UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

KIMBERLY SLATER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Cause No. 3:14-cv-1055 RLM-MGG
	)	
BIOMET, INC., *et al.*,	)	
	)	
Defendants.	)	

OPINION AND ORDER

Kimberly Slater 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. Slater. I disagree with Biomet's proposed universal bar date and analysis as to Ms. Slater's products liability and negligence 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. Slater, 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. Slater 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 any 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 the following publicly available information put a 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 a 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," Biomet doesn't show that these materials would've had the cumulative effect of putting all plaintiffs on constructive notice of a potential claim by February 10, 2011. Biomet's knowledge that it possessed 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.

III. MS. SLATER'S BACKGROUND

Ms. Slater received a Biomet M2a Magnum implant in North Carolina in March 2007. She says she began to experience hip pain seven to nine months later. She underwent four revision surgeries between May 2008 and April 2009. The second revision, in June 2008, was performed to provide irrigation, debridement, and to replace the femoral head. The surgery uncovered a large collection of fluid and metallosis. The third revision, in January 2009, was performed to deal with an infection, and it uncovered metal debris. Ms. Slater said she never saw her operative reports.

Ms. Slater says that around the fourth revision she "knew something was wrong," but that she "didn't know what it was." Ms. Slater contacted an attorney in 2009 to discuss a potential medical malpractice claim. The attorney told her that she didn't have a malpractice case against the surgeon but said nothing about Biomet. Ms. Slater says she didn't know the implant was metal-on-metal or that it was made by Biomet until 2013. She contacted an attorney again in 2013 in response to a television commercial and then filed on April 13, 2014.

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 North Carolina, so North Carolina law governs. Under North Carolina law, statutes of limitations are procedural, and so North Carolina courts apply North Carolina statutes of limitations, Boudreau v. Baughman, 368 S.E.2d 849, 857 (N.C. 1988), as will I.

V. DISCUSSION

A personal injury plaintiff must file within three years of when the cause of action accrues. N.C. Gen. Stat. § 1-52(5). Personal injury claims "shall not accrue until bodily harm to the claimant or physical damage to his property becomes apparent or ought reasonably to have become apparent to the claimant, whichever event first occurs." § 1-52(16).

How much did Ms. Slater need to know for the three-year limitations period to start running? In simpler contexts, a plaintiff's knowledge that there's a problem is sufficient to start the limitations period. For example, knowledge that a roof leaks puts a plaintiff "on inquiry as to the nature and extent of the problem." Pembee Mfg. Corp. v. Cape Fear Constr. Co., 329 S.E.2d 350, 354 (N.C. 1985). There's an obvious potential cause to a leaky roof – poor installation by the roofer.

Medical claims often involve a more complex trigger. "Especially in the medical field, plaintiffs may lack the expertise to know whether the ill effects they have suffered are a result of someone's wrongdoing, or merely an unexpected

result, or inevitable or unforeseeable risk of their treatment." Black v. Littlejohn, 325 S.E.2d 469, 481 (N.C. 1985).[4] Revision surgery within months of a hip implant could, without additional information, mean medical malpractice, a problem with the device, an unpreventable infection, or any other "inevitable or unforeseeable risk of [ ] treatment." *Id.*

In medical situations, "[w]here causation of an injury is unknown, the action accrues when both the injury and its cause have been (or should have been) discovered. Where the injury and causation are known, but not that there has been any wrongdoing, the action is held to accrue when the plaintiff discovered, or by due diligence should have discovered, the wrongdoing." *Id.* at 482 (italics omitted). In the Black case, the plaintiff received drastic surgery for an illness that, years later, she learned could have easily been treated with a drug. *Id.* The claim accrued only on discovery of the simpler procedure years later, which alerted her to her doctor's negligence. *Id.* Needing revision alone, even needing four revisions, mightn't be a strong enough clue of the wrongdoing, especially when Ms. Slater claims not have known of metallosis.

Ms. Slater admits that she knew something was wrong by the time of the fourth revision surgery – enough to have contacted an attorney about a potential malpractice claim. This knowledge would be enough to trigger the limitations period as to a malpractice claim. But "the action is held to accrue when the

[4] Black v. Littlejohn analyzes the limitations period for medical malpractice claims, which requires determining when "the injury . . . is discovered or should reasonably be discovered by the claimant." N.C. Gen. Stat. § 1-15(c). Even though the case analyzes a different statute's "discovery rule," the reasoning applies just as well to § 1-52(16).

plaintiff discovered, or by due diligence should have discovered, the wrongdoing." *Id.* The possibility that the device itself failed inside her, "the wrongdoing," didn't occur to Ms. Slater until years later when she saw an attorney advertisement suggesting so.

Biomet might prevail on its statute of limitations defense, but not on summary judgment. There's a genuine issue of material fact as to when Ms. Slater knew or should've known of the alleged wrongdoing, the failure of the implant. Her knowledge that something was wrong, with the complexities of medical treatment, might not have been enough to put her on inquiry notice as to the failure of the device itself. That's what North Carolina law seems to require and it's a question of fact that can't be resolved now. Biomet's motion is thus denied as to the product liability and negligence claims (Counts I-II).

Different provisions govern the remaining claims. Ms. Slater's breach of warranty claims have a four-year limitations period that accrues "when the breach occurs, generally "when tender of delivery is made." N.C. Gen. Stat. § 25-2-725(1), (2); *see* Boudreau v. Baughman, 368 S.E.2d 849, 854 (N.C. 1988) (applying limitations period to implied warranty claims). "Tender of delivery" was the time of implant, March 2007. Four years thus elapsed before Ms. Slater filed.

There's 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." § 25-2-725(2). Neither party mentions the existence or nonexistence of an explicit warranty of future performance. Without evidence of such a warranty, the breach of warranty

claims (Counts III-IV) are time-barred and Biomet's motion is granted as applied to them.

Ms. Slater also sues under the North Carolina Unfair and Deceptive Trade Practices Act. Actions for damages under this statute must be brought within four years of when "the cause of action accrues," § 75-16.2, "at the time of the invasion of the plaintiff's right," Newton v. Barth, 788 S.E.2d 653, 662 (N.C. Ct. App. 2016). Fraud or misrepresentation under the UDTPA accrue based on the "discovery rule" described above. S.B. Simmons Landscaping & Excavating, Inc. v. Boggs, 665 S.E.2d 147, 150 (N.C. Ct. App. 2008); Hunter v. Guardian Life Ins. Co., 593 S.E.2d 595, 601 (N.C. Ct. App. 2004). But Ms. Slater doesn't argue fraud or misrepresentation; she argues that Biomet violated the statute simply through sale of a defective product. Biomet says the cause of action accrued "when the violation occur[ed]," Hinson v. United Fin. Servs., Inc., 473 S.E.2d 382, 387 (N.C. Ct. App. 1996), upon sale of the defective product. Ms. Slater doesn't address the issue in her response brief. In particular, she makes no argument that the "discovery rule" should apply here too. Biomet's motion is thus granted as to the UDTPA claim (Count V).[5]

[5] Ms. Slater also argues that Biomet waived its statute of limitations arguments when it didn't file a timely responsive pleading. *See* Fed. R. Civ. P. 8(c)(1); Wood v. Milyard, 132 S. Ct. 1826, 1832 (2012). On February 14, 2014, I granted a stay of "[a]ll case specific responsive pleadings deadlines, including the filing of answers . . . until such time as the parties agree that the obligations contemplated by the Settlement Agreement have been completed." [Doc. No. 1418]. The parties haven't presented any such agreement and so the stay is still in effect. Biomet didn't waive any affirmative defense by not filing an answer.

VI. CONCLUSION

The court GRANTS Biomet's motion for summary judgment [Doc. No. 117] as to Ms. Slater's breach of warranty and statutory claims (Counts III-V), and DENIES Biomet's motion as to her products liability and negligence claims (Counts I-II).

SO ORDERED.

ENTERED: March 26, 2017

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