UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 2391)	)	
	)	CAUSE NO. 3:12-MD-2391
This Document Relates to All Cases	)	

OPINION AND ORDER

The attorneys for Biomet and the attorneys who have served on the two plaintiffs' steering committees have impressed me. They have cooperated wherever possible, while firmly protecting the interests of those in the groups they represent. They have met deadlines with remarkable regularity, and appear to have done all they can do to move these cases forward. I have been fortunate to work with them in this MDL docket, and to be able to see their work. That said, Biomet has placed two head-scratching summary judgment motions before me, and this order tries to deal with them. Because most invoke expert opinion testimony, decision had to await the ruling on motions to exclude expert testimony. The reader should proceed with my opening comments in mind.

A.

First, Biomet has filed what purports to be a summary judgment motion addressed to some of the individual claims in this docket based on a "state of the art" theory. Biomet contends that its metal-on metal devices were "state of the art"

from the time they were first designed, manufactured, and marketed until 2013 (when Biomet stopped producing metal-on metal devices), or at least 2011 (when the FDA issued a public notice of concern regarding metal-on metal hip implants), and that it is entitled to judgment as a matter of law in the remaining metal-on metal cases because the plaintiffs haven't presented any device-specific evidence to the contrary.

Biomet argues that it marketed its second-generation metal-on metal devices based on studies that showed few adverse effects after five years of wear, and a clinical study showing that the products had far less wear debris and could support larger femoral heads than metal-on-polyethylene devices, reducing dislocation. Biomet says that reports indicating a connection between metal-on-metal devices and elevated metal ion levels only surfaced after the products were being marketed. Dr. St. John and Dr. Schroeder, Biomet's experts, opined that: Biomet's knowledge of the impact of metal ions was consistent with the knowledge available at the time; Biomet incorporated new knowledge into its instructions for use as it became available; and testing complied with ASTM standards and all other applicable codes and standards. Biomet thus claims its metal-on metal devices were designed, labeled, and sold based on the best data reasonably available at the time, and that concerns about metallosis weren't "generally recognized" or even known at the time.

Biomet argues that plaintiffs' expert Mari Truman's opinion doesn't create a genuine issue of material fact on these points. She says that Biomet's testing

was deficient because it didn't involve more extreme testing designed to mimic more active patients. Even if her opinion is admissible (and I have determined that it is), Biomet says that the testing it applied was the state of the art when the M2a implants were developed.

Ms. Truman's report argues that all metal-on metal implants were defective because the metal-on-polyethylene designs offered safer alternatives. Biomet argues that her opinion ignores the potential benefits from metal-on metal implants, especially as they were perceived during the 1990s through mid-2000s. Biomet also says that the kinds of metal-on-polyethylene devices on which Ms. Truman based her conclusions - highly cross-linked metal-on-polyethylene implants - were in development at the same time as the metal-on metal devices, but hadn't had significant clinical testing and weren't as widely accepted yet. Biomet argues that the metal-on-polyethylene devices shouldn't be treated as alternative designs for the metal-on metal devices, but as different devices entirely. The different materials in each type of design have their advantages and disadvantages, Biomet says, making them appropriate for some persons and inappropriate for others.

"State of the art" can be a pertinent (possibly determinative) part of the defense case in product liability suits in most states. But the definition varies from state to state, as does the role the concept plays in a case. Biomet says (and the plaintiffs only agree up to a point) that "state of the art" is an affirmative defense in Arizona, Iowa, Louisiana, Missouri, Nebraska, New Hampshire, and New Jersey,

and that it creates a presumption of non-liability in Indiana and Kentucky. Biomet says (without full agreement from the plaintiffs) that the following states require a plaintiff to show an alternative design (which Biomet says the plaintiffs can't do): Alabama, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, New York, Ohio, South Carolina, Texas, West Virginia, and Wisconsin. Biomet appears to believe that while the laws of those states vary somewhat, they are close enough to fit within a single definition it offers: "Biomet defines the state of the art for this motion as the best technology reasonably available for MoM hip implants during the time Biomet developed and marketed the implants or, as alternatively phrased (but with a consistent meaning), what was reasonably known an technologically feasible regarding MoM hip implants." [Doc. No. 3437 at 2]. But the court would need to engage in a side-by-side comparison to see which states use a substantially identical definition.

Biomet is correct that transferee courts often resolve summary judgment motions before considering suggestion of remand of cases to the transferor court or district where trial is to be held. I told counsel early on that I didn't intend to do that in this case, because there is less delay when the judge applying the law doesn't have to learn that law from scratch, and it was unfair to make all cases wait here while I studied a body of law that didn't apply to those cases. As I stated in the December 21, 2015 scheduling order: "With regard to the parties' general experts all summary judgment motions...that are heavily dependent upon the

unique law of a specific state (other than Indiana) may be left to the transferor court following remand." [Doc. No. 3047, 13].

While Biomet discusses the "state of the art" doctrines in nineteen states, the Plaintiffs Steering Committee reports that, according to its review of the pending unsettled cases, there are plaintiffs from 39 states and the District of Columbia. I think that count might elide upcoming forum selection issues in cases directly filed in this court, as well as looming choice of laws issues. Biomet's motion doesn't identify which constituent cases it targets with this summary judgment motion.

Biomet also concedes that once I make some sort of state-of-the-art ruling, the unique facts of the individual cases will have to be examined to see when the device was constructed, when it was implanted, and so on. But, Biomet says, "MDL courts often make rulings that are then applied later to individual cases, which is what Biomet seeks with this motion," citing discovery rulings in the Welding Fume Products Liability Litigation, MDL No. 1535, 2010 U.S. Dist. LEXIS 146067, at *31, 297 n.236 (N.D. Ohio June 4, 2010). But an enormous gulf separates rulings on the admissibility of evidence and what Biomet might be seeking from this ruling.

Biomet seems to be asking me to study and then articulate, or synthesize, the state-of-the-art law of nineteen different states and make some sort of declaration – it couldn't be a judgment or an order of the sort contemplated by Fed. R. Civ. P. 56(g) – that might or might not apply to a case in which one of

those states provide the rule of decision, depending on the specific facts of that case. Any such undertaking would indefensibly slow the process in this docket, which is now in its sixth year, and includes a case that landed in the federal court system in September 2011 and arises from a June 2008 surgery. Time in this court is better spent on other matters, with application of state law left to the transferor courts, which more often than not are located in the state whose law provides the rule of decision. I am denying Biomet's state-of-the-art summary judgment motion without prejudice to its renewal after remand to the transferor courts.

B.

Biomet's other summary judgment motion is directed to the Taper, ReCap, and metal-on-polyethylene cases, which represent a very small fraction of the total number of cases filed in this MDL docket. Although Biomet hasn't specifically identified which cases its motion applies to, I count only four: *Price v. Biomet* (3:14cv275), *Gearon v. Biomet* (3:14cv2099), *White v. Biomet* (3:16cv115), and *Glynn v. Biomet* (3:15cv491). *Price* involves a Taper device, *Gearon* involves a ReCap device, and *White* and *Glynn* are metal-on-polyethylene cases. The Judicial Panel on Multidistrict Litigation centralized the *Price* case here after it expanded the scope of the docket to include Taper devices. Although the MDL was never officially expanded to include the ReCap and metal-on-polyethylene hip implants, those cases were filed directly in the Northern District of Indiana, using the direct

filing method outlined in the February 15, 2013 Case Management Order [Doc. No. 242], and neither the PSC nor Biomet objected to their inclusion.

The December 2015 scheduling order stayed all metal-on-polyethylene cases until they were activated for case specific discovery, and established a time line for expert reports and deposition that were "not case-specific." [Doc. No. 3047]. Under that order, case-specific discovery was limited to:

> interrogatories, requests for production, requests for admission, and depositions of (a) the plaintiffs, (b) the implanting surgeon, (c) the revising surgeon, (d) the Biomet representative who processed the request for the product used during the implant surgery, (e) any separate Biomet representatives who were present in the operating room during the implant or revision surgery, and (f) one additional fact witness per side.

[Doc. No. 3047 at p. 6-8]. The order indicated that plaintiffs' originating counsel (not the PSC) would conduct those depositions, but it made no provision for any other case- or device- specific expert discovery, and neither the Plaintiffs Steering Committee nor Biomet ever sought to amend the scheduling order to include additional or modified procedures for the Taper, ReCap, and metal-on-polyethylene cases. When the Plaintiffs Steering Committee elected to focus its efforts and limited resources on the metal-on-metal cases that make up the majority of the MDL docket, the Taper, ReCap, and metal-on-polyethylene plaintiffs were pretty much left to fend for themselves. Their efforts to take expert depositions (other than those identified in the scheduling order) during case-specific discovery met with resistance, and, for reasons which aren't altogether clear, these plaintiffs and the Plaintiffs Steering Committee elected not

to seek my assistance in resolving their discovery disputes until Biomet filed its summary judgment motion.

In support of its motion, Biomet asserts that most jurisdictions require plaintiffs to present design-specific expert testimony regarding defect and causation to survive summary judgment, and that the plaintiffs in the Taper, ReCap and metal-on-polyethylene cases haven't met that burden because the testimony of their expert on design defect, Mari Truman, was generic (not design specific) and unreliable for the reasons stated in its *Daubert* motion.

The plaintiffs respond that summary judgment is inappropriate because:

(1) State laws differ significantly as to the *prima facie* case that must be presented to prove that a product is defective.

(2) Ms. Truman's testimony is reliable, admissible, and creates a genuine issue of fact as to whether the Taper and ReCap devices are defective.

(3) The Declarations of Causation submitted by Dr. Paul Dimond and Dr. B. Sonny Bal in *White v. Biomet* (3:16cv115) and *Glynn v. Biomet* (3:15cv491) create a genuine issue as to whether the metal-on-polyethylene hip implant is defective.

(4) Given the limitations on case-specific discovery, the plaintiffs haven't had an opportunity to conduct the kind of device-specific expert discovery needed to justify its opposition to Biomet's motion for summary judgment.

Biomet is correct that in many states, expert testimony is required to prove design defects. *See, e.g.*, Show v. Ford Motor Co., 659 F.3d 584 (7th Cir. 2011)

(holding that design-defect litigation under Illinois law requires expert evidence); Lara v. Delta Int'l Mach. Corp., 174 F. Supp. 3d 719, 740 (E.D.N.Y. 2016) ("New York law requires plaintiffs to proffer expert testimony as to the feasibility and efficacy of alternative designs."). Without expert testimony that the Taper or ReCap designs were defective, and with testimony in the record favorable to the metal-on-polyethylene design, Biomet argues that the cases involving those designs must be decided in Biomet's favor. I disagree.

Biomet's motion is largely premised on its assumption that its motion to exclude Ms. Truman's report and testimony would be granted, but I denied the motion to exclude Ms. Truman's opinion testimony. Ms. Truman opined that all metal-on-metal devices (and Biomet's Taper and ReCap implants are metal-on-metal devices) are defectively designed, thus creating a genuine issue of fact as to those devices that cannot be resolved on summary judgment.

Ms. Truman lauded metal-on-polythene devices as the best alternative (the alternate design in the state-of-the-art arguments), but Dr. Dimond and Dr. Bal provided Expert Declarations of Causation to the effect that the metal-on-polythene devices implanted in their patients were defective. Biomet contends that opinions of Dr. Dimond and Dr. Bal about the cause of the injuries suffered by Mr. White and Mr. Glynn are unreliable and so don't establish that there was a defect in the metal-on-polyethylene devices. Again, I disagree. As shown by the material submitted with their Expert Declarations of Causation, Dr. Dimond and Dr. Bal are qualified orthopedic surgeons who performed the

surgeries in question. Their Declarations of Causation were submitted in compliance with my December 15, 2016 order [Doc. No. 3272] entered by the parties' agreement and at Biomet's urging, and create a genuine issue of fact as to whether Biomet's metal-on-polythene hip implant is defective, as alleged. That Ms. Truman might have opined that the metal-on-polyethylene device is a reasonably safe alternative to the metal-on-metal device doesn't erase the opinions offered by Drs. Dimond and Bal that a defect in the metal-on-polyethylene devices implanted in Mr. White and Mr. Glynn caused their injuries.

While the evidence presented precludes summary judgment on the plaintiffs' defective design claims, their responses to Biomet's motion raise a matter of some concern - the status of case-specific expert discovery in the Taper, ReCap, and metal-on-polyethylene cases. As I noted in the December 21, 2015 scheduling order: "[I]t's my task under 28 U.S.C. § 1407 to get these cases as close to trial-ready as is reasonable before remanding them to transferor courts, so taking the [case-specific] depositions before remand seems more consistent with the MDL process." [Doc. No. 3047 at p. 7, 8].

Case-specific discovery remains open in the metal-on-polyethylene cases (*White* and *Glynn*) until September 14, 2018, so time remains to conduct device-specific expert depositions in those cases. If the plaintiffs wish to conduct such discovery in this court and require my assistance in resolving any discovery disputes, they need only ask.

But all discovery has closed with respect to the remaining Taper and ReCap cases (*Price* and *Gearon*). I denied the plaintiff's motions for voluntary dismissal and for suggestion of remand in those cases in February 2016 and again in November 2016, based in part on Biomet's belief that the plaintiffs would continue to benefit from coordinated discovery. To deny those plaintiffs that benefit now would be unduly prejudicial to Mr. White and Mr. Glynn. Accordingly, I will offer both plaintiffs the option to file a motion to amend the scheduling order to allow device-specific expert depositions in this court, or to file a motion for suggestion of remand, so that they might conduct that discovery - discovery not yet undertaken in cases in the MDL docket - in the transferor court.

C.

For the foregoing reasons:

(1) Biomet's motions for summary judgment related to the Taper, ReCap, and metal-on-polyethylene devices [Doc. No. 3388] is DENIED on the merits.

(2) Biomet's motions for summary judgment relating to the state-of-the-art defense [Doc. No. 3390] is DENIED, without prejudice.

(3) If the plaintiffs in *White v. Biomet* (3:16cv115) and *Glynn v. Biomet* (3:15cv491) wish to take device-specific expert depositions, they should file a motion to that effect within 14 days from the date of this order, and should indicate in that motion whether local counsel will conduct the

deposition, with or without the assistance of the Plaintiffs Steering Committee.

(4) The plaintiffs in the *Price v. Biomet* (3:14cv275) and *Gearon v. Biomet* (3:14cv2099) shall have 14 days from the date of this order to file a motion to amend the scheduling order to allow device-specific expert depositions or, alternatively, a motion for suggestion of remand. If they elect the later, the Plaintiffs Steering Committee should address the effect, if any, remand would have on the plaintiffs' obligations under the December 7, 2015 Amended Holdback Order [Doc. No. 3022] in its response.

SO ORDERED.

ENTERED: February 8, 2018

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