UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF INDIANA SOUTH BEND DIVISION

JOHN FAHY,)
Plaintiff)
v.) Cause No. 3:15-CV-218 RLM-MGG
BIOMET ORTHOPEDICS, LLC, et al.,)
Defendants)

OPINION AND ORDER

John Fahy sued Biomet for damages in connection with the alleged failure of his Biomet M2a Magnum hip implant. Biomet moved for summary judgment, arguing Indiana's statutes of limitations bars all of Mr. Fahy's claims based on (1) a proposed date on which all plaintiffs were on constructive notice of potential claims and (2) facts specific to Mr. Fahy. I disagree with Biomet's proposed universal bar date and DENY its motion as to Mr. Fahy's strict product liability and negligence claims (Counts 1, 2 and 5), but grant the motion as to the breach of negligent misrepresentation, warranty, and deceptive trade practices/consumer protection claims (Counts 3, 4, 6, 7 and 8), for the reasons stated below.

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. <u>Protective</u>

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. Fahy, 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. Fahy 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 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 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

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 Metalon-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/MedicalD evices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal HipImplants/ucm241604.htm; Information for Patients Who Have Metal-on-Metal FOOD & DRUG ADMIN. (last updated Feb. Implants, 10. https://web.archive.org/web/20110528045143/http://www.fda.gov/MedicalD evices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetal HipImplants/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.

<u>In re Zyprexa Prods. Liab. Litig.</u>, 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. Fahy's Background

Mr. Fahy received a Biomet Taper implant in his left hip in Minnesota in February 2010. After the surgery, he developed a staph infection at the surgery site and began to experience intense pain. The staph infection was unresponsive to antibiotic treatment, and Mr. Fahy's surgeon told him that the Taper needed to be removed due to the failure of the antibiotic therapy. Mr. Fahy underwent his first revision surgery on April 10, 2010, during which components of the Taper were removed and an antibiotic spacer was implanted. It wasn't his last; Mr. Fahy had other surgeries and procedures on August 11, 2010, June 25, 2011, November 1, 2011, and June 20, 2012 (when he underwent his last revision surgery), due to infection and fluid build-up. Mr. Fahy asserts that he first heard of a possible problem with some of the metal-on-metal hips in 2014, when he saw commercials on late night television and got an email indicating that there were possible problems with hip implants. He filed suit against Biomet in the District of Minnesota on May 11, 2015, and the case was transferred to this MDL docket.

IV. CHOICE OF LAW

"[S]ince federal jurisdiction is based on diversity of citizenship, the choiceof-law rules to be used are those choice-of-law rules of the states where the actions were originally filed." <u>In re Air Crash Disaster Near Chicago</u>, 644 F.2d 594, 610 (7th Cir. 1981). Minnesota generally applies the statute of limitations of the jurisdiction whose substantive law applies. Minn. Stat. § 541.31; <u>Blake Marine Group</u>, <u>Inc. v. CarVal Investors LLC</u>, 829 F.3d 592, 595 (8th Cir. 2016).⁴

Although the traditional rule still applies in Minnesota, see Glover v. Merck & Co., 345 F.Supp. 994, 998-99 (D. Minn. 2004), Biomet urges me to engage in a multi-factor choice of law analysis and apply Indiana's shorter statute of limitations, citing, i.e., Kolberg-Pioner, Inc. v. Belgrade Steel Tank Co., 823 N.W.2d 669, 673 (Minn. App. 2012). Before applying a choice-of-law analysis, however, I must find that a conflict exists and that both states' laws can be constitutionally applied (that each state has significant contacts such that applying its law would not be arbitrary or fundamental unfair). Whitney v. Guys, Inc., 700 F.3d 1118, 1123 (8th Cir. 2012); Nodak Mut. Ins. Co. v. Am. Family Mutual Ins. Co., 604 N.W.2d 91, 93–94 (Minn.2000); Jepson v. Gen. Casualty Co. of Wisconsin, 513 N.W.2d 467, 469 (Minn.1994). Biomet contends that both requirements have been satisfied. I disagree.

While the statutes of limitations in Minnesota and Indiana differ with respect to Mr. Fahy's product liability, negligence, and negligent misrepresentation claims, Indiana doesn't have sufficient contacts to justify

⁴ Minn. Stat. 541.31, Subdivision 1 provides:

⁽a)..."[I]f a claim is substantively based:

⁽¹⁾ upon the law of one other state, the limitation period of that state applies; or

⁽²⁾ upon the law of more than one state, the limitation period of one of those states chosen by the law of conflict of laws of this state applies.

⁽b) The limitation period of this state applies to all other claims.

applying its law. This case was filed in Minnesota, by a citizen of Minnesota, and asserts claims under Minnesota law. The device was sold in Minnesota, the original and revision surgeries occurred there, and this case will be remanded to the district court in Minnesota for trial, if Mr. Fahy prevails on summary judgment. The only connections the case has to Indiana is that it was transferred here as part of the MDL and the defendants are Indiana citizens. Those limited contacts with Indiana don't justify applying Indiana law. *See Allstate Ins. Co. v. Hague*, 449 U.S. 302, 312–13 (1981). Minnesota law, including its statutes of limitation, therefore applies. *See* Minn. Stat. § 541.31; Blake Marine Group, Inc. v. CarVal Investors LLC, 829 F.3d at 595; Glover v. Merck & Co., Inc., 345 F.Supp.2d at 999; American Mutual Liability Ins. Co. v. Reed Cleaners, 122 N.W.2d 178, 180 n. 1 (Minn. 1963); In re Daniel's Estate, 294 N.W. 465, 469 (1940).

V. DISCUSSION

With one exception, Biomet based its arguments exclusively on Indiana law, which doesn't apply. Biomet made a cursory argument in a footnote to its memorandum that Mr. Fahy's product liability and breach of warranty claims "are time-barred even under Minnesota law." [Doc. No. 82 at p. 12, n.9]. Citing Minn. Stat. § 541.05, Subd. 2 (strict liability claims "arising from the manufacture, sale, use or consumption of a product shall be commences within four years") and Minn. Stat. § 336.2-725(2) ("A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to

future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.")

A cause of action for strict product liability accrues Under Minnesota law when there is: "(1) a cognizable physical manifestation of the disease or injury, and (2) evidence of a causal connection between the injury or disease and the defendant's product, act, or omission." Huggins v. Stryker Corp., 932 F.Supp.2d 972, 984 (D. Minn. 2013) (quoting Hildebrandt v. Allied Corp., 839 F.2d 396, 398 (8th Cir. 1987)); see also Block v. Toyota Motor Corp., 5 F.Supp.3d 1047, 1058 (D. Minn. 2014); Mack v. Stryker Corp., Civ. No. 10-2993, 2010 WL 4386898, at *2 (D. Minn. Oct. 28, 2010).

The summary judgment record doesn't indicate that Mr. Fahy had actual or constructive knowledge of a possible connection between the Taper and injury from metal debris when he had his first revision on April 12, 2010. Mr. Fahy knew that the Taper implant had to be removed in April 2010 because of a staph infection that didn't respond to antibiotic treatment, but there's no indication the hip implant caused the original staph infection or the recurring infections that required later revisions. With the complexities of medical treatment, that information might not have been enough to put him on inquiry notice as to the failure of the device itself.⁵ That's what Minnesota law requires, I can't resolve

⁵ For reasons previously stated, Biomet's suggestion that Mr. Fahy knew or should of known of a causal connection between the device and his injury by February 10, 2011 based on its "bar date" argument is unpersuasive. Assuming for the sake of argument, that Mr. Fahy had actual or constructive knowledge no later than June 20, 2012, when he had his final revision surgery, the strict liability claims in his complaint fell within the applicable four year statute of limitations.

this question of fact on summary judgment. Biomet's motion is denied as to the strict liability claims (Counts 1 and 2).

Different provisions govern the remaining claims. Mr. Fahy's breach of warranty claims have a four-year limitations period that generally accrues "when tender of delivery is made." Minn. Stat. § 336.2-725(2). "Tender of delivery" was the time of implant, February 2010, so four years elapsed before Mr. Fahy filed his claims.

Minnesota has a "discovery rule" for breach of warranty claims too, but only when the "warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance." *See* Minn. Stat. § 336.2-724(2). Neither party mentions the existence or nonexistence of an explicit warranty of future performance. Without such an explicit warranty, the breach of warranty claims (Counts 3, 7 and 8) are time-barred and Biomet's motion is granted as applied to them.

Mr. Fahy's negligence and negligent misrepresentation claims are timely under Minnesota's six-year statute of limitations for personal injury actions, Minn. Stat. § 541.05 subd. 1(5). See Huggins v. Stryker Corp., 932 F.Supp.2d 972, 984 (D. Minn. 2013). Biomet doesn't contend otherwise, but argues in the alternative that Mr. Fahy's negligent misrepresentation claim and his claims under Minnesota's deceptive trade practices and consumer protection laws should be dismissed because both require proof of causation, and Mr. Fahy hasn't shown that he reasonably relied on any statements by Biomet or its employees in deciding which device to use. In response, Mr. Fahy simply asserts

that causation is a disputed fact and that the issues on summary judgment were supposed to be limited to Biomet's statute of limitations defense. But he presented no evidence that would support his position or authority that would limit the scope of Biomet's summary judgment motion to statute of limitations issues.

The scheduling order entered in MDL 2391 on December 21, 2015 provided that: "If the [summary judgment] motion asserts grounds other than the statute of limitations, the PSC may seek additional time in which to conduct discovery on those additional issues, in accordance with Fed. R. Civ. P. 56(d)." [Doc. No. 3047 at ¶ 3(C)]. Mr. Fahy didn't ask me for additional time and hasn't pointed to any evidence that would support judgment in his favor on his negligent misrepresentation, deceptive practices, or consumer protection claims. Biomet's motion for summary judgment must be granted with respect to those claims. See 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").

VI. CONCLUSION

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The court GRANTS Biomet's motion for summary judgment [Doc. No. 81]

as to Mr. Fahy's breach of warranty, negligent misrepresentation, deceptive trade

practices and consumer protection claims (Counts 3, 4, 6, 7 and 8), and DENIES

Biomet's motion as to Mr. Fahy's strict liability and negligence claims (Counts 1,

2 and 5).

SO ORDERED.

ENTERED: March 26, 2017

/s/ Robert L. Miller, Jr.

Judge

United States District Court