

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

<p>IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION</p>	<p>MDL No. 2775 Master Docket No. 1:17-md-2775</p> <p>JUDGE CATHERINE C. BLAKE</p> <p>THIS DOCUMENT RELATES TO THE FOLLOWING CASE:</p> <p><i>Williams v. Smith & Nephew, Inc.</i>, No. 1:14- cv-3138</p>
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MEMORANDUM

Smith & Nephew moved for summary judgment on the Williams family’s claims.¹ Mot. for Summ. J., ECF 5102-1 (“Mot.”). The Williamses opposed Smith & Nephew’s motion, Opp’n to Mot., ECF 5175 (“Opp’n”), and Smith & Nephew replied, Reply in Supp. of Mot., ECF 5272. The court heard oral argument on December 19, 2023. For the following reasons, the court will grant Smith & Nephew’s motion for summary judgment.

BACKGROUND

This case is part of a multidistrict litigation (“MDL”) concerning the Birmingham Hip Resurfacing Device (“BHR”), an artificial hip, developed, designed, manufactured, and sold by Smith & Nephew. The BHR replaces the hip joint with metal components in an effort to restore the patient’s hip functionality. The BHR’s two components rub against one another during movement of the patient’s hip joint, and both are made of cobalt and chromium metal alloys.

¹ The Williams family includes the plaintiffs Lewis Williams III, Chrystal Williams, and Michael Stelmack. Mr. Stelmack is the personal representative of the estates of former plaintiffs Lewis Williams Jr. and Angela Williams, who are the deceased parents of Lewis III and Chrystal. Mr. Stelmack is the subject of a pending unopposed motion to substitute, Mot. to Substitute, ECF 5174, which will be granted.

Friction between the metal components may result in the release of metal debris which can accumulate in a patient's joints and blood stream. That metal debris can cause pain, metallosis, and other serious complications necessitating corrective surgery or revision to a different device.² Lewis Williams Jr. had a BHR implanted in 2006.

I. Case-Specific Factual Background

Mr. Williams was an active person before he began experiencing pain in his hips, groin, and thighs in the early 2000s. Opp'n Ex. 2 at 7:15-24, ECF 5175-2. He first saw Dr. Henry Boucher complaining of that pain on October 4th, 2005. *Id.* at 7:12-14. Dr. Boucher reviewed x-rays of Mr. Williams' hip and found signs of severe degenerative osteoarthritis. *Id.* at 10:1-3. As treatment, Dr. Boucher determined that Mr. Williams was an appropriate candidate for a hip replacement. *Id.* at 12:25-13:6. After they discussed replacement options and the risks and benefits of the different types of bearing surfaces available, Mr. Williams said that he would conduct his own research before deciding whether to go ahead with a hip replacement. *Id.* at 13:7-14:4.

Mr. Williams' family testified that he was "leery of having something, you know, implanted," and "really did not want any foreign device or anything in his body." Opp'n Ex. 9 at 32:13-17, 33:19-24, ECF 5175-9. He was generally skeptical about medical care, given "the historical disparities and care for Black men specifically." Opp'n Ex. 10 at 29:15-19, ECF 5175-10. Because of his misgivings, Mr. Williams was the type of person who would have conducted his own research before agreeing to surgery. Opp'n Ex. 9 at 62:15-63:13; Opp'n Ex.

² The court provides only the minimum facts about the BHR necessary to resolve the pending motion. The court has described the basic facts of this MDL in several prior opinions.

10 at 24:3-25:3. Nevertheless, Mr. Williams trusted Dr. Boucher more than other doctors. Opp'n Ex. 10 at 29:12-14.

While Mr. Williams was mulling his options, in August of 2006, Smith & Nephew paid for Dr. Boucher to travel to Birmingham, England for training on the BHR. Opp'n Ex. 1 at 81:4-22, ECF 5175-1; Opp'n Ex. 2 at 45:21-48:5. The training entailed didactic sessions, discussions of indications and tricks for implantation, and observing procedures to learn technique from experienced surgeons. Opp'n Ex. 1 at 81:4-22. Smith & Nephew required surgeons to complete this training before they could begin implanting the BHR. *Id.* at 82:8-9. During the training, Smith & Nephew described certain supposed benefits of the BHR over other metal-on-metal devices. *Id.* at 154:11-15. Specifically, Smith & Nephew claimed that the device's "as cast" manufacturing process improved the final product's metallurgy and rendered its performance superior to competitor devices. *Id.* at 154:16-155:13. Smith & Nephew also claimed that the failure rate of the device would be between one and three percent at ten years after implantation. *Id.* at 156:12-19.

At the time of Dr. Boucher's training, Smith & Nephew knew that surgeon training was critical to the performance of the BHR. Opp'n Ex. 3 at 84:9-87:6, ECF 5175-3. Implanting the BHR was a different process than a traditional total hip arthroplasty procedure, "[s]o you have to learn to put in a BHR device correctly." *Id.* at 86:17-22. Smith & Nephew developed a "revolutionary" training procedure that was "very involved" and "costly" "to make sure that [surgeons] all had the best possible surgical technique." *Id.* at 86:22-87:6. Nevertheless, as with anything, there was a learning curve associated with performing the procedure to implant a BHR. *Id.* at 87:7-11. In a 2015 interview, one of the BHR's inventors, Dr. Derek McMinn, stated that his first 1000 hip resurfacing implants, which were implanted in the 1990s, had a ten-year failure

rate of 4.7%, and his subsequent 3,000 resurfacing implants had a failure rate that was five percent better. Opp'n Ex. 5 at 198:20-199:9, ECF 5175-5. Thus, Dr. McMinn concluded that "the learning curve for hip resurfacing is 1,000 cases." *Id.* Recognizing that earlier surgeries might be more vulnerable to errors, Smith & Nephew provided an individual to join surgeons "in the operating room for the first couple cases to help them." Opp'n Ex. 3 at 88:4-7.

Smith & Nephew did not mention a learning curve in Dr. Boucher's training. Opp'n Ex. 1 at 188:25-189:7; Opp'n Ex. 2 at 50:7-51:13; Opp'n Ex. 6 at 10:13-12:16, ECF 5175-6. Dr. Boucher testified that information about a learning curve would have been "meaningful," but that "when we're considering a new procedure and a learning curve, you have to know yourself and . . . it's your responsibility." Opp'n Ex. 2 at 50:20-51:13. Nevertheless, he would have wanted to know "as much information about the risk of failure and revision surgery as possible," and would have shared that information with Mr. Williams as part of the process of deciding whether to proceed with surgery. *Id.* at 59:11-22, 61:5-16; *see* Opp'n Ex. 6 at 11:3-17.

On August 7th, 2006, Mr. Williams returned to Dr. Boucher and said that he would like to proceed with a hip replacement surgery. Opp'n Ex. 2 at 14:9-16. Dr. Boucher again reviewed the treatment options available to Mr. Williams and suggested that he undergo a resurfacing procedure rather than a traditional hip replacement, given that he was only in his forties at the time and a "resurfacing would offer a different potential longevity and even potential activity." *Id.* at 15:6-22. Dr. Boucher recommended that Mr. Williams select a BHR based on his experience and Smith & Nephew's training. *Id.* at 26:18-27:20. Mr. Williams elected resurfacing, and Dr. Boucher advised him of the risks specific to that procedure, including the possibility of implant failure, loosening, or release of metal wear into the body. *Id.* at 24:10-25:6,

25:19-23. He did not describe a learning curve or disclose that Mr. Williams would be the subject of one of his first BHR surgeries.

On September 21st, 2006, just a month after Dr. Boucher completed his training, he performed surgery on Mr. Williams to implant a BHR device consisting of a size 56 acetabular shell and size 50 femoral head. *Id.* at 24:6-9, 26:7-11. Six weeks later, Mr. Williams reported that he was “pleased” with the surgery and had “minimal pain.” *Id.* at 28:2-24. And in two additional follow-up appointments, Mr. Williams maintained that he was happy with his implant and Dr. Boucher confirmed that it remained “in alignment and well-fixed.” *Id.* at 28:25-30:3.

By 2011, Smith & Nephew was aware that the failure/revision rate of the BHR when used with an R3 acetabular shell in a total hip arthroplasty was significantly higher than projected.³ Opp’n Ex. 12 at 1-2, ECF 5175-12. Moreover, Smith & Nephew also knew that the revision numbers were likely artificially deflated because of surgeon underreporting. Opp’n Ex. 15, ECF 5175-15. These numbers were not directly relayed to surgeons including Dr. Boucher.

Mr. Williams met with Dr. Boucher in May of 2011 and reported that he was “doing very well” with respect to his BHR hip. Opp’n Ex. 2 at 31:1-17. Mr. Williams was by that point experiencing pain in his other hip, and Dr. Boucher determined that a second resurfacing might be appropriate. *Id.* at 30:8-17, 32:11-33:11. A year later, in May of 2012, Dr. Boucher again reviewed the risks of resurfacing with Mr. Williams, including the potential for the release of metal debris. *Id.* at 33:1-24.

³ The Williamses cite data regarding failure rates of the BHR when used as part of a total hip arthroplasty, which is a different procedure than the resurfacing Mr. Williams underwent. Nevertheless, Smith & Nephew became aware of higher-than-expected failure rates specific to the BHR around the same time.

In late 2012, Mr. Williams began losing weight and showing signs of fatigue. Opp'n Ex. 9 at 40:6-41:15; Opp'n Ex. 10 at 33:18-35:15. Around the same time, he began complaining about a popping or clicking noise coming from his implant when he walked. Opp'n Ex. 9 at 43:10-17. He was diagnosed with congestive heart failure/cardiomyopathy in early 2013. Opp'n Ex. 2 at 35:13-16; Opp'n Ex. 9 at 42:1-23; Opp'n Ex. 10 at 35:19-36:22.

On June 13th, 2013, Mr. Williams saw Dr. Boucher. Opp'n Ex. 2 at 34:25-35:2. At that appointment, Mr. Williams explained his recent diagnosis and complained of squeaking in his BHR hip and pain in his other hip. *Id.* at 35:3-16. Dr. Boucher ordered that Mr. Williams' metal ion levels be taken. *Id.* at 35:17-18. Mr. Williams' cobalt levels were measured at 26.9 parts per billion, which Dr. Boucher considered "very high." *Id.* at 69:3-25. In Dr. Boucher's opinion, Mr. Williams' "implant was the reason his metal ion levels were elevated." *Id.* at 75:20-76:2.⁴

Based on the popping sound and heightened cobalt levels, Dr. Boucher recommended revision of the BHR, and the surgery was completed on July 10th, 2013. *Id.* at 35:25-36:12. During the surgery, Dr. Boucher did not observe any major issues with the implant, including fluid collection, evidence of a pseudotumor, loosening, lysis, or bone loss. *Id.* at 36:13-37:3. Dr. Boucher replaced the BHR with a ceramic femoral head and poly insert and felt that the surgery "went well." *Id.* at 37:4-9. Four weeks after surgery, Mr. Williams' cobalt levels had dropped to 7.6 parts per billion, which was "much improved." *Id.* at 37:19-38:4. On December 30th, 2013, Dr. Boucher replaced Mr. Williams' non-BHR hip using another ceramic-on-poly construct. *Id.*

⁴ No non-circumstantial evidence at this point connects Mr. Williams' heightened cobalt levels to his cardiomyopathy diagnosis. Mr. Williams' father apparently died of a heart attack at age 56. Opp'n Ex. 9 at 13:16-14:14. The Williamses assert, without an affidavit or other evidence, that "Mr. Williams retained an interventional cardiologist . . . who is of the opinion that the Cobalt from the BHR caused him to develop cardiomyopathy over time," and that he is willing to testify to that opinion. Opp'n at 15-16. For purposes of this opinion, the court will assume that the Williamses' assertion is correct.

at 39:18-40:1. Shortly thereafter, Mr. Williams' metal levels were measured again and had dropped even further, to 1.1 parts per billion, which was "close to normal." *Id.* at 40:2-19.

Mr. Williams' health briefly improved after the BHR was removed, Opp'n Ex. 9 at 49:1-13, but things took a turn shortly thereafter and Mr. Williams unfortunately died on December 12th, 2015. Am. Compl. ¶ 46, ECF 44 (in 14-cv-3138).

II. Procedural History

The Williamses filed suit on October 6th, 2014. Compl., ECF 1 (in 14-cv-3138). Following preliminary motions practice, the Williamses' case was consolidated with related cases as part of the court's MDL. After Mr. Williams' death, the Williamses filed a Short Form Complaint in the MDL, adopting the Master Amended Consolidated Complaint ("MACC") and asserting wrongful death and survivorship claims for strict products liability (Count I), negligence (Count II), strict liability failure to warn (Count III), negligent failure to warn (Count IV), negligent misrepresentation (Count V), negligence per se (Count VI), breach of express warranties (Count VII), manufacturing defect (Count VIII), and punitive damages (Count IX). Short Form Compl. ¶¶ 16, 22, ECF 213. Several of the Williamses' claims were dismissed when the court granted in part Smith & Nephew's motion to dismiss the MACC. *See In re Smith & Nephew Birmingham Hip Resurfacing ("BHR") Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732 (D. Md. 2018) ("*BHR Preemption Ruling*"). Specifically, the court dismissed as preempted the claims for strict products liability (Count I), strict liability failure to warn (Count III), and manufacturing defect (Count VIII). The negligence-based claims (Counts II, IV-VI) were allowed to proceed, along with the breach of express warranties (Count VII) and punitive damages (Count IX) claims.

LEGAL STANDARD

Summary judgment will 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). “A dispute is genuine if ‘a reasonable jury could return a verdict for the nonmoving party.’” *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012)). “A fact is material if it ‘might affect the outcome of the suit under the governing law.’” *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Accordingly, “the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment.” *Anderson*, 477 U.S. at 247-48. The court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 572 U.S. 650, 657 (2014), and draw all reasonable inferences in that party’s favor, *Scott v. Harris*, 550 U.S. 372, 378 (2007). Nevertheless, “the nonmoving party must rely on more than conclusory allegations, mere speculation, the building of one inference upon another, or the mere existence of a scintilla of evidence.” *Humphreys & Partners Architects, L.P. v. Lessard Design, Inc.*, 790 F.3d 532, 540 (4th Cir. 2015) (quoting *Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013)).

ANALYSIS

I. Previously Decided Claims

Smith & Nephew contends that the majority of the Williamses’ remaining claims were denied when the court granted it summary judgment on certain theories of liability asserted by plaintiffs who received BHR implants with a large modular femoral head (“MFH”) size. In May of 2021, Smith & Nephew moved for summary judgment as to all claims brought by plaintiffs who received a BHR with an MFH of 50 mm or larger. Large Femoral Head Mem. at 1, ECF

3496 (“LFH Mem.”). Mr. Williams’ BHR had a 50 mm MFH, Opp’n Ex. 2 at 26:7-11, and the Williamses’ case was included in a list of the cases subject to Smith & Nephew’s motion, LFH Mot. for Summ. J. Ex. A at 6, ECF 2762-3. The court granted summary judgment to Smith & Nephew on claims for “failure to warn the FDA, and negligence and negligence per se claims based on failure to report adverse events, failure to train surgeons, and ‘misbranding’ predicated on any statement in the FDA approved label,” as well as punitive damages. LFH Mem. at 5-6. Smith & Nephew asserts that the LFH decision denied the Williamses’ negligent failure to warn (Count IV), negligence (Count II), negligence per se (Count VI), and punitive damages (Count IX) claims. Additionally, in its reply Smith & Nephew points out that the Williamses did not contest its substantive arguments about the insufficiency of their express warranty (Count VII) claim.

In their opposition, the Williamses make arguments supporting the merits of negligent failure to warn and negligent training claims, but do not provide any explanation as to how those theories of liability survived the LFH decision. Their support for the express warranty claim is cursory and does not address Smith & Nephew’s contention that no warranty was ever made. Opp’n at 30. Without any explanation as to why the LFH decision is not controlling, the court concludes that it has already granted Smith & Nephew summary judgment on the Williamses’ negligent failure to warn, negligence, negligence per se, and punitive damages claims. And by failing to respond to Smith & Nephew’s arguments, the Williamses have abandoned their express warranty claim. *Ferdinand-Davenport v. Child’s Guild*, 742 F. Supp. 2d 772, 777 (D. Md. 2010); *Mentch v. E. Sav. Bank, FSB*, 949 F. Supp. 1236, 1247 (D. Md. 1997). The court will therefore grant (or reaffirm) Smith & Nephew’s motion for summary judgment on Counts II, IV, VI, VII, and IX.

II. Negligent Misrepresentation

That leaves the Williamses' negligent misrepresentation claim. To prevail on a claim for negligent misrepresentation under Maryland law, the Williamses must show that: (1) Smith & Nephew owed Mr. Williams a duty of care and negligently asserted a false statement; (2) Smith & Nephew intended that Mr. Williams act upon its false statement; (3) Smith & Nephew knew that Mr. Williams would likely rely on its false statement which would cause loss or injury; (4) Mr. Williams justifiably took action in reliance on the statement; and (5) Mr. Williams suffered damage proximately caused by Smith & Nephew's negligence. *Lloyd v. Gen. Motors Corp.*, 397 Md. 108, 135-36 (2007). Silence or omission can constitute a false statement when a defendant "negligently misrepresented the truth by affirmatively representing only a fragment of the entire picture." *Lubore v. RPM Assocs., Inc.*, 109 Md. App. 312, 340-41 (1996).

Smith & Nephew challenges the sufficiency of the evidence supporting several of the elements of the Williamses' negligent misrepresentation claim. First, it argues that it never made any false statements to Dr. Boucher or Mr. Williams, or that claims based on those statements are preempted, because it provided information consistent with the FDA-approved label. Mot. at 15-18. And second, it contends that Mr. Williams did not justifiably rely on the alleged misrepresentation or that it did not proximately cause his injuries because there is no evidence that any information would have changed Dr. Boucher's recommendation of the BHR. Mot. at 18-19.

The Williamses root the entirety of their negligent misrepresentation argument on Smith & Nephew's alleged failure to disclose information about the learning curve to Dr. Boucher. Opp'n at 20-29. Under the Williamses' theory, Smith & Nephew knew (either actually or constructively) that the 1-3% revision rate was inaccurate because it did not account for the

learning curve in a surgeon's early procedures, did not tell Dr. Boucher about this caveat with the intent that his patients would rely on the accuracy of the 1-3% revision rate, and that, had Smith & Nephew disclosed details of the learning curve, Dr. Boucher would have told Mr. Williams, and, based on that information, Mr. Williams would have forgone implantation of the BHR. Even assuming that failure to describe the learning curve is not a preempted attack on FDA-approved information, *but see Sedgwick Mem. at 17-18, ECF 2977*, the Williamses' argument relies on impermissible speculation and an untenable chain of inferences, and therefore fails to make out a viable negligent misrepresentation claim.

First, there is no evidence to show that the learning curve data were related to Mr. Williams' injuries. In a negligent misrepresentation case, "the plaintiff must show not only that he would not have performed the act from which the injury resulted but for the misrepresentation, but also that the fact misrepresented was the proximate cause of the injury." *Lavine v. Am. Airlines, Inc.*, __ A.3d __, No. 2917, 2011 WL 13377948, at *6 (Md. Ct. Spec. App. Dec. 1, 2011) (quoting *Lustine Chevrolet v. Cadeaux*, 19 Md. App. 30, 35 (1973)); *see Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 104 (D. Md. 2020) ("A warning is legally adequate when it explains the risk which the plaintiff alleges has caused the injury." (quoting *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989))). The learning curve data described a risk of surgical error. The Williamses contend that Mr. Williams' injuries were the result of heightened levels of cobalt due to metal ions released by the BHR during its normal function. Not only have the Williamses' presented no evidence to link the metal ion release to surgical error; the record demonstrates that Dr. Boucher properly implanted Mr. Williams' BHR. Opp'n Ex. 2 at 28:2-30:3, 31:1-17, 36:13-37:3. Moreover, there is ample evidence that Dr. Boucher warned Mr. Williams of the risk of metal ion release. *Id.* at 24:10-25:6, 25:19-26:2, 33:1-34:16.

The Williamses have only shown, at best, that the alleged misrepresentation was a but for and not a proximate cause of Mr. Williams' injuries.

Second, the Williamses have not shown that Smith & Nephew was aware of specific details about the learning curve at the time of Dr. Boucher's training or Mr. Williams' surgery to make its statement of a 1-3% revision rate false. The evidence in this case describing the learning curve comes from a 2015 video interview of Dr. McMinn which was played during the deposition of another witness. Opp'n Ex. 5 at 198:20-199:9 (deposition of Timothy Band). The Williamses have presented no evidence to demonstrate when Dr. McMinn explained these specific learning curve data to Smith & Nephew. When pressed at oral argument, the Williamses' counsel contended that Smith & Nephew at least had constructive knowledge of Dr. McMinn's learning curve data but offered no evidence to show that Dr. McMinn was an agent of Smith & Nephew. Essentially, the Williamses speculate that, because Smith & Nephew personnel knew that training was important and the procedure was new and difficult, they must also have known about the learning curve. It is not reasonable to infer knowledge of specific data from general concerns. And to the extent Smith & Nephew knew about a general, non-statistical learning curve, so did Dr. Boucher, yet he did not disclose that information to Mr. Williams. Opp'n Ex. 2 at 50:20-51:13; *see Morris*, 491 F. Supp. 3d at 103-05 (“[E]ven where a warning is inadequate, a [misrepresentation] claim fails where the doctor was already aware of the risk the allegedly deficient warning should have communicated.” (citing *McClure v. Sci. Spinal*, 11 F. App'x 154, 159 (4th Cir. 2001))).

Third, the Williamses ask the court to infer that Mr. Williams would have foregone implantation of the BHR if Dr. Boucher had explained the learning curve to him. They point to evidence that Mr. Williams was generally suspicious of medical procedures and that he delayed

implantation to conduct his own research. Opp'n Ex. 9 at 32:13-18, 33:19-24, 62:15-63:13; Opp'n Ex. 10 at 24:3-25:3, 29:11-20. But Smith & Nephew points out that Mr. Williams trusted Dr. Boucher, *see* Opp'n Ex. 10 at 29:12-14, and that there is no evidence that Dr. Boucher would have changed his recommendation of the BHR based on the learning curve. Though the court *could* infer that Mr. Williams would have avoided the BHR on this evidence, that this inference is necessary to connect the speculation described above weighs in favor of Smith & Nephew.

Finally, the Williamses argue that, once Smith & Nephew had data about the BHR's higher-than-expected failure rate in 2011, it should have explained those data to Dr. Boucher, who would have relayed the information to Mr. Williams, who would have sought treatment for BHR failure sooner than he did. This speculative chain of events suffers from the same defects already described. Furthermore, there is no evidence to show that Smith & Nephew made *any* statements to Dr. Boucher or Mr. Williams between 2011 and 2013, and the contention that Smith & Nephew should have affirmatively communicated new information about the BHR's revision rate to surgeons is the essence of a failure to warn claim, *see Gourdine v. Crews*, 405 Md. 722, 739 (2008), which this court has already denied.

CONCLUSION

For the reasons stated, the court will grant Smith & Nephew's motion for summary judgment. A separate order follows.

1/8/2024
Date

/s/
Catherine C. Blake
United States District Judge