UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

DYNEL MILES, Plaintiff	)	
v.	)	Cause No. 3:14-CV-1983 RLM-MGG
BIOMET ORTHOPEDICS, LLC, *et al.*, Defendants	)	

OPINION AND ORDER

Dynel Miles sued Biomet for damages in connection with the alleged failure of her hip implant. Biomet moved for summary judgment, arguing that the applicable statutes of limitations bars her claims based on (1) a proposed date on which all plaintiffs were on constructive notice of potential claims and (2) facts specific to the plaintiff. In response, Ms. Miles moved to amend her complaint "to state with more specificity the chronology of events", delete her claim under New York's General Business Law, and add a claim under Florida's consumer protection statute. For the following reasons, I grant Biomet's motion for summary judgment and deny Ms. Miles's motion to amend.

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. Miles, 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. Miles 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 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. If 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 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]

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]

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[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 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.

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/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/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. MS. MILES'S BACKGROUND

A Ringloc device was implanted in Ms. Miles's right hip on December 7, 2005. She began experiencing pain soon afterwards, and was her surgeon told her on December 30, 2005 that the Ringloc had failed and that she needed revision surgery. The Ringloc system was removed during revision surgery on January 2, 2006, with a diagnosis of "failed acetabular component."

Ms. Miles contacted an attorney in January 2006 to discuss the possibility of a lawsuit against her surgeon. Ms. Miles also requested a product catalogue from Biomet to see if she might have a claim against it. She did so after seeing commercials about lawsuits against other metal-on-metal hip manufacturers.

On October 22, 2014, Ms. Miles filed this suit alleging that the device implanted in December 2005 was defective and asserting claims for strict product liability, breach of warranty, negligence, negligent misrepresentation, fraud, loss of consortium and a violation of New York's General Business Law. Ms. Miles amended her complaint in November 2014, to allege that her implant was defective because it caused excessive amounts of cobalt and chromium to wear and corrode, leading to rejection of the implant and other bodily harm, and that the defect caused her implant to fail, requiring the January 2, 2006 revision surgery. [Doc. No. 5 at ¶¶ 23, 33-34].

IV. CHOICE OF LAW

When a case is filed directly in the MDL transferee court, the court applies the law, including the 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 device in this case was prescribed, purchased, and implanted in Florida, so Florida choice of law rules govern. Florida courts apply the law with the "most significant relationship" to the claim. Brown v. Nat'l Car Rental Sys., Inc., 707 So. 2d 394, 395 (Fla. Dist. Ct. App. 1998). Because the injury, implant, and revision occurred in Florida, Florida presumptively has the most significant relationship, so Florida law, including its statutes of limitations, applies.

V. DISCUSSION

Ms. Miles had to file her claims for product liability, breach of warranty, negligence and fraud within four years from the time "the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence." Fla. Stat. Ann. §§ 95.031(2)(a) and (b) and 95.11.[4] But how much does she need to know for the limitations period to run?

[4] Ms. Miles doesn't dispute Biomet's assertion that she can't prevail on her claim under the New York General Business Law (Count 11) because no relevant conduct occurred in New York, *see* Goshen v. Mut. Life Ins. Co., 774 N.E.2d 1190, 1195 (N.Y. 2002), and the claim is barred by the applicable three-year statute of limitations, which accrues at the time of injury. *See* Lucker v. Bayside Cemetery, 114 A.D.3d 162, 175 (N.Y. App. 2013); Wender v. Gilberg Agency, 276 A.D.2d 311, 312 (N.Y. App. 2000), and withdrew the claim in her proposed second amended complaint.

The statute of limitations begins to run Under Florida law "when the plaintiff is aware of an injury and the possible involvement of a product." In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig., MDL No. 2004, 2016 WL 873814, at *2 (M.D. Ga. Mar. 4, 2016) (applying Florida law); Univ. of Miami v. Bogorff, 583 So. 2d 1000, 1004 (Fla. 1991); Babush v. Am. Home Products Corp., 589 So. 2d 1379, 1381 (Fla. Dist. Ct. App. 1991).

Ms. Miles's claims accrued by January 2006, when she became aware that she had injuries related to the Biomet hip implant, sought product information from Biomet, and contacted an attorney about filing a lawsuit against her physician. Her complaint was filed more than eight years later, so her claims are barred under the four-year statutes of limitations.

Ms. Miles argues that the limitations period was tolled until at least 2013 because Biomet "fraudulently concealed" the "true risks" associated with its metal-on-metal hip implant, and that neither she, nor her physician, was aware of those risks until blood tests in 2013, 2014 and 2015 revealed increased levels of Chromium and Cobalt. Her argument is factually and legally unsupported.

Florida's statutes of limitations can only be tolled for reasons enumerated in Fla. Stat. § 95.051, *See* HCA Health Servs. Of Fla., Inc. v. Hillman, 906 So.2d 1094, 1099 (Fla. Dist. Ct. App. 2004), and fraudulent concealment is not among the exceptions enumerated in that statute.

Florida courts recognize that equitable estoppel can bar a statute of limitations defense, *see* Major League Baseball v. Morsani, 790 So.2d 1071, 1077 (Fla. 2001), but require the plaintiff to show "that the defendant willfully induced

the plaintiff to forego suit until after the limitations period has ended." In re Chiquita Brands Int'l, Inc. Alien Tort Statute and Shareholder Derivative Litig., 690 F.Supp.2d 1296, 1316 (S.D. Fla. 2010) (*quoting* Fox v. City of Pompano Beach, 984 So.2d 664, 667 (Fla. Dist. Ct. App. 2008)). Ms. Miles hasn't made the required showing.

VI. Motion to Amend

Fed. R. Civ. P. 15(a) governs amendments to pleadings and provides that leave to amend should be freely given "when justice so requires."

> In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of a movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposting party by virtue of allowance of the amendment, futility of the amendment, etc.—the leave sought should, as the rules require, be freely given.

Foman v. Davis, 371 U.S. 178, 182 (1962).

In her motion, Ms. Miles asserts that the purpose of the amendment is "to state with more specificity the chronology of events in support of her response to Defendants' Motion for Summary Judgment." But the proposed second amended complaint attached to her motion would do much more than that. It would drop her claim under New York's General Business Law, and would add new claims (*i.e.*, that the device implanted in January 2006 was also defective and that Biomet violated Florida's Deceptive and Unfair Trade Practices Act).

Ms. Miles offers no explanation for why she didn't move to amend sooner; she didn't file a memorandum in support of her motion and hasn't cited any authority for the relief she seeks. The deadline for dispositive motions has passed

and the MDL docket is nearing its final stages. Allowing Ms. Miles to amend her complaint to add new claims at this late stage would result in undue delay and unduly prejudice the defendant. Accordingly, I must deny Ms. Miles motion.

VII. CONCLUSION

For the foregoing reasons, Biomet's motion for summary judgment [Doc. No. 107] is GRANTED and Ms. Miles's motion for leave to file a second amended complaint [Doc. No. 115] is DENIED.

SO ORDERED.

ENTERED: March 26, 2017

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