UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

ABIGAIL CUTTER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Cause No. 3:15-cv-434 RLM-MGG
	)	
BIOMET, INC., *et al.*,	)	
	)	
Defendants.	)	

OPINION AND ORDER

Abigail Cutter sued Biomet for damages in connection with the alleged failure of her Biomet M2a Magnum hip implant. Biomet moved for summary judgment, arguing that her claims are time-barred based on (1) a proposed date on which all plaintiffs were on constructive notice of potential claims and (2) facts specific to Ms. Cutter. I disagree with Biomet's proposed universal bar date and analysis as to Ms. Cutter's products liability, negligence, and Consumer Protection Act claims.

I. STANDARD OF REVIEW

Summary judgment is appropriate when the pleadings, discovery materials, disclosures, and affidavits demonstrate no genuine issue of material fact, such that the movant is entitled to judgment as a matter of law. Protective Life Ins. Co. v. Hansen, 632 F.3d 388, 391-92 (7th Cir. 2011). I must construe the evidence and all inferences that reasonably can be drawn from the evidence in the light most favorable to Ms. Cutter, as the non-moving party. Anderson v.

Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). As the moving party, Biomet bears the burden of informing me of the basis for its motion, together with evidence demonstrating the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If Biomet meets that burden, Ms. Cutter can't rest upon the allegations in the pleadings, but must "point to evidence that can be put in admissible form at trial, and that, if believed by the fact-finder, could support judgment in [her] favor." Marr v. Bank of Am., N,A., 662 F.3d 963, 966 (7th Cir. 2011); *see also* Hastings Mut. Ins. Co. v. LaFollette, No. 1:07-cv-1085, 2009 WL 348769, at *2 (S.D. Ind. Feb. 6, 2009) ("It is not the duty of the court to scour the record in search of evidence to defeat a motion for summary judgment; rather, the nonmoving party bears the responsibility of identifying the evidence upon which he relies."); Hammel v. Eau Galle Cheese Factory, 407 F.3d 852, 859 (7th Cir. 2005) (summary judgment is "not a dress rehearsal or practice run; it is the put up or shut up moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of events").

II. The Proposed Bar Date

First, Biomet asks me to establish a bar date applicable to all plaintiffs. Biomet argues that enough information was publicly available to put a reasonable plaintiff on notice by February 10, 2011 that her injury might be connected to Biomet's M2a Magnum metal-on-metal hip implant. As Biomet sees it, if a plaintiff was injured on or before February 10, 2011, the statute of

limitations would begin to run then. For a plaintiff was injured after February 10, 2011, the statute of limitations would begin to run on the date of injury.

The discovery rule postpones the accrual of a cause of action until the plaintiff knew, or through exercise of reasonable diligence should have known, that she was injured. *See, e.g.*, Fla. Stat. § 95.031(2)(b); 735 Ill. Comp. Stat. 5/13-213(d); N.C. Gen. Stat. § 1-52(16); Wash. Rev. Code § 7.72.060(3); Martin v. Arthur, 3 S.W.3d 684, 690 (Ark. 1999); In re Med. Review Panel of Howard, 573 So. 2d 472, 474 (La. 1991); Moreno v. Sterling Drug, Inc., 787 S.W.2d 348, 351 (Tex. 1990).

Biomet contends that this publicly available information put any reasonable plaintiff on notice of a potential claim by the proposed bar date: the device's Instructions for Use, articles in medical journals, press reports, and the Food and Drug Administration's websites. The Instructions for Use for Biomet's metal-on-metal hip implants disclosed that using the device could pose a risk of exposure to metal debris, including osteolysis, metal hypersensitivity, and elevated metal ion levels. Eight 2010 medical journal articles raised concerns about the risks associated with metal-on-metal hip implants, including an editorial in the Journal of Arthroplasty, the official, peer-reviewed journal of the Association of Hip and Knee Surgeons. *See* Ross Crawford et al., *Metal on Metal: Is it Worth the Risk?*, J. ARTHROPLASTY, Sept. 2010, at 1.[1]

[1] *See also* Joseph Daniel et al., *Renal Clearance of Cobalt in Relation to the Use of Metal-on-Metal Bearings in Hip Arthroplasty*, 92 J. BONE & JOINT SURGERY 840 (2010); C. Delaunay et al., *Metal-on-Metal Bearings Total Hip Arthroplasty: The Cobalt and Chromium Ions Release Concern*, 96 ORTHOPAEDICS & TRAUMATOLOGY: SURGERY & RESEARCH 894 (2010); Brian M. Devitt et al., *Cobalt Ions Induce Chemokine Secretion in*

Biomet argues that news reports from early 2010 reporting on the risks of metal debris with metal-on-metal hip implants also put plaintiffs on notice of potential claims. *See, e.g.*, Barry Meier, *As Use of Devices Grows, Studies Raise Concerns*, N.Y. TIMES, Mar. 4, 2010.[2] More news reports followed DePuy's August 2010 recall of two ASR metal-on-metal hip implants. *See, e.g.*, Natasha Singer, *Hip Implants Are Recalled by J. & J. Unit*, N.Y. TIMES, Aug. 27, 2010.[3]

Last, Biomet contends that the FDA notified the public when it launched two websites discussing potential health risks of metal-on-metal hip implants by February 10, 2011. *See Concerns about Metal-on-Metal Hip Implant Systems*, FOOD & DRUG ADMIN. (last updated Feb. 10, 2011), https://web.archive.org/web/20110214064145/http://www.fda.gov/MedicalD

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a Variety of Systemic Cell Lines, 81 ACTA ORTHOPAEDICA 756 (2010); Monika Huber et al., *Postmortem Study of Femoral Osteolysis Associated with Metal-on-Metal Articulation in Total Hip Replacement*, 92 J. BONE & JOINT SURGERY 1720 (2010); Takao Imanishi et al., *Serum Metal Ion Levels after Second-Generation Metal-on-Metal Total Hip Arthroplasty*, 130 ARCHIVES ORTHOPAEDIC & TRAUMA SURGERY 1447 (2010); Ajay Malviya et al., *Metal-on-Metal Total Hip Arthroplasty*, 92 J. BONE & JOINT SURGERY 1675 (2010); Michael C. Parry et al., *Thresholds for Indirect DNA Damage Across Cellular Barriers for Orthopaedic Biomaterials*, 31 BIOMATERIALS 4477 (2010).

[2] *See also* Barry Meier, *When New Hips Go Bad*, N.Y. TIMES, Mar. 4, 2010; Barry Meier, *Alert Follows Withdrawal Of Hip Device*, N.Y. TIMES, Mar. 10, 2010; Harvard Health Letters, *Hip Replacement Candidates Have Several Surgical Options*, SUN-SENTINEL, Mar. 24, 2010; Sue Scheible, *You Don't Have to Be Old to Get a New Knee, Hip or Shoulder*, NEB. CITY NEWS-PRESS, Apr. 5, 2010; Peter Benesh, *Stryker Promotes Hip Technology*, INVESTOR'S BUS. DAILY, Apr. 16, 2010.

[3] *See also* Jonathan D. Rockoff & Jon Kamp, *J&J's Latest Recall: Hip-Repair Implants*, WALL ST. J., Aug. 27, 2010; Nora Tooher, *Litigation Mounts over DePuy Hip Replacement Device*, LAWYERS WEEKLY USA, Oct. 4, 2010; Nelson Daranciang, *Woman Sues over Hip Implant Device*, HONOLULU STAR-ADVERTISER, Oct. 27, 2010; Steve Daniels & Silvia Gambardella, *Hip Implant Recalled Amid Concerns About Heart Failure, Dementia*, ABC NEWS, Dec. 1, 2010; Barry Meier, *The Implants Loophole*, N.Y. TIMES, Dec. 17, 2010; Barbara Peters Smith, *The Enemy Within*, SARASOTA HERALD TRIB., Dec. 21, 2010.

evices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal HipImplants/ucm241604.htm; *Information for Patients Who Have Metal-on-Metal Hip Implants*, FOOD & DRUG ADMIN. (last updated Feb. 10, 2011), https://web.archive.org/web/20110528045143/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241766.htm. These websites warned that metal-on-metal hip implants might leave debris that could damage bones and tissue surrounding the implant, and encouraged people to contact their physicians if they experienced any symptoms. Biomet argues that the combined effect of the Instructions for Use, journal articles, press reports, and FDA warnings put any reasonable person on notice of the connection between Biomet's device and an injury from exposure to metal and metal debris no later than February 10, 2011.

Three district court decisions in MDL dockets inform Biomet's analysis. In In re Avandia Marketing, Sales Practices and Products Liability Litigation, Judge Rufe held that a bar date was appropriate because the cumulative effect of publicity about a prescription drug's relationship to adverse cardiovascular events was sufficient, as a matter of law, to put an individual who had been injured on notice that Avandia could be to blame. No. 07-MD-01871, 2012 WL 3205620, at *4 (E.D. Pa. Aug. 7, 2012). This publicity included:

1. a New England Journal of Medicine study finding that Avandia increased the risk of heart problems by forty-three percent;

2. a joint statement from the American College of Cardiology, the American Diabetes Association, and the American Heart Association expressing concern and advising patients to speak to their physicians;

3. an FDA advisory committee conclusion that Avandia increased heart risk;

4. FDA action requiring that a warning be added to Avandia's label;

5. the drug manufacturer sending letters to healthcare professionals on studies linking Avandia and heart health;

6. the drug manufacturer publishing a "Dear Patient" letter about the risks of heart problems;

7. a wave of media attention following the above, including lead stories on the national nightly news; and

8. numerous lawsuits filed against the drug manufacturer, leading to the formation of the MDL.

Id. at *3. Evidence that Avandia prescriptions dropped by forty-five percent and sales by fifty-four percent as of the proposed bar date showed that these events "were regarded as significant by physicians, patients, and attorneys." *Id.* at *4.

In the MDL docket involving Vioxx, Judge Fallon applied a bar date to multiple plaintiffs based on:

1. a medical study finding that Vioxx triggered a significant increase in abnormal cardiovascular events;

2. media reports linking Vioxx to cardiovascular risks;

3. a new Vioxx label that the manufacturer submitted, the FDA approved, and resulted in substantial press coverage;

4. filing of a class action; and

5. the manufacturer removing Vioxx from the market, triggering "arguably the largest and most-publicized prescription drug withdrawal in this country's history."

In re Vioxx Prods. Liab. Litig., 522 F. Supp. 2d 799, 803, 808, 814 (E.D. La. 2007). The court held that "[b]oth the national and local media coverage of the withdrawal of Vioxx from the market were sufficient to put the plaintiffs on notice of a potential link between their alleged injuries and the use of Vioxx." *Id.* at 808.

In the Zyprexa litigation, Judge Weinstein held that a bar date was appropriate when:

1. the FDA announced it would require an additional warning on the drug's label;

2. leading medical associations issued a consensus statement concluding that Zyprexa posed a risk; and

3. the drug manufacturer distributed a "Dear Doctor" letter to physicians nationwide informing them of the label change.

In re Zyprexa Prods. Liab. Litig., 727 F. Supp. 2d 101, 107 (E.D.N.Y. 2010); *see also* Burrell v. Astrazeneca LP, No. CIV.A. 07C01412(SER), 2010 WL 3706584, at *6 (Del. Super. Sept. 20, 2010) (establishing a bar date in litigation regarding Astrazeneca's Seroquel).

I can't say that, as a matter of law, the notice to a reasonable plaintiff of a potential claim against Biomet approached what happened in the Avandia, Vioxx, and Zyprexa cases. First, in both the Avandia and Zyprexa cases, the manufacturer published or distributed letters alerting patients or physicians to the risks associated with the product. This would have been the simplest way for Biomet to put all of its customers on notice of a potential claim, and Biomet chose not to do so.

Second, two of the three cases included substantially more press coverage than that surrounding Biomet. For example, in the Vioxx case, Judge Fallon noted that the press coverage was "arguably the largest and most-publicized prescription drug withdrawal in this country's history." In re Vioxx Prods. Liab. Litig., 522 F. Supp. 2d at 803. In addition, the coverage in Vioxx was the result of the company pulling its product from the market. Biomet didn't opt to make such a clear signal to consumers of its product's potential risk.

Third, two of the three cases included statements from leading medical associations highlighting risks associated with the product. Biomet points to no such statements here.

Fourth, Biomet doesn't demonstrate how a reasonable plaintiff would have seen or understood the Instructions for Use that Biomet argues should have put her on notice. They're directed to the operating surgeon, not the patient. While the Instructions for Use caution about "histological reactions involving various sizes of macrophages and fibroblasts," they then backtrack, explaining that "similar changes may occur as a precursor to or during the healing process."

They explain that "[p]articulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid," which could "result[ ] in osteolysis." They explain a report associating articulating surfaces and "increased genotoxicity." They also add necessary caveats, that the report "did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions . . . might be responsible for the observed data," cautioning that "an association does not necessarily mean a causal relationship." Biomet might show how a reasonable surgeon would have been aware of the product's risks, but doesn't show how a reasonable plaintiff should have seen or understood the document.

Last, in two of the three cases, either a class action had been filed or an MDL formed, with the consequent publicity and attorney advertising. The Biomet MDL wasn't formed until well over a year after Biomet's proposed bar date.

Under even the most liberal construction of the states' "discovery rules," I can't say these materials would have had the cumulative effect of putting all plaintiffs on constructive notice of a potential claim by February 10, 2011. What Biomet knew by the proposed bar date can't be attributed to the reasonable plaintiff. Biomet didn't target information to patients notifying them of the possible risks or demonstrate that reasonable plaintiffs are reading medical journals or the FDA website. Without a torrent of press coverage surrounding a decision to pull the product from the market or to change its label, Biomet hasn't shown that a reasonable plaintiff would know of a potential claim. I decline

Biomet's request to establish a February 10, 2011, bar date that would apply to every plaintiff.

III. MS. CUTTER'S BACKGROUND

Ms. Cutter received a Biomet M2a Magnum implant in her left hip in March 2008 and then in her right hip the next month. She says she began to experience hip pain while in physical therapy soon after her surgeries. She had revision surgery on her right hip implant in June 2008 to correct for stem subsidence. A new stem component was implanted during the surgery.

Ms. Cutter says she began to experience hip pain again in 2014. In December 2014 she started to have cognitive problems, and her nails became lumpy and turned yellow. She Googled "lumpy yellow thumb nails" in May 2015 and learned that metal poisoning was a possible cause. A June 2015 blood test revealed high levels of cobalt and chromium. Ms. Cutter had revision surgery on her left hip on July 24, 2015 and on her right on August 10, 2015. She filed suit on September 22, 2015 -- more than three years from her initial revision, but within three years of when she began to re-experience hip pain.

IV. CHOICE OF LAW

When a case is filed directly in the MDL transferee court, the court applies the law, including choice-of-law rules, of the state where the case originated. *E.g.*, In re Watson Fentanyl Patch Prods. Liability Litig., 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013). It's "appropriate to treat a foreign direct-filed case as if it

had been filed in the state where the plaintiff purchased and was prescribed the subject [product]." *Id.* (internal quotations omitted). The Magnum was prescribed, purchased, and implanted in Washington, so Washington choice-of-law rules govern. Washington courts apply the law with the "most significant relationship" to the claim. Rice v. Dow Chem. Co., 875 P.2d 1213, 1217 (Wa. 1994). Because the injury, implants, and revisions occurred in Washington, Washington presumptively has the most significant relationship. *See* Hai v. STL Int'l, Inc., No. 43877-1-II, 2014 WL 1494107, at *5 (Wash. Ct. App. Apr. 15, 2014). Biomet's domicile in Indiana doesn't counter that. I will apply Washington law.

V. DISCUSSION

Products liability claims must be brought within "three years from the time the claimant discovered or in the exercise of due diligence should have discovered the harm and its cause." Wash. Rev. Code § 7.72.060(3). The statute of limitations for a personal injury plaintiff is three years from when the cause of action "accrues," §§ 4.16.006, 4.16.080(2), and for the Consumer Protection Act it's four, § 19.86.120. In general, a "cause of action accrues and the statute of limitations begins to run when a party has the right to apply to a court for relief." Shepard v. Holmes, 345 P.3d 786, 790 (Wash. Ct. App. 2014). Washington courts interpret "accrual" to include a "discovery rule" exception for "claims where injured parties do not, or cannot, know they have been injured." *Id.* (applying discovery rule to "accrual" under Consumer Protection Act); *see* Green v. A.P.C.,

960 P.2d 912, 915 (Wash. 1998) (applying discovery rule to "accrual" for personal injury). Biomet hasn't presented evidence of a precise time when Ms. Cutter had a right to apply for relief, so the discovery rule applies to all these claims.

How much does Ms. Cutter need to know for the limitations period to run? The critical moment is "when the plaintiff knew or should have known the essential elements of the claim." *Id.* at 913. "[T]he claimant in a product liability case must have discovered, or in the exercise of due diligence should have discovered, a factual causal relationship of the product to the harm" for the statute of limitations to run. N. Coast Air Svcs., Ltd. v. Grumman Corp., 759 P.2d 405, 406 (Wash. 1988). Ms. Cutter's statute of limitations couldn't run until she knew, or through exercise of due diligence should have known, that her injury was the result of her hip implant.

Biomet argues that Ms. Cutter had this knowledge at the time of her first revision surgery. Ms. Cutter's first revision wasn't for metallosis, but for stem subsidence. The hip implant simply didn't fit quite right and needed to be resized. Biomet hasn't shown that she knew anything at the time to suggest that the device might be poisoning her. Biomet doesn't show knowledge of the harm, let alone "a factual causal relationship to it." *Id.* Biomet also can't show that she "knew or should have known the essential elements of the claim." Green v. A.P.C., 960 P.2d at 913. Had Ms. Cutter sued Biomet after her first revision, it's unclear as to what she would have sued for. She didn't have symptoms for years after that event.

The next possible date is Biomet's proposed universal bar date, which I already disregarded as putting anyone on constructive notice of a claim, at least without proof that Ms. Cutter herself had seen the various reports and articles discussed. Even if she had seen them, she would have had no reason to think she had been injured because she wasn't in pain until 2014. The next possible date for discovery is when she began to feel pain in 2014, but this is within one to two years of when she sued, and so it wouldn't run afoul of the statutes of limitations.

So I must deny Biomet's motion as to all those claims that rely on the discovery rule. These include the strict products liability claim (First Cause of Action), the negligence-based personal injury claims (Fourth and Fifth Causes of Action), and the Consumer Protection Act claim (Seventh Cause of Action).

Ms. Cutter and Biomet disagree on the standard for triggering the breach of warranty cause of action. Biomet says it's governed by the UCC, under which a breach of warranty claim accrues "when the breach occurs," generally "when tender of delivery is made." § 62a.2-725(2). Ms. Cutter says it's governed by the same "discovery rule" accrual for the personal injury common law claims. *See* § 4.16.080(3) ("Except as provided in RCW 4.16.040(2), an action upon a contract or liability, express or implied, which is not in writing, and does not arise out of any written instrument . . . .").

Biomet is correct on this point. The statute is explicit as to its application to breach of warranty claims. Ms. Cutter also cites Kittitas Reclamation Dist. v. Spider Staging Corp., 27 P.3d 645 (Wash. Ct. App. 2001) for its analysis of breach

of warranty claims, but this case applies the UCC provision, not the general common law breach of contract provision. Because the UCC provision applies, "tender of delivery" was the time of implant in 2008. More than four years elapsed before Ms. Cutter filed this suit.

There is a "discovery rule" for breach of warranty claims too, but only when the "warranty explicitly extend[ed] to future performance of the goods and discovery of the breach must await the time of such performance." *See* § 62a.2-725(2); Kittitas Reclamation Dist. v. Spider Staging Corp., 27 P.3d 645 (Wash. Ct. App. 2001). Neither party mentions the existence or nonexistence of an explicit warranty of future performance. Ms. Cutter cites Kittitas as an example of the "discovery rule" for breach of warranty claims, but again this only applies where there's explicit warranty to future performance. I'll interpret their silence as lack of dispute as to its nonexistence, so the discovery rule doesn't apply.

Fraudulent concealment tolls the limitations period for a breach of warranty claim. Giraud v. Quincy Farm & Chem., 6 P.3d 104, 111 (Wash. Ct. App. 2000). To benefit from this, Ms. Cutter must show that Biomet concealed the information about the risks of its product. *Id.* While there isn't enough evidence to show that Ms. Cutter was on constructive notice of the risk of Biomet's hip implant device, there also isn't enough to show that Biomet concealed it. The Instructions for Use discussed earlier made known to physicians that studies had shown a connection between the product and metallosis. Ms. Cutter can't be expected to have had this information, but there's no evidence that Biomet hid it. Fraudulent concealment thus doesn't toll the

limitations period. The breach of warranty claims (Second and Third Causes of Action) are time-barred and Biomet's motion is granted as applied to them.

Last are the misrepresentation claims. Biomet contests these claims on the merits in addition to the statute of limitations. Both claims require justifiable reliance by the plaintiff. *See* Van Dinter v. Orr, 138 P.3d 608, 609 (Wash. 2006). Ms. Cutter says she was unaware of any statements of Biomet before having the implant and offers no evidence indicating reliance. "[T]he nonmoving party bears the responsibility of identifying the evidence upon which he relies," *see* Hastings Mut. Ins. Co. v. LaFollette, No. 1:07-cv-1085, 2009 WL 348769, at *2 (S.D. Ind. Feb. 6, 2009), and hasn't done so. Biomet's motion is thus granted as to the negligent and fraudulent misrepresentation claims (Fifth and Sixth Causes of Action).

VI. CONCLUSION

The court GRANTS Biomet's motion for summary judgment [Doc. No. 59] as to Ms. Cutter's breach of warranty and misrepresentation claims (Second, Third, Fifth, and Sixth Causes of Action) and DENIES Biomet's motion as to her products liability, negligence, and Consumer Protection Act claims (First, Fourth, and Seventh Cause of Action).

SO ORDERED.

ENTERED: March 26, 2017

/s/ Robert L. Miller, Jr.
Judge
United States District Court