UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

VINCENT PIZZITOLO,	)	
	)	
Plaintiff	)	
	)	
v.	)	Cause No. 3:12-CV-570 RLM-MGG
	)	
BIOMET ORTHOPEDICS, LLC,	)	
	)	
Defendant	)	

OPINION AND ORDER

Vincent Pizzitolo sued Biomet for damages in connection with the alleged failure of his Biomet M2a Magnum hip implant. Biomet moved for summary judgment, arguing that all of his claims are time-barred by the applicable statutes of limitations based on (1) a proposed date on which all plaintiffs were on constructive notice of potential claims and (2) facts specific to Mr. Pizzitolo. I deny Biomet's motion for the reasons that follow.

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 Mr. Pizzitolo, 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, Mr. Pizzitolo 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 his 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 his 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 he 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 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.

III. MR. PIZZITOLO'S BACKGROUND

Mr. Pizzitolo received a Biomet Magnum implant in his right hip in March 2008, and began experiencing pain in his hip in late 2010. He discussed the problem with his treating surgeon, Dr. Lance S. Estrada, who told Mr. Pizzitolo that he believed the acetabular cup had slipped and that he would need revision surgery, which occurred on January 24, 2011. Dr. Estrada stated in an affidavit that at the time of the revision surgery and until at least December 11, 2012, he didn't suspect that the device was defected; rather he believed, and told Mr. Pizzitolo, that it needed to be replaced because it shifted position.

Mr. Pizzitolo attests that he learned of the DePuy ASR hip implant recall through a television commercial placed by attorneys around March 2011, and contacted a law firm to determine whether he had a potential claim against Biomet for his implant. On September 22, 2011, the law firm sent Mr. Pizzitolo a letter stating:

> Thank you for contacting us regarding your potential product liability claim against Biomet, Inc. for their M2a-Magnum cup, their M2a-Magnum Tri-Spike cup, or their M2a-38 mm cup.
>
> When we accepted your claim, it was on an investigational basis, and further investigation into these devices has led us to decide not to pursue the litigation. While we recognize that your hip metal on metal implant is similar to the recalled DePuy implant and that your problems may very well be related to design problems with the implant, Biomet has not recalled the device and there is a lack of incriminating published medical evidence at this time specific to the Biomet products. Accordingly, [the firm] h[as] not engaged and will not engage in any activity on your behalf and we will be closing our file in this matter.

> This does not mean that you do not have a valid claim. Since attorneys' opinions differ, we encourage you to seek the advice of other counsel. Please note that there are strict time limits for filing a lawsuit. Once the time limit expires (if it has not already), you are forever barred from bringing suit. If you wish to pursue alternative counsel, we would strongly encourage you to do so as soon as possible.

[Doc. No. 204-4]. After seeing more advertising suggesting that Biomet hip implants were defective, Mr. Pizzitolo contacted another attorney, and filed his complaint on February 27, 2012.

IV. CHOICE OF LAW

Mr. Pizzitolo's complaint was originally filed in the Eastern District of Louisiana, and is governed by Louisiana choice of law rules. *See* In re Watson Fentanyl Patch Prod. Liab. Litig., 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013) (recognizing that the "choice of law rules that apply are those of the state where the case originated"). Under those rules, Louisiana law provides the statute of limitations on Mr. Pizzitolo's claims. *See* La. Civ. Code Ann. art. 3549 ("when the substantive law of this state would be applicable to the merits of an action brought in this state, the prescription and preemption law of this state applies").

V. DISCUSSION

Products liability claims under Louisiana law must be brought within one year from the date of injury. La. Civ. Code Ann. art. 3492. The statute of limitations for redhibition claims varies, but in all cases it is at least one year. La. Civ. Code Ann. art. 2534.

"[T]he mover bears the burden of proving prescription." Taranto v. Louisiana Citizens Prop. Ins. Corp., 62 So. 3d 721, 726 (La. 2011). But "if the petition is prescribed on its face, then the burden of proof shifts to the Plaintiff to negate the presumption by establishing a suspension or interruption." Id. Mr. Pizzitolo's complaint was filed on February 27, 2012, more than a year after his January 24, 2011, revision surgery, the latest possible date of his injury. Mr. Pizzitolo's action is time-barred on its face, unless he can prove that the statutes of limitations were tolled.

Mr. Pizzitolo contends that the limitations periods were tolled until March 2011 under Louisiana's version of the discovery doctrine, the *contra non valentem* doctrine, because he reasonably relied on his surgeon's statement that the Biomet device had shifted position, rather than being defective, and didn't learn about the DePuy recall or contact an attorney to inquire about a potential lawsuit until March 2011.

The *contra non valentem* doctrine "is based on the theory that when the claimant is not aware of the facts giving rise to his or her cause of action against the particular defendant, the running of prescription is . . . suspended until the tort victim discovers or should have discovered the facts upon which his or her cause of action is based." In re Med. Review Panel of Howard, 573 So. 2d 472, 474 (La. 1991). "Prescription does not run against one who is ignorant of the facts upon which his cause of action is based, as long as such ignorance is not willful, negligent[,] or unreasonable." Id. "When prescription begins to run depends on the reasonableness of a plaintiff's action or inaction . . . in light of

plaintiff's own information and the diagnoses he received." Raborn v. Albea, 144 So. 3d 1066, 1072 (La. Ct. App. 2014). Under Louisiana law, the limitations period is tolled if the plaintiff "reasonably relied on [his] treating physician regarding the cause" of the injury. Lapuyade v. Rawbar, Inc., 190 So. 3d 1214, 1224 (La. Ct. App. 2016). Ignorance of the true cause of the injury isn't willful or inexcusably negligent when a plaintiff relies on a treating physician's opinion that is supported by medical records. Id. at 1225.

Dr. Estrada attested that "at no time prior to December 11, 2012, did he know, appreciate, suspect, or tell Mr. Pizzitolo that the Biomet hip implant device was defective or that he was aware that there was anything wrong with it, other than that it needed replacement because it had shifted position." [Doc. No. 204-5]. Medical reports from a pre-surgery appointment and the operative report include Dr. Estrada's opinion that the device had slipped or shifted. [Doc. Nos. 204-6 and 204-7].

Biomet argues that Lapuyade doesn't control because Mr. Pizzitolo was on constructive notice at the time of his surgery of potential claims based on the warnings disclosed in the device's Instructions for Use. As already discussed, Biomet hasn't demonstrated how a reasonable plaintiff (including Mr. Pizzitolo) would have seen or understood the Instructions for Use. Biomet's reliance on Raborn v. Albea, 144 So. 3d 1066 (La. Ct. App. 2014) to support its argument is misplaced. In Raborn, the court held that the plaintiff was on constructive notice of an implanted medical device's defect despite a physician's failure to diagnose the defect because the product's insert disclosed the adverse effects of the device

that the plaintiff experienced. Id. at 1072–1073. The court found that the product's "insert, *which was available to [the plaintiff] at the time of his surgery*," disclosed the risks associated with the product. Id. at 1072. But Mr. Pizzitolo presented evidence indicating that the Instructions for Use weren't available to him [Doc. No. 204-2], and Biomet hasn't presented any evidence to the contrary.

Mr. Pizzitolo stated in his affidavit that he asked Dr. Estrada what caused his injury and his physician told him that "the hip had slipped or come loose," requiring revision surgery. [Doc. No. 204-1]. In a separate affidavit, Dr. Estrada attested that he told Mr. Pizzitolo that the implant "needed replacement because it had shifted positions" and disclosed that he didn't suspect that the device was defective, and medical records from December 2010 and January 2011 reiterate Dr. Estrada's opinion that the device had slipped or shifted. [Doc. Nos. 204-5, 204-6 and 204-7]. Mr. Pizzitolo's discussion with his treating surgeon about the cause of his injury demonstrated reasonable diligence and his reasonable reliance on his surgeon's opinion tolls the statutes of limitations. Lapuyade v. Rawbar, Inc., 190 So. 3d 1214, 1224 (La. Ct. App. 2016).

But for how long?

Biomet argues that Mr. Pizzitolo's admission that he consulted with attorneys in early 2011 demonstrates that he had notice of his claims before March 2011. But Mr. Pizzitolo attested that he was "fairly certain" that he learned of the DePuy ASR hip implant recall through a television commercial no earlier than March 2011 and then contacted a law firm handling ASR cases to determine whether he might have a claim against Biomet. [Doc. No. 204-1]. Contacting a

lawyer to pursue a product liability claim against Biomet demonstrates that Mr. Pizzitolo was on notice of his claim. The only evidence in the record as to the date of Mr. Pizzitolo's outreach to an attorney, however, is his assertion that he was "fairly certain" it followed him seeing a television commercial no earlier than March 2011. The law firm's letter responding to Mr. Pizzitolo's inquiry is dated September 22, 2011.

Based on the evidence presented, a reasonable jury could find that Mr.Pizzitolo was on notice of his claims by March 2011, that the statutes of limitations for his products liability and redhibition claims were tolled until that time, and that his claims were timely filed.

VI. CONCLUSION

For the foregoing reasons, Biomet's motion for summary judgment [Doc. No. 195] is DENIED.

SO ORDERED.

ENTERED: March 26, 2017

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