR's revision rates and its design advantages in comparison to its competitors included the use of clinical data and specific statements about the ability of the device to resist wear due to its "as-cast" metallurgy. These assertions are far more specific than those made by the defendants in *Ragsdale* and *Rowan*, both of which were sufficient to submit the issue of reliance to a jury. Moreover, as in *Ragsdale*, the full picture of the revision rates which the plaintiffs contend should have been made available to Dr. Bowling was arguably peculiarly available to Smith & Nephew. There is evidence in the record that the ad hoc reports and data

Smith & Nephew received were not available to doctors. (ECF 2515-11, Ex. 9; ECF 2515-10, Ex. 8, Graves Ltr.; ECF 2515-3, Ex. 1, Bowling Dep. at 78).[9]

Finally, Smith & Nephew argues that its ad hoc data would not have provided a more accurate representation of the risk of revision to Redick, because data that was already public showed a higher incidence of revision in females than the undisclosed data. Smith & Nephew cites testimony by the plaintiffs' expert Mari Truman in which she discusses that for the year 2010, the Australian Registry Annual Report publicized revision rates by gender for all resurfacing devices. The revision rates for females for all resurfacing devices was slightly worse than the revision rates for females just for the BHR that were only disclosed in the ad hoc report Smith & Nephew had for the year 2010. (ECF 2593-5, Truman Dep. at 213–14). Smith & Nephew contends that because Dr. Bowling read the publicly available registry data, he could not have been misled by Smith & Nephew's materials that drew attention to the BHR's market-leading overall revision rates. While a jury could reasonably make such a conclusion, the court believes a jury could also reasonably infer that a surgeon looking at the publicly available Australian Registry annual reports would understand that all resurfacing devices posed a greater risk of revision for females, but they may not have appreciated from the aggregated resurfacing data the magnitude of the risk for the BHR specifically. And at the same time, the public report's data showed that the BHR performed better than its competitors overall, and the plaintiffs have cited evidence that in advertisements and letters to surgeons, Smith & Nephew consistently attempted to undermine literature that cautioned against

[9] To the extent that Smith & Nephew argues, relatedly, that it was unable to share the ad hoc reports with surgeons, as explained in the court's memorandum concerning Smith & Nephew's motion to exclude the testimony of Dr. Shapiro, it would not have been necessary to disclose the entirety of the reports to avoid misrepresenting the magnitude of the risk of revision to Ms. Redick; rather Smith & Nephew could have altered its marketing approaches to avoid making the omission of the data materially misleading.

metal-on-metal implants by arguing that the BHR outperformed its competitors for all patients. (*See, e.g.*, ECF 2515-4, Ex. 2, at 45). Whether Dr. Bowling could reasonably rely on those representations in light of information that all resurfacing devices posed a greater risk to patients like Ms. Redick is thus a material dispute of fact for the jury. Accordingly, both parties' motions for summary judgment on the plaintiffs' negligent misrepresentation claims will be denied.

III. Remaining Negligence Claims

In their remaining common-law negligence claims, the plaintiffs seek to prove that Smith & Nephew was negligent in (1) failing to report adverse events to the FDA; (2) making off-label statements during Dr. Bowling'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 North Carolina's 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

The plaintiffs contend that a failure to report adverse events to the FDA, in violation of the PMA, constitutes negligence *per se*. Smith & Nephew argues this claim is preempted because the claim would not give rise to recovery under state law in the absence of Smith & Nephew's federal obligations under the PMA, citing *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 852 (E.D.N.C. 2016). While the court does not necessarily agree with Smith & Nephews's argument, *see In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig. ("In re THA")*, 401 F. Supp. 3d 538, 563 (D. Md. 2019), the claim suffers from the same causal deficiencies as the plaintiffs' 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. Bowling's risk assessment of the BHR implant for Ms. Redick. Accordingly, summary judgment will be awarded to Smith & Nephew on this claim.

b. Training

The plaintiffs argue off label statements during Dr. Bowling's training relating to the magnitude of risk of revision in the BHR can form the basis of a negligent training claim for failing to provide training required by federal law, citing *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 493 (W.D.N.C. 2017). In *Burrell*, the court acknowledged that a negligent training claim could survive preemption to the extent a manufacturer failed to provide the training required, but the plaintiff in that case failed to show any such violation of the FDA's mandated training. *Id.* at 493. *See also In re BHR*, 300 F. Supp. 3d at 745 ("[I]nsofar as the plaintiffs pin their negligence claims to conduct that breached preexisting federal requirements" to adequately train surgeons "they avoid express preemption."). This case mirrors *Burrell* in that the theory under which the plaintiffs' claims could survive preemption is sound, but no evidence exists that Smith & Nephew failed to provide the required training. This court has already held that the PMA condition that required Smith & Nephew to implement a training program did not include requirements as to what the training must include and excluded as preempted testimony which suggested Smith & Nephew had a duty to modify the training and testimony that the training should have informed surgeons of a 1,000-surgery learning curve.[10] *See Daubert* Ruling, 2021 WL 781682, at *3, 7–8. There is

[10] To the extent the plaintiffs argue that the evidence of a 1,000-surgery learning curve disclosed by Dr. McMinn is relevant not because surgeons should have been informed of it, but because the revision rates discussed during the training may have been better explained by McMinn's experience and thus were not accurate, that may support a remaining negligent misrepresentation

some evidence that the approved training program for the BHR included lectures covering "anticipated PMA approved indications, contraindications, warnings, and precautions (as known at the time and reinforced after approval)." (ECF 2592-18, Ex. 17, at 5). But in their response to Smith & Nephew's *Daubert* motion, the plaintiffs appear to have acknowledged that the training program was required to "harmonize" with the device's labeling. (ECF 2427 at 88). Once the FDA approved the training program, there appears to have been "no requirement to make updates to that program[.]" *Daubert* Ruling, 2021 WL 781682, at *8. A claim that Smith & Nephew had a duty to change its program would add to or differ from the requirement to merely implement the program and is preempted. *Id.* But to the extent the plaintiffs claim that misleading revision rates were touted as part of the training program, such evidence may support a non-preempted negligent misrepresentation or breach of express warranty claim.

c. Misbranding

The plaintiffs also seek to hold Smith & Nephew liable for negligence under a second negligence *per se* theory—Smith & Nephew's marketing and trainings contained non-FDA approved statements, messages, and information that violate federal regulations and parallel North Carolina law, citing two provisions of the North Carolina Code—Section 106-134(1), a provision of the North Carolina Food, Drug and Cosmetic Act ("NCFDCA"), and Section 14-117, North Carolina's criminal false advertising provision. The court addresses each theory in turn.

Section 106-134 of the NCFDCA provides that a drug is misbranded if "its labeling is false or misleading." N.C. Gen. Stat. Ann. § 106-134. Smith & Nephew argues that any negligence

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or breach of express warranty claim, but it does not demonstrate that Smith & Nephew violated any FDA-mandated training requirements.

claim based on a violation of this provision would be an attempt to challenge the FDA's approved labeling, and is thus preempted. *See Daubert* Ruling, 2021 WL 781682, at *6.

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).

Recognizing that they are precluded from challenging the BHR's FDA-approved labeling in this case, the plaintiffs argue that the statute defines "labeling" to include not just representations that accompany a product, but also false or misleading advertising, pointing to the NCFDCA's definition of what is to be considered "misleading." That definition refers to "labeling" and "advertising" as distinct concepts, however, and "labeling" is separately defined to mean "all labels and other written, printed, or graphic matter (a) upon an article or any of its containers or wrappers, or (b) accompanying such article." N.C. Gen. Stat. Ann. §§ 106-121(11) (defining "labeling"), 101-121(15) (defining "misleading"). Thus, in order to prove that Smith & Nephew violated the NCFDCA's misbranding provision, under § 106-134, the plaintiffs would have to show that the FDA-approved labeling that accompanied the product was misleading, a claim which is preempted.[11]

[11] The plaintiffs do not rely on a separate provision of the NCFDCA that prohibits false or misleading advertising of a food, drug, device, or cosmetic. *Id.* § 106-138.

Section 14-117 of the North Carolina Code makes it a criminal misdemeanor to directly or indirectly "make public, disseminate, circulate or place before the public" in any format "an advertisement of any sort regarding merchandise . . . or any other thing so offered to the public, which advertisement contains any assertion, representation or statement of fact which is untrue, deceptive or misleading[.]"[12] Proof of a violation requires proof of criminal intent, as the provision is violated only when the advertising is "done willfully and with intent to mislead." *Id.* The plaintiffs represent that they intend to offer essentially the same evidence underlying their negligent misrepresentation and breach of warranty claims to support a theory that Smith & Nephew made the conscious and willful decision to advertise the BHR using overall revision rates, in order to mask that the overall rates were substantially lower than the rates for females and men needing small head sizes. The court will reserve for a time closer to or during trial the question whether such evidence will be sufficient to submit the issue of criminal intent to a jury.

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In sum, the plaintiffs' negligence claim based on a failure to report adverse events to the FDA fails because the plaintiffs have failed to show sufficient evidence of causation, and the plaintiffs' negligence claims based on allegations that Smith & Nephew's surgeon training program was inadequate or a theory that Smith & Nephew violated the NCFDCA's misbranding provision are preempted. The court will reserve ruling on the plaintiffs' theory of negligence *per se* based on a violation of N.C. Gen. Stat. Ann. § 14-117.

[12] It appears that the violation of a statute punishable as a criminal offense may support a theory of negligence *per se* under North Carolina law. *See, e.g.*, *Baldwin v. GTE South, Inc.*, 335 N.C. 544, 546 (1994).

IV. Breach of Express Warranty

"A claim for breach of express warranty pursuant to N.C. Gen. Stat. § 25–2–313 requires proof of (1) an express warranty as to a fact or promise relating to the goods, (2) which was relied upon by the plaintiff in making his decision to purchase, (3) and that this express warranty was breached by the defendant." *Harbor Point Homeowners' Ass'n, Inc. ex rel. Bd. of Directors v. DJF Enterprises, Inc.*, 206 N.C. App. 152, 162 (2010) (internal quotation marks omitted).

The plaintiffs contend that Smith & Nephew's marketing of the BHR by specifically asserting certain success rates in comparison to its competitors constituted an express warranty about the performance of the BHR. The plaintiffs argue this claim is not preempted as it arises from non-FDA approved statements Smith & Nephew disseminated to surgeons, including Dr. Bowling, and that it is entitled to summary judgment as statements regarding the risks of revision to women were misleading as a matter of law and caused Ms. Redick's injuries. Smith & Nephew argues that any claim for breach of express warranty is preempted, that the plaintiffs have failed to identify any express warranties made to Ms. Redick, and that the plaintiffs cannot show Ms. Redick relied on any warranties made.

a. Preemption

Smith & Nephew's preemption arguments are predicated on the theory that any breach of warranty claim the plaintiffs might pursue requires proof that the BHR was unsafe and unreasonably dangerous, which claims are preempted. *See In re BHR*, 300 F. Supp. 3d at 743, 745. But the plaintiffs' claim here does not require such proof. The plaintiff's claim is that Smith & Nephew made express warranties about the BHR revision rates which were not accurate. As this court has previously held, that claim parallels an ongoing obligation under the PMA approval to

disseminate truthful, accurate, and not misleading statements about the device and therefore is not preempted. *See id.* at 745.

b. Existence of and Breach of an Express Warranty

"An express warranty is created when, as to the goods being sold, a seller makes any affirmation of fact or promise, provides any description, or furnishes any sample or model, and such affirmation, description, or sample becomes part of the parties' contract." *McDonald Bros. v. Tinder Wholesale, LLC*, 395 F. Supp. 2d 255, 267 (M.D.N.C. 2005) (internal quotation marks omitted).

Smith & Nephew argues the plaintiffs have failed to identify any express warranties made to Ms. Redick, citing her deposition testimony that she does not recall any specific information from a BHR brochure she reviewed (ECF 2515-19, Ex. 17, Redick Dep. at 95) and noting that her testimony that she read "positive" descriptions of the BHR online (*id.* at 170) is merely opinion and does not create a warranty. Ms. Redick does not dispute this, but argues that specific statements and affirmations were made to Dr. Bowling during BHR trainings and in BHR marketing materials regarding the magnitude of risks of revision for patients like Ms. Redick which informed his recommendation of the BHR to his patient. *Cf. McCauley v. Hospira, Inc.*, No. 1:11CV108, 2011 WL 3439145, at *6 (M.D.N.C. Aug. 5, 2011) (recognizing that "specific words, promises, affirmations, or statements" made by drug company to patients *or their physicians* could constitute an express warranty, but holding the plaintiff failed to identify any such statements at the motion to dismiss stage).

Smith & Nephew further contends its representations regarding the magnitude of the risk of revision were not inaccurate or misleading. The plaintiffs, on the other hand, contend Smith & Nephew's representations were misleading as a matter of law and the BHR failed to live up to

Smith & Nephew's representations. *See McDonald Bros.*, 395 F. Supp. 2d at 267 (breach of an express warranty may be established where the defendant's representations as to the product's performance "did not live up to the defendant's representations"). For the reasons stated above in the court's discussion of the plaintiff's negligent misrepresentation claim, whether Smith & Nephew's representations as to the risks of revision for female patients and patients needing smaller head sizes were inaccurate or misleading is a question for the jury.

c. Reliance and Causation

The parties' arguments regarding reliance and causation as to the breach of express warranty claim also mirror their reliance arguments with regard to negligent misrepresentation. If a jury were to conclude that Smith & Nephew breached an express warranty when it marketed the BHR by misleading surgeons as to the magnitude of the risk of revision for patients like Redick, there is evidence Redick relied on Smith & Nephew's warranties, as Redick chose the BHR almost entirely on Dr. Bowling's recommendations to her, which were based in part on Smith & Nephew's representations as to the magnitude of the risk of revision. *See* above, Section II.b. Whether marketing that included at least some information from the ad hoc data and reports Smith & Nephew possessed would have altered Dr. Bowling's understanding of the risks to Ms. Redick given other available information at the time is a material dispute of fact for the jury. *See id.* Accordingly, both parties' motions for summary judgment as to the plaintiffs' breach of express warranty claim will be denied.

V. Punitive Damages

Smith & Nephew argues summary judgment should be granted as to the availability of punitive damages because, even if the plaintiffs succeed on any of their claims, they present no evidence of fraud, malice, or willful or wanton conduct. In North Carolina, punitive damages may

be awarded where it is proved by clear and convincing evidence that the defendant's actions were fraudulent, malicious, or willful. *Schenk v. HNA Holdings, Inc.*, 170 N.C. App. 555, 559–60 (2005) (citing N.C. Gen. Stat. Ann. § 1D–15); *see also Rowan*, 332 N.C. at 18. Willful and wanton conduct is defined as "the conscious and intentional disregard of and indifference to the rights and safety of others, which the defendant knows or should know is reasonably likely to result in injury, damage or other harm." N.C. Gen Stat. Ann. § 1D-5(7). The plaintiffs argue 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's actions were willful. 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

The plaintiffs move 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 the plaintiffs' motion as to defenses Smith & Nephew has disclaimed.[13]

[13] These defenses include: comparative fault of the plaintiffs and others (Third and Fourth Affirmative Defenses); superseding cause (Fifth Affirmative Defense); statute of limitations and laches (Eighth and 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); misuse of product (Twenty-Ninth Affirmative Defense).

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 the plaintiffs' failure to warn claim: Smith & Nephew had no post-sale duty to warn the plaintiffs (First Affirmative Defense); Dr. Bowling was aware of the risks of the BHR (Nineteenth Affirmative Defense); applying the learned intermediary doctrine, any duty to warn the plaintiffs was discharged by providing adequate warnings to surgeons (Twentieth Affirmative Defense); and no additional warnings were required, as the BHR was not unreasonably dangerous (Twenty-First Affirmative Defense). (*See* ECF 663 at 1, 114–115). As explained above, Smith & Nephew is entitled to judgment on the plaintiffs' failure to warn claim because any claim based on a failure to warn surgeons or the plaintiffs directly is preempted and the plaintiffs cannot meet the causation element of a failure to warn claim based on a failure to warn the FDA.

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 North Carolina, an injured person has a duty to "take reasonable efforts to minimize loss." *Smith v. Childs*, 112 N.C. App. 672, 683 (1993). Smith & Nephew contends summary judgment as to this defense is premature as the plaintiffs have not provided evidence of damages at all, and that evidence is uniquely in the hands of the plaintiffs. But the plaintiffs have produced evidence of damages in this matter, (*see* ECF 2516-5, Ex. C, Second Am. Pl. Fact Sheet at Section VII), and Smith & Nephew asked a number of questions during Ms. Redick's deposition concerning her damages claims, (*see* ECF 2515-19, Ex. 17, P. Redick Dep at 149–54). 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 the plaintiffs' motion as to this affirmative defense.

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

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

As to their claim that Ms. Redick 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. Redick smoked up to a half a pack of cigarettes a day until about 2014, (ECF 2515-19, Ex. 17, P. Redick Dep. at 59), and testimony by its expert Dr. Seyler that smoking decreases bone health and increases the risk of bone fracture, (ECF 2593-14, Ex. M, Seyler Rep. at 10). However, as explained in the court's memorandum addressing the plaintiffs' motion to exclude Dr. Seyler's testimony, Dr. Seyler never opines that smoking was a cause of Ms. Redick's hip implant failure. Smith & Nephew has failed to identify any evidence that would support an inference that smoking caused Ms. Redick's injuries. *See Maye v. Gottlieb*, 125 N.C. App. 728, 730 (1997) ("In order to avoid a directed verdict for plaintiff on contributory negligence, defendants must have presented more than a scintilla of evidence that plaintiff was negligent. . . . Evidence creating a mere possibility or conjecture is not sufficient[.]").

Smith & Nephew further contends that Ms. Redick failed to exercise ordinary care (Twenty-Seventh Affirmative Defense) because she failed to heed Dr. Bowling's warning that the BHR was a metal device, citing her testimony that she does not recall receiving such a warning and that she would not have agreed to have a metal device implanted, along with Dr. Bowling's

testimony that he did explain the BHR was a metal-on-metal device. Any discrepancy between Ms. Redick's and Dr. Bowling's recollections regarding the warnings Ms. Redick 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. Redick's decision to get the BHR implant despite warnings that it contained metal was negligent and at the same time maintain, as it has throughout this litigation, that the BHR was safe.

Finally, as to a failure to follow warnings accompanying the product (Twenty-Eighth Affirmative Defense), Smith & Nephew has proffered no evidence to support this defense. Smith & Nephew does not identify specific warnings accompanying the product which Ms. Redick failed to follow; rather it argues that Ms. Redick accepted whatever warnings of risk were given and agreed to the BHR in order for the opportunity to return to her active lifestyle.

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

c. Failure to Provide Timely Notice (Twenty-Fifth Affirmative Defense)

Smith & Nephew asserts as a defense to the plaintiffs' breach of express warranty claim that the plaintiffs failed to provide timely notice of the alleged breach. The plaintiffs counter that the failure to provide timely notice is not an affirmative defense to a breach of warranty claim, but rather is a precondition to recovery that the plaintiff must prove. *See Maybank v. S.S. Kresge Co.*, 302 N.C. 129, 133 (1981). While the plaintiffs correctly state the law, *Maybank* also makes clear that the issue of seasonable notice is one for the jury where, as here, "the plaintiff is a lay consumer and notification is given to the defendant by the filing of an action within the period of statute of limitations[.]" *Id.* at 136. Accordingly, the court will reserve ruling on the issue of timely notice.

d. 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, the plaintiffs' motion for summary judgment as to these defenses will be deferred.

Smith & Nephew also claims the plaintiffs are 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 health care provider, insurance company, Medicare or any other collateral source (Thirty-Fourth Affirmative Defense) or any lost earnings provided by the plaintiffs' employers 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, the plaintiffs' motion as to these defenses will be deferred.

e. State of the Art (Thirty-Sixth Affirmative Defense)

Smith & Nephew's Thirty-Sixth Affirmative Defense is that the plaintiffs' claims fail because the BHR was designed, manufactured, and marketed in accordance with the state of the art. The plaintiffs argue they should be granted summary judgment as to this defense because "state of the art" is not a defense to a products liability action in North Carolina. *See, e.g.*, *Graham v. Coca Cola*, 257 N.C. 188, 196–97 (1962) (agreeing that a plaintiff's requested instruction that the defendant's installation of modern and generally approved of machinery and appliances in connection with the manufacture of its product does not preclude a finding of liability was a "correct statement of the law"); *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.*, 159 N.C. App. 135, 141 (2003) ("compliance with governmental standards is not determinative of whether [a] product

is defective"); *Goodman v. Wenco Foods, Inc.*, 333 N.C. 1, 17 (1992) ("Proof of compliance with government standards is no bar to recovery on a breach of warranty theory: although such evidence may be pertinent to the issue of the existence of a breach of any warranty, it is not conclusive."). Smith & Nephew does not appear to disagree with the plaintiffs as to the law in North Carolina on this point, but argues that under the court's preemption ruling, FDA-approval of the BHR recognizes that the device was fit for market and the BHR cannot be labeled unreasonably dangerous. That much is true, but that is Smith & Nephew's preemption defense, not its state of the art defense, and it is not clear that the FDA's PMA approval is relevant to the plaintiffs' remaining claims that Smith & Nephew made misleading and non-FDA approved assertions as to the success rate and advantages of the BHR in comparison to its competitors. Accordingly, the court will reserve ruling on the admissibility of any "state of the art" evidence at trial.

f. 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 the plaintiffs stated claims for relief as to negligent misrepresentation and breach of warranty 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.

g. Remaining Affirmative Defenses

The remaining affirmative defenses (Second, Seventh, Fourteenth, Fifteenth, Seventeenth, and Eighteenth 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 and denied in part. Consistent with the court's prior rulings, the plaintiffs' negligent misrepresentation, breach of express warranty, and negligence claims based on false or misleading statements are not preempted. The plaintiffs' motion for summary judgment is granted as to Smith & Nephew's Eleventh, Twenty-Seventh, and Twenty-Eighth Affirmative Defenses. The court will deny or reserve ruling on the balance of the plaintiffs' motion. The court will grant Smith & Nephew's motion for summary judgment as to the 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 the NCFDCA's misbranding statute. The court will deny or reserve ruling on the balance of Smith & Nephew's motion. A separate Order follows.

5/17/2021
Date

/s/
Catherine C. Blake
United States District Judge