

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

IN RE: BIOMET M2a MAGNUM HIP)
IMPLANT PRODUCTS LIABILITY) Cause No. 3:12-MD-2391
LITIGATION (MDL 2391))

ORDER

I have reviewed the proposed pretrial orders submitted by the parties and the objections thereto, made modifications to both, and propose to send the attached Suggestion of Remand/Explanation to Transferee Courts with each remand and transfer order. I believe the proposed order explains my handling of the parties' disagreements. Any objections to the modified order should be submitted by **September 4, 2018**.

SO ORDERED.

ENTERED: August 24, 2018

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

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NORTHERN DISTRICT OF INDIANA
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This Document Relates to All Cases)
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_____))

SUGGESTION OF REMAND/EXPLANATION TO TRANSFEREE COURTS

These product-liability cases involve the alleged failure of the M2a series of metal-on-metal hip implant systems—the M2a-Magnum™ and M2a-38™. On October 2, 2012, the Judicial Panel on Multidistrict Litigation, or "the Panel," transferred the first actions to this Court for consolidated and coordinated pretrial proceedings.¹ In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig., 896 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012). The plaintiffs claimed that the design of these devices "generate[d] high levels of metal ions, cause[d] metallosis in the surrounding tissue and/or fail[ed] early." Nearly 3,000 cases have entered this docket; most have settled. As the transferee court, the Northern District of Indiana

¹The JPML later transferred actions involving the M2a-Taper™ to this Court, by 2018 one case involving this product remained in this multidistrict litigation, and I suggested remand of this case on May 30, 2018. [See [Doc. No. 3595](#)]. A small number of cases involving Biomet's ReCap Resurfacing System™ and its metal-on-polyethylene devices were directly filed in this district pursuant to the case management order entered on February 15, 2013. Several of these cases were transferred pursuant to 28 U.S.C. § 1404(a) on May 30, 2018. [See [Doc. No. 3595](#)].

maintains on its web site a summary of actions taken in this docket. <http://www.innd.uscourts.gov/mdl-2391>. The Panel docket number is MDL-2391; this court's docket number is 3:12md2391RLM-MGG.

Pursuant to Rule 10.1(b) of the Rules of Procedure of the Panel, this order suggests to the Panel that the cases listed in Exhibit A should be remanded to their appropriate transferor jurisdictions. These cases will no longer benefit from centralized proceedings; and the remaining case-specific issues are best left to the transferor courts to decide. No plaintiff has consented to trial of cases in the MDL court. See Lexecon. Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26 (1998). By separate orders, I am transferring, pursuant to 28 U.S.C. § 1404(a), cases that I allowed to be filed directly in the MDL docket to the courts in which they otherwise would have been filed. This order summarizes the coordinated proceedings thus far and offers guidance to transferor courts after remand.

Two things must be explained to fully understand what has been done in the MDL and what remains to be done in the transferee courts. First, a partial settlement in 2014 resolved more than 90 percent of the cases then pending, and progress came to a halt as individual plaintiffs decided whether to join in the settlement (at least 90 percent had to agree for purposes of Biomet's offer) and since most of the plaintiff's steering committee members no longer had cases in the docket after the settlement, a new plaintiffs' steering committee was put in place. The history most pertinent to transferee courts relates to what happened after the second steering committee was up and running. Second, I

avoided deciding questions of substantive state law. The laws of 44 states provide the rules of decision in the case in this MDL docket. Were I to try to understand and apply each of those state-specific laws, parties would have had to wait far longer for resolution, and I would be less likely to get the case right than a judge more familiar with that state-based rule of decision.

The defendants in these cases can be collectively thought of as “Biomet.” The defendants named in the lawsuits filed in the Northern District of Indiana or transferred to the MDL include: Biomet, Inc.; Biomet Orthopedics, LLC; Biomet Manufacturing, LLC; and Biomet U.S. Reconstruction, LLC (collectively, “Biomet”). To the extent the plaintiffs named other Biomet corporate entities in their complaints, the parties stipulated to their dismissal in 2013, [[Doc. No. 444](#)],² and I issued an order in 2015 dismissing such defendants in cases filed after the entry of the stipulation. [[Doc. No. 2972](#)].

John D. Winter (Patterson Belknap Webb & Tyler LLP) serves as Biomet’s lead counsel, and John D. LaDue and Erin Linder Hanig (both of LaDue Curran Kuehn LLC) serve as liaison counsel. They have served in those capacities since the outset of the MDL docket. I appointed the first plaintiffs’ steering committee (“PSC I”) in December 2012, as well as the plaintiffs’ executive committee and co-lead counsel and outlined their duties.³ [[Doc. No. 127](#)].

² Biomet Manufacturing, LLC was known as “Biomet Manufacturing Corp.” at the time of the stipulation.

³ At the time of its termination, PSC I consisted of (executive committee members are in boldface): **Thomas R. Anapol** (Anapol Schwartz); **Anne Andrews** (Andrews & Thorton); **Richard J. Arsenault** (Neblett, Beard & Arsenault); Daniel C. Burke (Parker & Waichman); Wayne Fisher (Fisher, Boyd, Brown & Huguenard); **Peter**

Before the Panel created MDL-2391 and transferred cases to this court, Biomet had collected 19.5 million documents, applied search terms to those documents, and used predictive coding to begin producing documents, all in 2012. In April 2013, PSC I asked me to order Biomet to engage in a collaborative application of predictive coding to the total universe of documents Biomet collected, and Biomet opposed this request. I denied PSC I's request after concluding that Biomet's production was sufficient under the Rules of Civil Procedure and balancing the cost to Biomet and the potential benefit to the plaintiffs of starting over. [[Doc. No. 763](#)].

I entered a case management order on February 15, 2013 ("CMO I"). [[Doc. No. 242](#)]. That order required the plaintiffs to serve on Biomet a completed plaintiff fact sheet and a medical record release authorization for health care providers for each plaintiff. Those fact sheets served as limited case-specific interrogatories. After receiving a plaintiff's fact sheet, Biomet served a

Flowers (Foote, Meyers, Mielke & Flowers); Brenda S. Fulmer (Searcy, Denney, Scarola, Barnhart & Shipley); **Shelly Hutson** (Clark Love & Hutson); Lawrence L. Jones (Jones Ward); Michelle Kranz (Zoll, Kranz & Borgess); **Douglass A. Kreis** (Aylstock, Witkin, Kreis & Overholtz); W. Mark Lanier (The Lanier Law Firm); Hadley L. Matarazzo (Faraci Lange, LLP); Michael L. McGlamry (Pope, McGlamry, Kilpatrick, Morrison & Norwood); Joseph A. Osborne (Babbitt, Johnson, Osborne & LeClainche); Scott A. Powell (Hare, Wynn, Newell & Newton); Ellen Relkin (Weitz & Luxenberg); **Daniel S. Robinson** (Robinson, Calcagnie, Robinson, Shapiro, Davis, Inc.); Joseph H. Saunders (Saunders & Walker); Tayjes Shah (The Miller Law Firm); Navan Ward, Jr. (Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.); and Genevieve M. Zimmerman (Meshbesher & Spence).

Robert T. Dassow and Frederick R. Hovde (both of Hovde Dassow + Deets) served as liaison counsel, and Mr. Anapol and Mr. Lanier served as co-lead counsel.

defendants' fact sheet. PSC I and Biomet could also serve (1) master sets of requests for production; (2) master sets of interrogatories; and (3) master sets of requests for admission, but the parties couldn't serve any other discovery requests without a court order, and discovery was otherwise stayed. CMO I also included a privilege log protocol that specifically identified the required information for any privilege log and the documents the parties need not log, as well as a specific procedure for me to decide any disputes about the privilege description or the substantive claim of privilege in the event the parties couldn't resolve the issue. CMO I incorporated a stipulated order about the production of electronically stored information, which identified the format in which the parties should produce paper documents and electronically stored information.⁴ [[Doc. No. 242, Exh. B](#); see also [Doc. No. 396](#) relating to electronically stored information].

On December 10, 2013, I entered a scheduling order that set deadlines for pleading amendments, discovery, dispositive motions, and bellwether trials.⁵

⁴ CMO I also incorporated several other orders, entered the same day, including the Seventh Circuit's Standing Order Relating to the Discovery of Electronically Stored Information and an agreed upon protective order. [[Doc. No. 242, Exhs. A and C](#)].

⁵ This order required Biomet to (1) certify its production with respect to an initial set of 28 document custodians by January 3, 2014; (2) certify the production of an additional set of 39 identified document custodians and otherwise complete its production by May 12, 2014; (3) complete its privilege log production by April 11, 2014. Biomet certified the production of its initial document custodians within the time provided by the Scheduling Order. [[Doc. No. 1164](#)].

[\[Doc. No. 1118\]](#). I vacated that scheduling order on February 3, 2014, in light of the master settlement agreement. [\[Doc. Nos. 1317 and 1317-1\]](#).

A considerable time interval followed, as PSC I worked to assure the requisite 90 percent of the plaintiffs joined the master settlement agreement, after which a second plaintiffs' steering committee got up to speed. The master settlement agreement led to the settlement and dismissal of most of the cases then in the docket, including the cases in which most steering committee members were counsel of record. As a result, I terminated PSC I on May 27, 2015 and appointed a new plaintiffs steering committee ("PSC II").⁶

A common benefit fund is commonly used in mass tort litigation to compensate attorneys for services that benefit all of the plaintiffs in the MDL docket. On December 7, 2015, I ordered a provisional six percent holdback of amounts obtained by plaintiffs via settlement after December 7, 2015, excepting *pro se* plaintiffs. [\[Doc. No. 3022\]](#). This order allocated five percent of the holdback for common benefit attorneys' fees and one percent for common benefit costs.

I entered a new scheduling order on December 21, 2015. [\[Doc. No. 3047\]](#). That order set forth deadlines for additional generic and case-specific discovery,

⁶ At this time, PSC II consists of (again, executive committee members are in boldface): **Brenda Fulmer** (Searcy, Denney, Scarola, Barnhart & Shipley, PA); **Navan Ward** (Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.); Amber Pang Parra (Justinian PLLC); J. Kyle Bachus (Bachus & Schanker, LLC); **Justin Presnal** (formerly with Fisher, Boyd, Johnson & Huguenard, LLP, but now with Simmons Hanly Conroy); Jasper Ward (Jones Ward); and **Ahmed Diab** (Gomez Trial Attorneys).

Ms. Fulmer and Mr. Navan Ward serve as co-lead counsel, and Mr. Diab serves as liaison counsel for PSC II.

motions to exclude expert testimony, and some dispositive motions. What follows is what was done in the MDL under each category, and what might remain to be done in the receiving court.

Generic Discovery: Likely to Be Applicable in All Cases: Non-Expert Discovery. Discovery from Biomet and its personnel was extensive. The December 2015 scheduling order limited PSC II to an initial list of deponents from the 67 document custodians whose responsive documents Biomet had produced to PSC I, and called for PSC II to provide a supplemental list of deponents from the 67 custodians as well as people whose names arose during the depositions of the persons named on the first list. [[Doc. No. 3047 at ¶ 5–6](#)]. PSC II subsequently served on Biomet a list of proposed custodian-deponents and completed depositions of 14 Biomet employees.⁷ These depositions were completed by December 26, 2016, the deadline set in the scheduling order. The plaintiffs had a full opportunity to seek discovery from Biomet; the scheduling order contemplated that no further discovery from Biomet would be allowed.

Generic Discovery: Likely to Be Applicable in All Cases: Expert Testimony, Objections, and Motion Practice. PSC II served the generic expert reports of Francis H. Gannon, M.D., George S. Kantor, M.D., and Mari Truman, M.S.M.E., P.E. on February 23, 2018. In turn, Biomet served the generic expert reports of Thomas Fleeter, M.D., Steven R. Schmid, Ph.D., P.E., F ASME, David Schroeder,

⁷ PSCI II also cross-noticed in this action additional Biomet employee and third-party depositions taken in state-court proceedings. Biomet has reserved all objections to the use and admissibility of these depositions in a case pending in this multidistrict litigation.

Daniel Schultz, M.D., Andrew I. Spitzer, M.D., and Kenneth St. John, Ph.D. on March 25, 2017.

On December 21, 2017, each side moved to exclude testimony as non-compliant with Federal Rule of Evidence 702 with respect to witnesses Schmid, Schroeder, Schultz, Spitzer, St. John, Truman, and Kantor. I denied these motions in part, and granted them in the following respects:

- (1) I excluded Mr. Schroeder's opinion regarding Biomet's compliance with codes, standards, and regulations to the role such compliance plays in device development and the development of the relevant Biomet devices;
- (2) I precluded Dr. Spitzer from testifying as a tribology expert;
- (3) I excluded Dr. St. John's opinion that metal-on-metal revision rates are artificially inflated;
- (4) I precluded Dr. Kantor from testifying about the risks associated with and the design defects of Biomet devices because the record didn't demonstrate that he considered sufficient data in developing his opinion; and
- (5) I excluded Dr. Kantor's opinion regarding the sufficiency of Biomet's testing and clinical studies.

[\[Doc. No. 3486\]](#).

No motions were filed to exclude testimony of Drs. Fleeter or Gannon before the deadlines for the *Daubert* challenges. Biomet might file such a motion in the transferor court; I think such a motion would be untimely because the deadline governed all motions to exclude under Federal Rule of Evidence 702. As

I understood what we were doing, the admissibility of opinions and testimony for all experts to be used at trial have been heard and ruled upon in the MDL. [[Doc. No. 3047 at ¶ 13](#)].

All of these witnesses have been deposed. I am allowing PSC II to take preservation depositions of their generic expert witnesses, but since the applicable substantive law will vary from state to state, I am leaving all rulings on any objections to the testimony elicited, as well as the decision whether to allow any particular plaintiff to substitute video for live testimony, to the transferor judges.

Case Specific Discovery. The December 21, 2015, scheduling order directed case-specific discovery to proceed in two groups, with additional discovery groups to be activated on a rolling basis. [[Doc. No. 3047 at ¶ 7-11](#)]. I didn't schedule bellwether trials at that point; in light of the Master Settlement Agreement, bellwether trials weren't needed to help understand the value of the claims.

Setting aside cases involving *pro se* plaintiffs,⁸ the cases were

⁸ The December 21, 2015 Scheduling Order stayed cases involving *pro se* plaintiffs. On December 14, 2016, I ordered *pro se* litigants to submit a Declaration of Intent indicating whether they wanted to continue pursuing their cases. [[Doc. No. 3270](#)]. If any plaintiff indicated that s/he sought dismissal, or didn't return the Declaration of Intent in time, that case would be dismissed without prejudice. With respect to *pro se* plaintiffs who returned their declarations indicating intent to litigate further, the order required them to either (1) submit a Plaintiff's Expert Declaration of Causation form filled out by an orthopedic surgeon or (2) attend an in-person hearing. The order expressly provided that the failure to choose either of these two courses of action would lead to dismissal with prejudice. All identified *pro se* plaintiffs eventually either obtained counsel or had their case dismissed by this court, with only a few exceptions; those cases are proceeding with case-specific discovery.

categorized into sequentially numbered discovery groups.⁹ As each group has been activated for limited case specific discovery, the parties have served and responded to particular interrogatories, limited requests for production, and particular requests for admission. The parties also could conduct 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. [See, e.g., [Doc. No. 3047 at ¶ 8, 10](#)].

The depositions I allowed might be enough for one individual case but not for another. What I allowed wasn't meant to be exhaustive, so any individual case might need another few depositions.

Issue-Specific Discovery. In a few selected cases chosen to tee up issues, the parties engaged in discovery with respect to statutes of limitation and repose and state-of-the-art defenses. That discovery consisted of (a) particular interrogatory questions; (b) limited document requests; and (c) plaintiff depositions, to enable Biomet to file motions for summary judgment on those grounds.

⁹ Discovery in Groups 1 through 4 is complete, while discovery in Group 5 will close September 14, 2018. I activated Group 6 for discovery on April 23, 2018, and discovery will close for that group on February 26, 2019. I will address a discovery schedule for all remaining cases in September 2018.

Statute of Limitations Discovery and Motion Practice. Biomet filed summary judgment motions in a test group of cases on the ground that the statute of limitations had elapsed in particular cases. Biomet argued that the applicable statute of limitations barred the plaintiffs' claims based on (1) a proposed bar date on which all plaintiffs were on constructive notice of potential claims and (2) facts specific to the plaintiffs. PSC II responded by arguing that (1) there was no set statute of limitations date that put all plaintiffs on notice and (2) facts specific to the individual plaintiffs' cases. I declined to accept Biomet's designated bar date to apply to all plaintiffs, but granted some of the summary judgment motions in whole or in part on other grounds. See [Pizzitolo](#); [Slater](#); [Brown](#); [Guynn](#); [Miles](#); [Fahy](#); [Cutter](#). A second round of statute of limitations summary judgment motions is before me at the time of this pretrial order.

Discovery going to the timeliness of suit only took place in selected cases, so some additional timeliness discovery might be needed in some cases.

Spoliation Discovery and Motion Practice. I also allowed discovery in a few selected cases with respect to a spoliation issue. I entered the first pretrial order on October 12, 2012. [[Doc. No. 3](#)]. Among other things, that order required parties to take reasonable steps to preserve documents and other records potentially relevant to these actions. On March 7, 2013, I entered an Explant Preservation Order, which governed the retrieval and analysis of M2a Magnum™ and M2a-38™ devices explanted from plaintiffs in this litigation, as well as any

tissue samples retrieved during any revision surgery. [[Doc. No. 279](#)]. I entered an Amended Explant Preservation Order on November 24, 2015. [[Doc. No. 3008](#)].

In September and November 2016, Biomet moved for summary judgment in some sample cases on the ground that certain plaintiffs had failed to preserve their M2a device, and this failure constituted either (1) a violation of the orders requiring preservation of explanted devices; (2) a demonstration of fault subject to the sanction of dismissal; or (3) spoliation. Because the explant surgeries had occurred before the suits were filed, so the plaintiffs didn't know of the duty to preserve until it was impossible to do so, I denied these motions. See [Spoliation Order](#).

I only addressed a handful of representative cases, and declined to consider state-specific spoliation rules. Given those limitations, a transferee court might see motion practice based on a state-law-based spoliation theory.

Three additional non-discovery matters should be addressed:

State of the Art Defense. Biomet moved for summary judgment in some cases on the ground that the M2a devices were state of the art and that plaintiffs had failed to demonstrate a feasible alternative design. I denied those motions without prejudice because the motions required the application of the law of many states, and I thought the transferor courts could decide those issues sooner and better. [[Doc. No. 3511](#)]. These issues might reappear after transfer.

Procedures on Remand or Transfer.

After receiving the Final Remand Order from the Panel, the clerk of this court will issue a letter to the transferor courts by email, setting out the process

for transferring the individual cases listed in the Final Remand Order. The letter and certified copy of the Final Remand Order will be sent to the transferor court's email address.

If a party believes that the docket sheet for a particular case being remanded is incorrect, a party to that case may, with notice to all other parties in the case, file with the transferor court a Designation Amending the Record. Upon receiving a Designation Amending the Record, the transferor court may make any needed changes to the docket. If the docket is revised to include additional documents, the parties should provide those documents to the transferor court.

If a plaintiff in a case identified on Exhibit A believes the case should not be remanded, he/she shall file a Notice of Objection to Pretrial Order and Suggestion of Remand within thirty days of this order, including in the Notice a basis for objection.

SO ORDERED.

ENTERED: _____

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