

**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:

Marla H. Hand et al. v. Smith & Nephew, Inc.,
Civil Case No. 1:17-cv-935-CCB

MEMORANDUM

Pending before the court is Smith & Nephew’s motion for summary judgment in BHR track action *Marla H. Hand et al. v. Smith & Nephew, Inc.*, No. 1:17-cv-0935. Smith & Nephew seeks summary judgment (ECF 644 in 17-cv-0935; ECF 3574 in master docket 17-md-2775) as to all remaining claims brought by Hand and her spouse James Nyeste (together, “Hand”) — breach of express warranty, a variety of negligence-based claims, punitive damages, and (for Nyeste) loss of consortium. Hand responded in opposition (ECF 655), and Smith & Nephew replied in support of its motion (ECF 663). The court heard oral arguments on May 4, 2022. For the reasons stated herein, the court will grant Smith & Nephew’s motion.

BACKGROUND

This case concerns injuries suffered by plaintiff Marla Hand and her spouse, James Nyeste, as a result of Hand’s use of the Birmingham Hip Resurfacing Device (“BHR”), an artificial hip implant developed, designed, manufactured, and sold by defendant Smith & Nephew.

The BHR

The Birmingham Hip Resurfacing (BHR) system is a Smith & Nephew prosthetic hip replacement product that, unlike a traditional total hip replacement, trims and caps — that is, resurfaces — the head of the femur. That femoral head component fits into a hemispherical acetabular cup that fits into a patient’s hip socket. The two pieces rub against one another during movement of the patient’s hip joint; both are made of cobalt and chromium metal alloys, and the BHR is thus a “metal-on-metal” product. The BHR received Pre-Market Approval from the U.S. Food and Drug Administration on May 9, 2006.

The friction between the metal components allegedly can cause metal debris to accumulate within the joint and bloodstream 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.

In June 2015, about nine years after initial approval, Smith & Nephew voluntarily recalled some BHR devices due to unreasonably high failure rates (including for complications due to metal debris) for certain demographic groups, including women, men age 65 or older, and men with femoral head sizes 46 millimeters or smaller.

Marla Hand and the Lead-up to Surgery

Hand, 66, and Nyeste are residents of Illinois. Hand had long had problems with her right hip, beginning in the late 1990s and including a hip dysplasia diagnosis and four surgical procedures from August 1998 to sometime before May 2001.

These difficulties with her right hip were unrelated, however, to her left hip. She first saw Dr. Craig Della Valle in November 2004 with complaints of left hip pain. He noted mild dysplasia on the left side, and Hand underwent non-surgical treatment for several years. By May

2007, however, her left hip pain had advanced to the point where she was significantly disabled and could no longer walk her dog or exercise.

Dr. Della Valle recommended a hip resurfacing for Ms. Hand's left hip. He had been trained on the BHR by Smith & Nephew in November 2006 and had by then performed 20 to 30 BHR implants, about two of which, he estimated, had been for women. (ECF 644-6, Ex. D, Della Valle Dep. at 10–11). In making recommendations or treatment decisions, Dr. Della Valle relies most on “peer-reviewed published data and peer-reviewed publications” as well as his experience, training, and conferences he has attended. (*Id.* at 99).

Hand and Dr. Della Valle had several discussions about the risks and benefits of a BHR and how it compared to a traditional total hip replacement; Hand also attended a patient education class and sought a second opinion from Dr. Scott Sporer. (ECF 644-5, Ex. C, Hand Dep. at 71, 84–86; ECF 644-6, Ex. D, Della Valle Dep. at 45). Dr. Della Valle told Hand that, compared to total hip replacement, resurfacing would preserve more of the femoral head, that the recovery theoretically would be easier, and that resurfacing could keep a young patient like her active. (ECF 644-5, Ex. C, Hand Dep. at 75). He did not guarantee the BHR's outcomes. (*Id.* at 82).

Dr. Della Valle warned Hand that, as a female, she was at a higher risk for revision. (ECF 644-6, Ex. D, Della Valle Dep. at 138–39). He was aware of this higher risk at the time and discussed the risk with his female patients. (*Id.* at 13–14, 110–11). At the time, that higher risk appeared specifically tied to femoral neck fractures, which tend to occur early, not long after implantation.

At the time, Dr. Della Valle also was aware that the BHR's metal-on-metal configuration might result in the release of metal ions into the bloodstream as a result of wear between the

components. (*Id.* at 140–41). At the time of Hand’s implant surgery, Dr. Della Valle’s custom and practice with resurfacing procedures was to tell patients that a metal-on-metal bearing carried additional risks such as this. (*Id.* at 41, 45). During the second opinion consultation with Hand, Dr. Sporer discussed the potential for increased metal ion concentration. (ECF 644-5, Ex. C, Hand Dep. at 78–79; ECF 644-7, Ex. E, May 23, 2007, Office Visit Notes with Dr. Scott Sporer).

The Patient’s Guide

Before her BHR implant surgery, Hand read the Smith & Nephew BHR Patient’s Guide, which Dr. Della Valle gave her in order to show her illustrations of resurfacing compared to total hip replacement. In a section describing the BHR’s bearing surface, the Patient’s Guide explained:

There may be risks associated with metal-on-metal implants, though. *While no evidence has been established on the subject, some are concerned that the increased level of metal ions found in the blood of metal-on-metal hip recipients may have negative effects on the human body.* For this reason, some surgeons may not implant such a device in a patient with kidney disease (since healthy kidneys filter ions from your body) or in women who are or may become pregnant.

(ECF 655-10, Patient’s Guide at 13) (emphasis added).

In a “Frequently Asked Questions” section addressing the expected outcomes of a BHR implant, the Guide explained:

It is impossible to say how long your implant will last because so many factors play into the lifespan of an implant. In the case of resurfacing, for instance, the metal-on-metal bearing surfaces of your new joint may extend its life longer than that of a traditional total hip replacement, but failure to comply with your physical rehabilitation regime may cause your implant to fail within months. A clinical study showed the BIRMINGHAM HIP Resurfacing implant had a survivorship of 98.4-percent at the five-year mark, which is comparable with the survivorship of a traditional total hip replacement in the under-60 age group.

(ECF 655-10, Patient's Guide at 22) (emphasis added). A 98.4% five-year survivorship rate in the under-60 age group represents a 1.6% revision rate.

Hand's Surgery and the Aftermath

Hand received a 42mm-head BHR implant in her left hip on June 25, 2007, when she was age 51.¹ Within several weeks, she had much less pain than before the surgery and had resumed exercise and dog-walking. She was back doing aerobics by October 2007. Her left hip was pain-free for almost ten years, but at a May 2013 annual BHR follow-up appointment, she reported new pain in her right (non-BHR) hip. (ECF 644-5, Ex. C, Hand Dep. at 112–15; ECF 644-6, Ex. D, Della Valle Dep. at 129). A blood test revealed elevated metal ion levels. (ECF 644-5, Ex. C, Hand Dep. at 112:10–114:22). In July 2013, she told her physical therapist that she was worried she might need a revision on the left hip (*Id.* at 143), and the records from that meeting state that she had recently been diagnosed with metal toxicity due to an implant malfunction (ECF 644-9, Ex. G, July 12, 2013 Physical Therapy Notes). By late 2016, Hand started to complain of pain on the left side. Her metal ion levels were elevated, and an MRI showed what Dr. Della Valle suspected was an adverse local tissue reaction.

Nine and a half years after Hand received the BHR — on December 5, 2016 — Dr. Della Valle performed a revision surgery on Hand's left hip. Hand had no pain on the left side by March 2017 and was back to a normal gait and unlimited moderate activities by December 2017.

The Australian Registry Data in 2006

Earlier cases in this multidistrict litigation have hinged on Smith & Nephew's October 2009 receipt of detailed data about the BHR's performance and elevated revision risk in women

¹ About a week before the June 2007 surgery was to take place, a Smith & Nephew representative emailed Dr. Della Valle to confirm a June 16, 2007, Chicago meeting with marketing and engineering employees to discuss bringing Dr. Della Valle onboard to help design a new cementless acetabular cup for the BHR's metal-on-metal bearing. (ECF 665).

and patients with smaller femoral head sizes — the so-called “ad hoc” data from the Australian Orthopaedic Association’s (AOA’s) National Joint Replacement Registry (the “Australian registry”). Hand argues that Smith & Nephew in fact knew about the elevated revision risk in women long before October 2009, as early as 2006.

In October of 2004, 2005, and 2006, the Australian registry published annual reports covering their data from the prior year. (*See* ECF 3477-14, AOA 2006 Annual Report). These reports were posted publicly and sent to Smith & Nephew by Australian registry director Stephen Graves. (ECF 655-2, Graves Dep. at 136:14-18).² The reports, Hand argues, revealed the gender difference in resurfacing product revision outcomes, though they were not disaggregated by company. Still, about 63.5% of the resurfacing data points in 2006 represented Smith & Nephew products.

The record contains no explicit confirmation that Smith & Nephew received the annual reports, but Smith & Nephew did periodically initiate contact with the Australian registry around that time. Most relevant to this litigation, Graves said that, in 2006,³ Smith & Nephew initially requested BHR information from the Australian registry but declined to proceed when they were told it would cost money. (ECF 655-2, Graves Dep. at 131:16-19). In 2007,⁴ the company requested summary data on the BHR’s outcomes and on the demographics of use — that is, the gender and age of the population receiving the BHR. (ECF 655-2, Graves Dep. at 131:20-23; “just very basic information” with “no detailed analysis,” per ECF 655-2 at 46:22–47:3). The next inquiry around the BHR was in October 2009, when Smith & Nephew requested a detailed

² “Q. . . . In 2004, 2005, 2006, did the registry send a copy of the annual report to Smith & Nephew? A. We did. But also I just need to reiterate the report is freely available online.” (ECF 655-2 at 136:14-18). When asked, he did not confirm that Smith & Nephew had actually received those annual reports he sent (ECF 655-2, Graves Dep. at 136:19-137:12), but they were publicly available.

³ It is unclear whether this was after May 2006, but the court assumes without finding that it was.

⁴ It is unclear whether this was before June 25, 2007, but the court assumes without finding that it was.

report around outcomes that captured the gender variation, the performance of the BHR, and the head size variation — the ad hoc data that marked the clear beginning of Smith & Nephew’s knowledge of gendered revision rates in past stages of this multidistrict litigation. (ECF 655-2, Graves Dep. at 47:5-6, 131:24-25, 138:4-9). Graves discussed this with Smith & Nephew representative Dr. Peter Heeckt. (ECF 655-2, Graves Dep. at 137:25-138:3). He did not recall telephone conversations with Smith & Nephew personnel about the BHR, but he said he would have had some. (ECF 655-2, Graves Dep. at 132:5-8).

The 2006 AOA report included breakdowns of resurfacing revision rates by gender and age. (ECF 3477-14, 2006 AOA report at 73, Table HT22 (listing resurfacings’ 3-year revision rate as 4.2% for women and 2.17% for men); *Id.* at 76). Of particular note would have been the report’s resurfacing revision rate breakdowns by gender and age:

<i>Sex and Age</i>	<i>Primary Resurfacing Hip Procedures, Cumulative Percent Revised</i>			
	1 year	2 years	3 years	4 years
Females by Age				
Female < 55	2.31	2.62	3.07	3.91
Female 55–64	2.65	4.04	5.21	5.21
Female ≥ 65	3.85	5.60	8.38	8.38
Males by Age				
Male < 55	1.24	1.52	1.75	2.15
Male 55–64	1.40	1.81	2.12	
Male ≥ 65	3.55	3.55	3.86	

(*Id.* at 76, HT26 (95% confidence intervals omitted)). Hand was under 55 years old at the time.

<i>Sex</i>	<i>Primary Resurfacing Hip Procedures, Cumulative Percent Revised</i>		
	1 year	2 years	3 years
Female	2.52	3.34	4.20
Male	1.61	1.90	2.17

(*Id.* at 73, HT22 (95% confidence intervals omitted)).

Age	<i>Primary Resurfacing Hip Procedures, Cumulative Percent Revised</i>			
	1 year	2 years	3 years	4 years
Age < 55	1.57	1.86	2.16	2.70
Age 55–64	1.75	2.46	3.04	
Age 65–74	3.24	3.47	4.16	
Age ≥ 75	8.38	8.38	8.38	8.38

(*Id.* at 71, HT18 (95% confidence intervals omitted)).

LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) provides that summary judgment should be granted “if the movant shows that there is no *genuine* dispute as to any *material* fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a) (emphases added). “A dispute is genuine if ‘a reasonable jury could return a verdict for the nonmoving party.’” *Libertarian Party of Va. v. Judd*, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012)). “A fact is material if it ‘might affect the outcome of the suit under the governing law.’” *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Accordingly, “the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment[.]” *Anderson*, 477 U.S. at 247–48. The court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (per curiam), and draw all reasonable inferences in that party’s favor, *Scott v. Harris*, 550 U.S. 372, 378 (2007) (citations omitted); *see also Jacobs v. N.C. Admin. Office of the Courts*, 780 F.3d 562, 568–69 (4th Cir. 2015). At the same time, the court must “prevent factually unsupported claims and defenses from proceeding to trial.” *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 526 (4th Cir. 2003) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993)).

ANALYSIS

Smith & Nephew moved for summary judgment on each of Hand's remaining claims: breach of express warranty, a variety of negligence-based claims (negligent misrepresentation as well as negligent failure to warn, negligence per se, and negligent failure to train), punitive damages, and loss of consortium. The court considers each in turn.

I. Breach of Express Warranty (Count VII)

Under Illinois law, “the 4-year statute of limitations begins to run for a breach of warranty claim upon delivery of the product ‘*regardless of the aggrieved party’s lack of knowledge of the breach.*’ Illinois courts have strictly construed this provision in just this manner.” *Hagen v. Richardson-Merrell, Inc.*, 697 F. Supp. 334, 341 (N.D. Ill. 1988) (citing Ill. Rev. Stat. ch. 26, ¶ 2–725 (1985) and *Moorman Mfg. Co. v. National Tank Co.*, 435 N.E.2d 443, 454 (Ill. 1982)).

There is, however, an exception for explicit warranty of future performance:

A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

810 Ill. Comp. Stat. 5/2-725(2). But this exception is narrow and requires that a plaintiff “allege that a clearly stated express written warranty guaranteeing future performance existed and was breached or offer a copy of an express warranty.” *Shipley v. Wright Medical Technology, Inc.*, 19-cv-2040, 2019 WL 13118996, at *6 (C.D. Ill. May 23, 2019) (quoting *Kim v. McNeill-PPC Inc.*, 2014 WL 4650101, at *3 (N.D. Ill. Sept. 12, 2014)). And even where a warranty is express, courts are reluctant to infer terms of prospective operation where not clearly stated. *Kim*, 2014 WL 4650101, at *3.

Hand's BHR was implanted on June 25, 2007; four years later was June 25, 2011. She filed her lawsuit on January 19, 2017. The plaintiffs argue that the Patient's Guide was the

foundation of her clear expectation of the BHR's future performance (particularly in women and those with dysplasia), and thus the Patient Guide contained the express warranty of future performance needed to qualify for the exception to the four-year statute of limitations. In particular, the Guide introduced its section on the BHR's benefits to patients by saying that "*the implant's rate of survivorship is comparable to standard total hip replacements after five years,*" then focusing on the BHR's advantages with regard to head size, bearing surfaces, and bone conservation. (ECF 655-5, Ex. 5, Patient's Guide at 12 (emphasis added)). The same Guide explicitly said it was impossible to know how long the implant would last because so many factors influenced its longevity. (*Id.* at 22). The language of the Patient's Guide falls short of the specific warranty contemplated by Illinois law. The exception for explicit warranty of future performance thus does not apply, and Mrs. Hand's breach of express warranty claim is time-barred. Summary judgment will be granted in Smith & Nephew's favor. The court need not reach the merits of her claim.⁵

II. Negligence-based claims (Counts V, IV, VI, and II)

A. Statute of Limitations

Under Illinois law, negligence claims alleging personal injury "shall be commenced within 2 years next after the cause of action accrued." Ill. Comp. Stat. 5/13-202.

In general, under Illinois law, the statute of limitations clock begins to run when facts exist that would authorize the bringing of a cause of action. *MC Baldwin Fin. Co. v. DiMaggio, Rosario & Veraja, LLC*, 845 N.E.2d 22, 30 (Ill. 2006). Illinois also uses the so-called discovery rule, so that the statute of limitations clock does not start running until the injured party knows or reasonably should have known both that she was injured and that her injury was *wrongfully caused* by another person. *See Golla v. General Motors Corp.*, 657 N.E.2d 894, 898 (Ill. 1995).

⁵ Hand said she was given a "very favorable" impression but that no promises, guarantees, or warranties were made or given to her. (ECF 644-5, Ex. C, Hand Dep. at 82:6-16, 235:15-25).

Stark v. Johnson & Johnson, 10 F.4th 823, 828 (7th Cir. 2021) (emphasis added). Illinois courts have understood as central the requirement that a plaintiff know her injury was wrongfully caused by another; it “does not mean knowledge of a *specific* defendant’s negligent conduct or knowledge of the existence of a cause of action.” *Stark*, 10 F.4th at 828–29 (citing *Castello v. Kalis*, 816 N.E.2d 782, 789 (Ill. 2004)). “The phrase refers to when the injured party learns that her injury *may stem from another’s negligence rather than natural causes*. That is enough for the law to expect the injured party to investigate a potential cause of action.” *Id.* at 829 (emphasis added). “The law is well-settled that once a party knows or reasonably should know both of his injury and that it was wrongfully caused, ‘the burden is upon the injured person to inquire further as to the existence of a cause of action.’” *Castello*, 816 N.E.2d at 789 (quoting *Witherell v. Weimer*, 421 N.E.2d 869, 874 (Ill. 1981)).

Illinois courts generally recognize as a disputed question of fact the time when the injured party knows (or should have reasonably known) of both her injury and that her injury was wrongfully caused by another. *Id.* (citing *Witherell*, 421 N.E.2d at 874). Yet courts may determine the issue as a matter of law when “there is a single, clear answer to be drawn from the undisputed facts in the record.” *Id.*

Hand knew no later than July 2013 that her injury may have stemmed from the BHR. A May 2013 blood test revealed her elevated metal ion levels (ECF 644-5, Ex. C, Hand Dep. at 113–14) and in July 2013 she reported to her physical therapists that she was concerned about those elevated ion levels, which she told them was connected to her hip implants and their degeneration.⁶ Hand told them that month that she was concerned she would need a left hip revision. (ECF 644-5, Ex. C, Hand Dep. at 143:16-19).

⁶ To substantiate this fact, Smith & Nephew’s memorandum cited pages 132 and 219 of the Hand deposition, but those pages are not included in Exhibit C to ECF 644 of case 17-cv-935-CCB.

But knowing that her metal ion levels were attributable to her implant is not the same as knowing her metal ion levels were caused by another's negligent conduct, as Illinois law requires to start the clock on her lawsuit. Smith & Nephew has not shown beyond genuine dispute that Hand knew another person's negligence was at the root of her implant's metal ion release. She may have known her metal ion levels might be elevated; FDA-approved language on the metal ion scientific literature specified that metal-on-metal total hip replacement patients experienced blood and urine metal ion concentrations, but that there was no conclusive evidence of significant detrimental effects. (ECF 663-2, Ex. B, BHR System Important Medical Information (December 2005) at 14). In addition to the BHR's labeling, Hand was warned in 2007 before the implant — likely by Dr. Della Valle and certainly by Dr. Sporer — that there was a potential for increased metal ion concentration, and she might very reasonably have believed that her implant's "malfunction" (a word used in her physical therapist's notes in July 2013, ECF 644-9 at 1) was not the result of wrongful conduct or negligence but rather in the natural and acceptable range of outcomes. She is owed this reasonable inference in her favor at the summary judgment stage. While she need not have been certain that negligence caused her injury, Smith & Nephew's burden at this stage is to show that there is no genuine dispute of material fact as to her knowledge of negligence as a possible cause of her injury, and it has failed to meet that standard in its briefing. The negligence-based claims are therefore not time-barred, and the court will address the merits of each.

B. Negligent Misrepresentation (Count V)

In order to state a claim for negligent misrepresentation under Illinois law, a party must allege:

- (1) a false statement of material fact;

- (2) carelessness or negligence in ascertaining the truth of the statement by the party making it;
- (3) an intention to induce the other party to act;
- (4) action by the other party in reliance on the truth of the statement;
- (5) damage to the other party resulting from such reliance; and
- (6) a duty on the party making the statement to communicate accurate information.

Tricontinental Industries, Ltd. v. PricewaterhouseCoopers, LLP, 475 F.3d 824, 833–34 (7th Cir. 2007) (quoting *First Midwest Bank, N.A. v. Stewart Title Guar. Co.*, 843 N.E.2d 327, 334–35 (Ill. 2006)). A misleading omission may be a relevant basis for a negligent misrepresentation claim. *See Kim v. State Farm Mut. Auto. Ins. Co.*, 2021 WL 2719112, at *9 (Ill. App. 2021).⁷

The plaintiff's reliance on the truth of the of the defendant's statement must be justifiable.

Kopley Group V., L.P. v. Sheridan Edgewater Props., 876 N.E.2d 218, 229 (Ill. App. 2007).

Hand has a narrow window in which to identify a misrepresentation. As noted in this court's prior rulings, statements predating the FDA's May 2006 approval of the BHR would challenge the FDA's PMA approval process and the FDA-approved BHR label. (*See Sedgwick Summ. J. Mem.*, ECF 2977 at 18). And because Hand's left hip implant surgery took place on June 25, 2007, any relevant misrepresentations must have occurred before then or else it would be impossible for Dr. Della Valle or Ms. Hand to have relied on them in choosing the BHR.⁸ This leaves just over a year: May 2006 to June 2007. While evidence from outside that time period is not necessarily irrelevant, it must point to a misrepresentation during that time period. These alleged misrepresentations must be inconsistent with the FDA label at the time of Hand's

⁷ The parties did not extensively brief the question of whether a misleading omission can be the basis of a negligent misrepresentation claim in a tort suit seeking non-economic damages, but the court assumes for the purposes of this opinion that it can be.

⁸ Representations after June 2007 include the November 2007 marketing letter from Mark Waugh (cited in Hand's response brief at ECF 655 at 14) and the non-public ad hoc registry data confirmed to have been sought and received by Smith & Nephew beginning in fall 2009 (ECF 2095, *Mosca Summ. J. Mem.* at 7).

surgery (and thus not shielded by the court’s earlier preemption rulings), and they must be false or misleading by omission. (*See Sedgwick Summ. J. Mem.*, ECF 2977 at 17).

1. Smith & Nephew’s alleged knowledge in 2006

Hand’s misrepresentation theory centers around alleged omissions. The first part of her theory argues that Smith & Nephew knew of women’s higher revision rates long before the October 2009 ad hoc data. Because 63.5% of the 2006 Australian registry report data came from Smith & Nephew, she says the company should have known that even the disaggregated report information spoke to the BHR’s outcomes. And she contends the mere existence of gender differences in revision rates is not the primary issue. Instead, it is the magnitude of the difference in men’s and women’s revision rates. This difference, she says, was great enough six months or a year post-implantation that Smith & Nephew should have seen something was amiss beyond just the already known gender-differentiated risk of failure due to early fractures in the femoral neck. That is to say, Hand argues that Smith & Nephew should have known in October 2006 (based on 2005 data) both that women had higher revision rates and there was some cause other than femoral neck fractures — i.e., metallosis.

Hand also points to evidence that might support an inference that Smith & Nephew knew of the gender-differentiated outcomes at the time — for example, a November 2006 company PowerPoint presentation (ECF 655-5, Ex. 5, “The future of BHR” at 8–29 of 127) indicating that Smith & Nephew wanted to reduce metal ion wear in the BHR. Hand argues that this shows Smith & Nephew knew at the time that metal ion wear was causing a high revision rate in women, but the record does not support this inference. At that time, it was known that metal ion wear was a potential concern (to the point that it was mentioned in the Patient’s Guide⁹ and the

⁹ ECF 655-10, Ex. 10, Patient’s Guide at 13.

label¹⁰) but that “there does not appear to be any conclusive evidence that elevated cobalt and chromium levels have any significant detrimental effects[.]” (ECF 663-2, Ex. B, BHR System Important Medical Information (December 2005) at 14). Hand has no evidence (other than higher revision risk numbers) that the cause was metallosis or that it was known to Smith & Nephew. A desire to reduce metal ion wear is consistent with the simultaneous understandings that metal ions are a potential source of concern and that there is no conclusive evidence about the nature and extent of their detrimental effects.

2. Voluntary communications that Hand alleges were misrepresentations

The second part of Hand’s misrepresentation theory is that any voluntary communications between Smith & Nephew and patients or surgeons during that time are tainted by the omission of the magnitude of women’s higher revision rates and their potential cause other than femoral neck fractures. In particular, she highlights four separate May 2006 to June 2007 voluntary and misrepresentative communications, each of which omitted any information about women’s higher revision rates:

- a) the April 2006 Patient’s Guide, which Hand read prior to implantation and which Dr. Della Valle would have referred to in pre-surgery discussions with Hand;
- b) Dr. Della Valle’s November 2006 BHR training seminar with Smith & Nephew;
- c) two instances when Smith & Nephew Sales representatives visited Dr. Della Valle to deliver BHR components for female patients who received their surgeries at some point before Hand; and
- d) a meeting between Dr. Della Valle and Smith & Nephew personnel in Chicago on June 16, 2007, and an email message ahead of that meeting.

¹⁰ ECF 644-11, Ex. I, BHR System Patient Information at 2 (SN_BHR_MDL_2419119) ¶ 3, bullet 5.

The court considers each in turn.

a. The Patient's Guide

The Smith & Nephew Patient's Guide provided to Hand is the cornerstone of Hand's claim that Smith & Nephew made misrepresentations directly to her, and Hand also argues that it also misrepresented the BHR to Dr. Della Valle. But there is insufficient evidence of false statements of material fact in the Patient's Guide, and in any event, Hand has failed to present a genuine dispute of material fact as to whether she relied on the Patient's Guide — as opposed to advice from her surgeon — for representations about gendered revision rates or any of the other possibilities she raises.

i. Revision Risk

First, the record does not support Hand's theory that the Patient's Guide (ECF 644-8, Ex. F, Patient's Guide) misrepresented the revision risk. The relevant¹¹ excerpt reads:

In general: "It is impossible to say how long your implant will last because so many factors play into the lifespan of an implant . . . A clinical study showed the BIRMINGHAM HIP Resurfacing implant had a survivorship of 98.4-percent at the five-year mark, which is *comparable with the survivorship of a traditional total hip replacement* in the under-60 age group."

(*Id.* at 22) (describing a 1.6% revision rate at five years) (emphasis added). It is consistent with FDA-approved information placing the five-year revision rate at 1–3%.¹²

Hand points first to the Guide's representation that the BHR's five-year survivorship rate of 98.5% (revision rate of 1.6%) was "comparable with the survivorship of a traditional total hip

¹¹ One other excerpt from the Patient's Guide discusses the risk of dislocation, the leading cause of implant failure, but this is not precisely on point for Hand's case. "While total hip implants dislocate at a rate of one to three-percent over the lifetime of the implant, a study of 2,385 BIRMINGHAM HIP Resurfacing patients found that dislocation occurred in only 0.3-percent of cases five years after surgery." (ECF 644-8, Ex. F., Patient's Guide at 13) (describing outcomes specific to dislocation).

¹² "The revision rate for the primary efficacy cohort was 1.47% at 5 years[.]" (ECF 663-2, Ex. B, BHR System Important Medical Information (Label) at 13; *see also* Table 13). The overall McMinn cohort had a 98.5% survivorship (95% confidence interval: 97.4–99.6%). (*Id.* at 17). *See also* ECF 2977, *Sedgwick* Summ. J. Mem. at 5, 17.

replacement in the under-60 age group” as contradicted by the 2006 AOA report. For resurfacings in the Australian registry (at that point, 63.5% BHR but also some other companies’ products), the report lists three-year revision rates of 2.16% for patients under 55 and 3.04% for patients 55–64, and it lists a 2.7% revision rate at four years for patients under 55, not listing a corresponding four-year statistic for patients 55–64. (ECF 3477-14, 2006 AOA report at 71, Table HH18). For conventional total hip procedures, the report lists three-year revision rates of 2.17% for patients under 55 and 2.10% for patients 55–64, and it lists a 2.74% revision rate at four years for patients under 55 and a 2.4% revision rate at four years for patients 55–64. (*Id.* at 70, Table HT16). The 2006 AOA report thus reveals some difference in traditional total hip outcomes and resurfacing outcomes, but not so big a difference as to render the Patient Guide’s statement a false statement of fact in its description of the revision rates as “comparable” to that of under-64 total hip patients.

Hand next points to the fact that the Guide describes only the overall revision rate rather than disaggregated subgroup rates. Omitting these facts and referring only to combined revision rates rendered the Patient Guide misleading, according to Hand. But her reliance on the Patient’s Guide for gendered outcomes is not supported by the record. Hand cites deposition testimony¹³ in which she says she would have wanted to know about the BHR’s “much higher” failure rate in women compared to men (ECF 655-11 at 221:7-10) and in patients with smaller femoral head sizes (*id.* at 221:11-15); she says she would not have put the BHR in her body had she known that information (*id.* at 221:16-21). But this question immediately followed questions about what Dr. Della Valle had told her and did not actually address the Patient’s Guide specifically, instead speaking to her general desire to know. A few questions later, the deposition does take up the

¹³ The Patient’s Guide is discussed in Hand’s deposition at ECF 655-11 at 221:23–226:6.

Patient's Guide (*Id.* at 221:23), and she was asked a series of questions about whether she remembered reading certain passages and whether she thought they were truthful. She did not say she had relied on any specific statement. Hand merely notes that she did not remember any specific information in the Guide suggesting a higher risk of revision in patients with hip dysplasia (*Id.* at 222:4-23). There is no concrete indication that she relied on this in making her decision to proceed with the BHR.

Further, Dr. Della Valle knew of the gendered revision rates at the time and shared with her the risk (albeit focused on possible femoral neck fracture). (ECF 644-6, Ex. D, Della Valle Dep. at 138:19–139:8). Any claim of reliance on the Patient Guide's omission of gender-differentiated outcomes is weakened by the fact that her surgeon had told her of women's higher revision rate.

Hand's point about the magnitude of the gender revision rate differences is well taken; perhaps she would have wanted to know if revision rates for women had been not just higher but much higher.¹⁴ But given that the Patient's Guide contained no information at all about gender-differentiated revision rates and what information she had about such differences came from Dr. Della Valle, she has not shown that her decision to proceed with the BHR was based on her reliance on the representations in (or omissions from) the Patient's Guide. Hand has failed to present a genuine dispute of material fact as to whether she relied on the Patient's Guide's alleged false statements of fact or omissions about revision rates.

ii. Metallurgy, Metal Ions, and Revision Trauma/Complexity

Second, Hand has failed to surface any evidence that Smith & Nephew had reason from May 2006 to June 2007 to doubt the Patient Guide's claims (ECF 655-10, Patient's Guide at 13)

¹⁴ The court does not address what degree of magnitude would be sufficient to support the claim.

about the BHR's metallurgy. As this court has ruled before, "it was not until 2015 that Smith & Nephew received data that undercut its assertions that the BHR's 'as-cast' metallurgy was responsible for a revision rate that was lower than its heat-treated competitors." (ECF 2977, *Sedgwick* Summ. J. Mem. at 18 (citing ECF 2757-11, Ex. 9, August 2015 E-mail regarding Kaiser Permanente analysis at 1 of 10)¹⁵). A November 2006 company presentation even includes a slide entitled "'As Cast' material has higher wear resistance." (ECF 655-5, Ex. 5, Nov. 2006 presentation, "The future of BHR" at 11 of 127). And Hand's expert, Dr. Bowling, concedes that design differences between the BHR and other devices did exist, that the BHR was outperforming other devices during the relevant time frame (ECF 643-5, Ex. C, Bowling Dep. at 133:32-25, 134:22–135:15) and that "there is scientific support for the assertion of the benefit that as cast Cobalt chrome produces less wear than heat treated Cobalt chrome" (*Id.* at 234:16-25). Finally, the record contains no evidence that Hand relied on the Patient's Guide for metallurgy information in choosing the BHR.

Third, the Patient's Guide did not omit the risk of metal ions; it warned that "some are concerned that the increased level of metal ions found in the blood of metal-on-metal hip recipients may have negative effects on the human body." (ECF 644-8, Ex. F., Patient's Guide at 13). Hand testified that she remembered this Patient's Guide section on metal ions. (ECF 655-11, Hand Dep. at 224:13-21). These representations were in line with the FDA-approved label at the time, and the 2006 AOA report does not contain information to the contrary; it does not even track metallosis as a cause of revision. Here, too, the record contains no evidence that she relied on this in choosing the BHR — especially because Dr. Della Valle believes he would have

¹⁵ The 2015 email described how the as-cast BHR's revision rate at 7 years was 17.2% compared to the heat-treated Corin's 16% revision rate at 7 years; the BHR was marketed as an improvement upon the Corin Cormet. (ECF 2757-10, Ex. 8, BHR Powerpoint at 10 of 30).

discussed, at least in general, metal wear (ECF 644-6, Ex. D, Della Valle Dep. at 41, 45, 143–44) and Dr. Sporer’s second opinion definitely did so (ECF 644-5, Ex. C, Hand Dep. at 78–79; ECF 644-7, Ex. E, May 23, 2007, office visit notes Dr. Scott Sporer).¹⁶

Finally, there was no material misrepresentation in the Patient’s Guide about whether a BHR revision surgery leading to a future total hip replacement would be “less complex and less traumatic” than a revision of a THA (ECF 644-8, Patient’s Guide at 4, 14). While Hand takes issue with the off-label use of a BHR as part of a BHR-THA total hip construct after revision, the statement that a post-BHR revision would be less traumatic and complex is consistent with the FDA-approved labeling.¹⁷ This statement in the Patient’s Guide was consistent with the labeling and therefore cannot be the source of liability. (*See also* ECF 2977, *Sedgwick* Summ. J. Mem. at 18). Nor did Hand receive a BHR-THA revision total hip construct in her 2016 revision, further undermining the theory — not shown in the record — that she chose the BHR with the possibility of a BHR-THA in mind. Deposition testimony indicates that Hand remembers reading this section of the Patient’s Guide but provides no indication of reliance. (ECF 655-11, Hand Dep. at 224:6-10).

b. Dr. Della Valle: The November 2006 training

Dr. Della Valle is the other possible conduit for a misrepresentation from Smith & Nephew. The narrow window of time between the BHR’s May 2006 PMA approval and Hand’s

¹⁶ Hand suggested during oral argument that the Patient Guide’s statements about cobalt chrome’s superiority, even if they do not stand on their own as misrepresentations, support the misrepresentation theory that Smith & Nephew underplayed women’s revision risk despite the 2006 AOA report. To the extent that the court considers this argument in assessing the existence of a misrepresentation, it is moot, as there is no genuine dispute of material fact about Hand’s lack of reliance on the Patient’s Guide for gender-differentiated revision outcomes.

¹⁷ “The BHR may make future revision surgery easier because hip resurfacing surgery leaves your femoral head in place and there is no large metal stem placed in the thighbone. Revision surgery of a total hip replacement where your femoral head has already been removed and a large stem is already in place can be a more difficult operation.” (ECF 644-11, Ex. I, BHR System Patient Information sheet at SN_BHR_MDL_2419119, columns 5–6).

June 2007 surgery severely constrains the set of possible misrepresentations that Smith & Nephew might have made to Dr. Della Valle. His treatment decisions rely most on “peer-reviewed published data and peer-reviewed publications” and also rely on his experience, training, and conferences he has attended. (ECF 644-6, Ex. D, Della Valle Dep. at 98:24–99:17). The conferences are particularly relevant here, as Dr. Della Valle attended and/or presented information at a November 2006 Smith & Nephew BHR training and certification course in England. (ECF 655-13, Ex. 13, Fourth Am. Def. Fact Sheet for BHR Track Cases at 20 ¶ 3(a)).

As with the Patient’s Guide, Hand’s argument revolves around alleged omissions as the core misrepresentation. But the record does not include information about the content of that training session beyond Hand’s assertions that it was the same as all other Smith & Nephew BHR training sessions. Hand’s expert, Dr. Jack Bowling, did not review records from the November 2006 England training. (ECF 655-8, Bowling Rep. at 1–2 of 26). He did review materials from Smith & Nephew sessions in October 2007, February 2008, June 2008, March 2009, September 2009, August 2010, April 2011, October 2011, December 2012, and September 2016, but each of those occurred after Hand’s surgery. (*Id.* at 23 of 26). The November 2006 conference appears to be absent from the expert report. Dr. Bowling’s opinion could not be based on Dr. Della Valle’s training prior to 2007, including the November 2006 training in England (ECF 3573-12, Bowling Dep. at 238:8-14), because he did not know about the materials or presentations at Dr. Della Valle’s training (*Id.* at 239:17-18) beyond his assumption that they would be similar because they were close together in time (*Id.* at 239:4-7). Indeed, he testified that his 2007 training may have been different from Dr. Della Valle’s 2006 training based on their different takeaways from the sessions:

“I can’t specifically speak to the training Dr. Della Valle did . . . because I have a different understanding. Dr. Della Valle testified that after his training, he felt

that this operation was most appropriately performed on a young male . . . Now, my training wasn't quite that clear. My training was around the same time — I believe only a few months differently — but I did not come out with the idea that femoral neck fractures were twice as likely in the female population.”

(ECF 3573-12, Bowling Dep. at 234:15–235:8). He later suggested that Dr. Della Valle may have “gleaned [the greater suitability for male patients] somehow from [his] own opinion.” (*Id.* at 236:11-12). Hand has failed to generate a record with enough information about the November 2006 training to support a genuine dispute over alleged misrepresentations by Smith & Nephew.

c. Sales Representative Deliveries

Contacts with Smith & Nephew sales representatives form the third possible conduit for misrepresentations by omission. Dr. Della Valle testified that he might have implanted about two BHRs into female patients (out of 20 to 30 overall) before he operated on Hand. (ECF 644-6, Della Valle Dep. at 10:22–11:1).¹⁸ Hand said at oral argument that for those two prior female BHR patients, a Smith & Nephew sales representative would have delivered the components to Dr. Della Valle. During those two encounters, Hand argued, the sales representatives committed negligent misrepresentation by not affirmatively mentioning Smith & Nephew's imputed knowledge of gendered revision risk from the 2006 AOA report. Dr. Della Valle would have expected the sales representatives to update him on any new information about the BHR.¹⁹ But Dr. Della Valle himself did not remember whether he learned about the revision risk gap from local representatives or from Smith & Nephew directly. (ECF 644-6, Della Valle Dep. at 82:22–83:4). At oral argument, Hand argued that her expert, Dr. Bowling, had opined that Smith & Nephew sales representatives communicated the same message as training, medical education,

¹⁸ “Q. Is it possible that maybe she was the third female patient? A. Possible. I didn't do that many females, so it's possible.” (ECF 644-6, Della Valle Dep. at 10:22–11:1).

¹⁹ “Q. Okay. Would you expect . . . Smith & Nephew reps to keep you updated on new information about the BHR? A. Generally, Yes.” (ECF 644-6, Della Valle Dep. at 82:16-19).

and marketing materials (ECF 3608-2, Bowling Report at 26). But the record contains no information about those two possible sales representative conversations predating Hand's implantation, and Hand's argument about misrepresentations during those encounters is entirely speculative. Mere conclusory statements that the sales representatives said the same things they always say are not enough to defeat summary judgment; without any indication that they spoke misleadingly, all that is left is a failure to warn claim. Hand has failed to create a genuine dispute of material fact as to whether unnamed Smith & Nephew representatives on unspecified dates misleadingly omitted information about high femoral revision risks during "possible" conversations about which we have no testimony.

d. The Chicago Email

Finally, Hand argues that the June 15, 2007, email from Smith & Nephew employee Brian Austin to Dr. Della Valle reveals a final voluntary communication in which Smith & Nephew omitted its alleged knowledge of gendered revision risk. The email confirms a meeting in Chicago the next day between Dr. Della Valle and Smith & Nephew engineering and marketing employees. During that meeting, those present would discuss bringing Dr. Della Valle on as a designer on "a new cementless acetabular cup for our Metal-on-Metal bearing. The BHR system is now 10 years old and although the design has excellent results it is time to make some improvements." (ECF 665, Email from Brian Austin to Craig Della Valle; latter sentence highlighted by counsel). Hand argues that this email (and presumably the meeting itself the next day) omitted information about the gendered revision risk and therefore constitutes negligent misrepresentation. Further, Hand argues that this email is evidence of deception on Smith & Nephew's part, because they told Dr. Della Valle they sought his help in addressing non-metal-

ion design issues while internal documents (most notably, the 2006 PowerPoint) indicated that metal ions were a concern.

There is nothing in the record to suggest this email is evidence of deception. In other communications, Smith & Nephew acknowledged and communicated concerns that existed about metal ion wear while noting — with language that tracked the FDA’s approval — that the research was inconclusive (ECF 644-11, Ex. I at 2 ¶ 3, bullet 5 (discussing risks to women of child-bearing age); *Id.* at 2 ¶ 5, bullet 8). Internal documents, like the 2006 PowerPoint, express a desire to minimize metal ion wear. These documents are consistent with the notion that metal ions were a known concern but were not yet proven by research to have certain negative effects in metal-on-metal hip recipients, specifically causing higher revision rates in women. With that context, the Chicago email lacks any taint. It names a design issue (the acetabular cup’s cement) and attempts to enlist Dr. Della Valle in addressing it. Any suggestion by Hand that the reference to the BHR’s “excellent results” triggers a duty to raise Smith & Nephew’s alleged knowledge of gendered revision risk borders on a backdoor failure to warn claim.

Regardless, nothing in the record suggests that Dr. Della Valle relied on this email or his meeting in Chicago for information about BHR revision rates’ gender differences, which he already knew existed. Hand has failed to create genuine disputes of material fact as to the misrepresentation itself and Dr. Della Valle’s reliance on it.

3. Conclusion

Because Hand has failed to demonstrate genuine disputes of material fact related to both misrepresentation and reliance, summary judgment will be granted to Smith & Nephew on the negligent misrepresentation count.

C. Negligent Failure to Warn (Count IV)

Smith & Nephew argues for summary judgment on the negligent failure to warn claim because Hand cannot show that any failure to report adverse events to the FDA within the relevant time period was the proximate cause of Hand's injuries.

Under Illinois law, a manufacturer has a duty to adequately warn and instruct the consumer or user about the dangers of its product of which it knew or (in the exercise of ordinary care) should have known at the time the product left the manufacturer's control. *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 198 (Ill. 1980); Illinois Pattern Jury Instructions (Civil) 400.07D.²⁰

Proximate cause encompasses two distinct requirements: cause in fact and legal cause: *Young v. Bryco Arms*, 821 N.E.2d 1078, 1085 (Ill. 2004) (internal citations omitted). Cause in fact is present "when there is a reasonable certainty that a defendant's acts caused the injury or damage. In deciding this question, we first ask whether the injury would have occurred absent the defendant's conduct." *Id.* (internal citations and quotations omitted). Legal cause "is established only if the defendant's conduct is so closely tied to the plaintiff's injury that he should be held legally responsible for it. The question is one of public policy — how far should a defendant's legal responsibility extend for conduct that did, in fact, cause the harm?" *Id.* at 1086 (internal citation omitted). "Although proximate cause is generally a question of fact, the lack of proximate cause may be determined by the court as a matter of law where the facts alleged do not sufficiently demonstrate both cause in fact and legal cause." *Id.* (internal citations omitted).

As the court has previously ruled, *In re BHR*, 300 F. Supp. 3d at 145, state failure to warn claims are not expressly preempted to the extent that they "parallel" federal-law duties and

²⁰ See Illinois Pattern Jury Instructions (Civil), § 400.00, Strict Product Liability, <https://www.illinoiscourts.gov/Resources/0d3c1376-a0f2-4920-97be-d106325b2510/400.00.pdf> at 27 of 32.

“support holding Smith & Nephew liable for its alleged failure to report specific information [about adverse incidents] to the FDA.” *Id.*; *see also Bausch v. Striker Corp.*, 630 F.3d 546, 549–50 (7th Cir. 2010). “Any claim that Smith & Nephew had a duty to warn the general public or the medical community is, however, expressly preempted because there is no such parallel federal requirement.” *In re BHR*, 300 F. Supp. 3d at 145; *see also McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005).

Accordingly, any state law claim alleging Smith & Nephew had a duty to warn Dr. Della Valle or Hand is preempted. Smith & Nephew argues that only two allegations remain that can support a failure to warn: (1) Smith & Nephew’s alleged failure to disclose to the FDA Australian registry ad hoc data that it obtained in October 2009; and (2) the company’s alleged failure to timely or adequately report adverse events to the FDA. As to the former, because Smith & Nephew obtained the ad hoc data in 2009 (over two years after Hand’s implantation surgery), it cannot support a failure to warn claim.

As to the latter, while Illinois law recognizes a common-law duty to warn, Smith & Nephew challenges proximate causation: Hand, they say, must show that adverse events reported to the FDA would have been made public such that the higher revision rates would have been incorporated into materials that Dr. Della Valle reviewed prior to Hand’s surgery. *See Sedgwick Mem.* at 13; *Redick Mem.* at 16–17; *Mosca Mem.* at 15; *Albritton Mem.* at 8–9.

As described in the negligent misrepresentation analysis (*see* § II.B, *supra*), Hand must identify a failure to warn the FDA between May 2006 (the PMA approval) and June 2007 (Hand’s implantation surgery). Hand points to a variety of allegations in the Master Amended

Consolidated Complaint²¹ but almost all fall outside that window, rendering them irrelevant to the question of causation in Hand's case.

Though it is somewhat unclear from the briefing, Hand seems to argue that the publicly available annual reports from the Australian registry (which Graves said he sent to Smith & Nephew in 2004, 2005, and 2006) comprised mostly Smith & Nephew data at the time and so Smith & Nephew had reason to know of the gendered outcomes. They failed to warn the FDA of the gendered outcomes revealed by the registry's reports; had they done so, the argument seems to be that the higher revision rates would have been made public in the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database and would have been incorporated into materials Dr. Della Valle reviewed — ostensibly, the November 2006 BHR training.

But these data were already public at the time, and Dr. Della Valle testified that he does not routinely check the MAUDE database and has never looked up BHR failure rates in that database. (ECF 644-6, Ex. D, Della Valle Dep. at 90:17–91:5). The record contains no information about the contents of the November 2006 training session. Together, these observations undermine the theory that Smith & Nephew's alleged failure to warn the FDA about the Australian Registry's annual reports was either the legal cause or the cause in fact of Hand's injuries. Accordingly, because there is no genuine dispute of material fact as to whether any failure to inform the FDA of adverse events caused Hand's injuries, the court will award summary judgment to Smith & Nephew on the failure to warn claim.

²¹ "Dear Doctor Letters, surgeon training materials, all advertising and promotional materials, IFUs, brochures to surgeons, press releases, direct-to-patient communications such as patient pamphlets, websites and other materials, and communications by its sales representatives." (ECF 124, BHR-MACC at 11 ¶ 32).

D. Negligence Per Se (Count VI)

Under Illinois law, the breach of a statutory duty does not constitute a separate cause of action for negligence per se. Instead, “Illinois treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence, though the violation may not always be conclusive on the issue of negligence.” *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010). The court construes this claim as one of common law negligence which Hand seeks to prove through evidence of a violation of the statute. *See Sedgwick Mem.* at 24. A plaintiff must show that “(1) the plaintiff is a member of the class of persons the statute or ordinance was designed to protect, (2) the injury is the type of injury that the ordinance was intended to protect against, and (3) the defendant’s violation of the statute or ordinance was the proximate cause of the plaintiff’s injury.” *Price ex rel. Massey v. Hickory Point Bank & Tr., Tr. No. 0192*, 841 N.E.2d 1084, 1089 (Ill. App. Ct. 2006).

Although negligence per se claims based on violations of federal law and the PMA are preempted or fail due to lack of causation, Hand points to three other allegations in the Master Amended Consolidated Complaint. First, Hand offers a citation to Illinois’s breach of express warranty statute.²² Hand’s breach of express warranty claim, however, is time-barred (*see* § I, *supra*), so this cannot support the negligence per se count. Second, Hand offers a reference to Illinois’s manufacturing defect statute²³ and strict products liability statute.²⁴ Both claims were

²² “Under Illinois Law, 810 Illinois Compiled Statutes Annotated 5/2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.” (ECF 124, BHR-MACC at 139–40 ¶ 426).

²³ “Defendant is liable pursuant to the manufacturing defect common laws and statutory regimes of each state where Plaintiffs reside. Specifically, . . . Illinois . . .” (ECF 124, BHR-MACC at 156–57 ¶ 598).

²⁴ “Under Illinois law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the BHR product outweighed the benefits, beyond the

dismissed from the case in March 2018 (ECF 609, Order; ECF 308, Mem. at 14–15) and likewise cannot support negligence per se. The court will therefore grant summary judgment to Smith & Nephew on the negligence per se count.

E. Negligent Failure to Train (Remainder of Count II)

Smith & Nephew moves for summary judgment on the negligent failure to train²⁵ allegation, the last remaining piece of the general negligence claim. The court has previously held that any claim that Smith & Nephew had a duty to change its training program would add to or differ from the requirement to merely implement the program, and such claims are therefore preempted. *Redick* Mem. at 28–29; *Sedgwick* Mem. at 24. A plaintiff’s negligent training claim could survive preemption to the extent Smith & Nephew failed to provide the training required. *In re BHR*, 300 F. Supp. 3d at 745.

There is no evidence Smith & Nephew failed to provide the required training to surgeons. “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” claim. *Redick* Mem. at 29. As described earlier (*see* § II.B, *supra*), the evidence does not support a negligent misrepresentation claim, and Hand has failed to establish an independent negligent failure to train claim. Summary judgment will be granted to Smith & Nephew on this count.

expectations of an ordinary consumer, such as Plaintiffs, and the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant’s possession, and Plaintiffs suffered injury and damages to themselves because of the BHR’s defective condition, as described herein and above.” (ECF 124, BHR-MACC at 92–93 ¶ 319).

²⁵ Hand alleges that Smith & Nephew breached its duty of ordinary care under Illinois law by “failing to properly train and educate physicians on the use of the BHR Resurfacing product . . . and defendant did not fulfil their duty to provide all necessary information to physicians.” (ECF 124 at 116–17)

III. Punitive Damages (Count IX)

“Illinois does not recognize a cause of action for punitive damages alone; punitive damages represent a type of relief rather than an independent cause of action.” *Brummel v. Grossman*, 121 N.E.3d 970, 998 (Ill. App. Ct. 2018). Because none of Hand’s claims for liability survive summary judgment, her claim for punitive damages also must fail. Accordingly, Smith & Nephew’s motion for summary judgment as to punitive damages will be granted.

IV. Loss of Consortium

For the same reasons as described regarding Hand’s punitive damages claim, Nyeste’s loss of consortium claim must fail. *McCreary v. Libbey-Owens-Ford Co.*, 132 F.3d 1159, 1167 (7th Cir. 1997) (“[A] claim for loss of consortium is derivative in nature and its viability depends upon the validity of the injured spouse's claims.”). Smith & Nephew’s motion for summary judgment will be granted as to loss of consortium.

CONCLUSION

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

5/17/2022
Date

/s/
Catherine C. Blake
United States District Judge