BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION	:	**MDL No. 2391**

DEFENDANTS BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET FAIR LAWN, LLC, BIOMET MANUFACTURING CORP., EBI LLC, AND MID ATLANTIC MEDICAL LLC'S RESPONSE TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS TO THE NORTHERN DISTRICT OF CALIFORNIA OR THE SOUTHERN DISTRICT OF NEW YORK PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

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PRELIMINARY STATEMENT

Defendants Biomet, Inc.; Biomet Orthopedics, LLC; Biomet Fair Lawn, LLC; Biomet Manufacturing Corp.; EBI LLC; and Mid Atlantic Medical LLC (collectively, "Biomet") hereby oppose the motion by Plaintiffs Leyda Ching and Diane Winningham ("Movants") to consolidate pretrial proceedings in the pending federal actions involving Biomet M^2a-Magnum hip replacement products (the "Magnum Actions" or "Actions").

These product-liability cases involving the alleged failure of a family of hip-implant devices will be dominated by plaintiff-specific discovery. They are in disparate procedural postures. Although the Panel has centralized actions involving other manufacturers' hip replacement products, the circumstances of these Actions are readily distinguishable. Indeed, it appears that Movants' counsel seek to use consolidation as a tool to *increase* the number of Magnum Actions for their own benefit, rather than to advance § 1407's proper ends.

If the Panel decides to consolidate over Biomet's objections, the Northern District of California is an inappropriate transferee district. The Southern District of New York or the District of New Jersey are far superior.

FACTUAL BACKGROUND

A. Hip Replacement Surgery

The hip is a ball-and-socket joint. The femoral head (the ball-like end of the upper femur) rotates within the acetabulum (socket). During hip replacement surgery, the femoral head and the bone and cartilage in the acetabulum are removed and replaced with implants made from materials including metal alloys, plastic, or ceramic. The implants are designed to create a new, smoothly functioning joint that replaces painful bone-on-bone contact.

For a variety of patient-specific reasons – including surgical error, idiosyncratic

biological reactions or hypersensitivity, an abnormally active lifestyle, overweight, and noncompliance with postoperative care instructions – the surgery may not succeed in the long term.[1] Because the results depend on so many patient-specific factors, manufacturers, as a general rule, do not warrant that their implants will last for a specified time period.[2] Nonetheless, joint replacement helps many patients return to work and activity, and can significantly improve quality of life.[3]

In the late 20th century, most hip replacements featured a metal stem and ball that moves against a polyethylene (plastic) acetabular cup. However, these devices had drawbacks, including relatively quick wear.[4] In the early 2000s, metal-on-metal ("MoM") devices, in which a metal ball moves against a metal cup, gained acceptance as an alternative that greatly reduced wear, while offering improved stability and greater range of motion.[5] *See generally* J.M. Cuckler, *The rationale for metal-on-metal total hip arthroplasty*, Clin. Orthop. Relat. Res., Dec. 2005; 441:132-6 (abstract at **Exhibit C**) (concluding that "long-term experiences with metal-on-metal . . . make this combination . . . the conservative choice for success").

As of the end of 2011, the United States Food and Drug Administration ("FDA") had cleared for marketing 186 submissions for MoM hip devices.[6] According to the FDA, only two MoM devices have been recalled (both voluntarily).[7] In 2008, Zimmer, Inc. recalled its Durom Acetabular Component due to higher-than-expected failure rates *for that specific device*, and in

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[1] *See* Biomet, Frequently Asked Questions – Knee and Hip Joint Replacement Technology (**Exhibit A**) at 2-3 (all Internet materials visited and saved July 18, 2012).
[2] *See id.* at 3.
[3] *See id.*
[4] *See* Biomet, M2a-Magnum Metal-on-Metal Hip (**Exhibit B**) at 1-2.
[5] *See id.*
[6] *See* FDA, Metal-on-Metal Hip Implant Systems (**Exhibit D**) at 1.
[7] *See* FDA, Recalls Specific to Metal-on-Metal Hip Implant Systems (**Exhibit E**) at 1.

2010, DePuy Orthopaedics voluntarily recalled its ASR XL Acetabular System because new data indicated higher-than-expected failure rates *for that specific device*.[8]

B. The Products At Issue

Biomet is based in Warsaw, Indiana.[9] Its subsidiaries manufacture a variety of orthopedic implants, including a line of MoM hip-replacement systems known as "M²a," which embraces a number of different designs.[10] The first M²a system, the M²a-Ringloc, was introduced in 1996; the M²a-Taper, the first M²a system introduced in the United States, became available in 2000.[11] The M²a-Magnum System, the family of products at issue here, was introduced in October 2004.[12] Other systems and products also exist in the M²a line.[13]

The M²a-Magnum System, in particular, was designed to provide maximum range of motion and stability through use of a larger femoral head (or "ball") for a given cup size than other MoM systems.[14] The M²a-Magnum System is comprised of various sizes of acetabular cups in two different basic models (Magnum and Magnum Tri-Spike); several styles of femoral head in a wide range of sizes, and various sizes of taper inserts, which join the head to a femoral stem.[15] The femoral stem is *not* part of the M²a-Magnum product family, although various

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[8] *See id.* at 1. In addition, Stryker recently recalled its metal Rejuvenate/ABG II modular neck stems due to "potential risks associated with fretting and corrosion at the modular neck junction." *See* FDA, Stryker Initiates Voluntary Product Recall of Modular-Neck Stems (**Exhibit F**) at 1. Stryker's modular neck stems were interchangeable parts intended to customize the femoral stem's shape to fit a patient's anatomy; they were not MoM devices per se. Biomet's M²a-Magnum System does not include modular neck stems.

[9] *See* Declaration of Kirk Bailey (**Exhibit G**) ¶¶ 2-3.

[10] *See* Biomet, M²a-Magnum Large Metal Articulation Brochure (**Exhibit H**) at 4-5.

[11] *See id.* at 4.

[12] *See id.* at 5; FDA, M²a-Magnum 510(k) Premarket Notification (**Exhibit I**) at 1.

[13] *See* Biomet, M²a-Magnum Large Metal Articulation Brochure (**Exhibit H**) at 4-5.

[14] *See* Biomet, M2a-Magnum Metal-on-Metal Hip (**Exhibit B**) at 1-2.

[15] *See* Biomet, M²a-Magnum Large Metal Articulation Surgical Technique Brochure (**Exhibit J**) at 11-14.

femoral stems are compatible with the M²a-Magnum System.[16] The M²a-Magnum acetabular cup component is also employed in *non*-MoM configurations. For example, in the Biomet Active Articulation Dual Mobility Hip System, an M²a-Magnum cup is used, but instead of directly touching the metal "ball," the cup interfaces with it via a plastic bearing.[17]

None of the elements in the Biomet M²a-Magnum System has been recalled. In fact, according to data from the National Joint Registries of Australia and England/Wales, hip replacement surgeries using M²a-Magnum devices have a "revision rate" (i.e., number of times per 100 observed component-years at which corrective surgery is required) lower to a statistically significant degree than that of MoM implants overall, and indeed, lower (although not to a statistically significant degree) from that of hip replacements generally.[18]

C. The Magnum Actions

Although Biomet has been marketing MoM products in the United States since 2000, and the M²a-Magnum System in particular since 2004, the first product-liability action involving the Magnum was not filed until July 22, 2008. (Likely not by coincidence, this was the very day Zimmer recalled its Durom cup.) Summary judgment was granted in Biomet's favor in 2009, and the decision was affirmed on appeal. *See Sumner v. Biomet, Inc.*, No. 7:08-CV-98, 2010 U.S. Dist. LEXIS 120952 (M.D. Ga. Nov. 16, 2010), *aff'd*, 434 F. App'x 834 (11th Cir. 2011).

In late 2011 and early 2012, after this Panel created MDLs relating to the Zimmer Durom

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[16] *See, e.g.*, Biomet, M²a-Magnum Large Metal Articulation Brochure (**Exhibit H**) at 6-7.

[17] *See* Active Articulation E1 Dual Mobility Hip System Design Rationale (**Exhibit K**) at 2-3.

[18] *See* Letter to Surgeons from Robert E. Durgin, Senior Vice President, Quality/Regulatory/Clinical Affairs, Biomet, Inc. (**Exhibit L**) at 1-3. The revision rate for the M²a-Magnum was 0.72 per 100 observed component years. By comparison, the revision rate for all total hip replacements was 0.74 per 100 observed component years in both the Australian and England/Wales data, and the revision rate for all MoM hip replacements was 1.23 per 100 observed component-years according to the Australian data and 1.73 per 100 observed component-years according to the England/Wales data. *See id.*

cup and two DePuy Orthopaedics MoM hip devices, the plaintiffs' bar set its sights on Biomet. The next-filed Magnum Action – since settled – was commenced in August 2011. *See Eriksson v. Biomet, Inc.*, No. 5:11-CV-00679-XR (W.D. Tex.). Other Actions were filed in late 2011 and the first weeks of 2012; some have already settled or been dismissed.[19]

In February 2012, the Panel centralized actions involving Wright Medical Technology's CONSERVE MoM hip implants over Wright's objections. *See In re Wright Med. Tech. Inc.*, MDL No. 2329, 2012 U.S. Dist. LEXIS 16410 (J.P.M.L. Feb. 8, 2012). Emboldened, the plaintiffs' bar filed another round of complaints against Biomet. Movants' counsel, in particular, sought to tee up an MDL with multiple filings in the Northern District of California, even though none of those cases has even a remote connection to that district.

As of today, there are 23 properly commenced Actions involving the M^{2}a-Magnum System yet to reach resolution. Biomet is aware of another 17 that have been filed but not served. Of all the active Magnum Actions, *just five firms*, all with leadership roles in existing MoM hip-device MDLs, have filed over half the total cases (21 out of 40), with Movants' counsel alone accounting for almost 20% of the total – more than any other firm.

STANDARD OF REVIEW

Section 1407 permits consolidation of civil actions pending in different districts when (1) those actions "involv[e] one or more common questions of fact," (2) consolidation would serve "the convenience of [the] parties and witnesses," and (3) consolidation would "promote the just and efficient conduct of [the] actions." The burden of demonstrating that transfer will

[19] *McCarroll v. Biomet Orthopedics, LLC*, No. 1:12-cv-0177 (S.D. Ind.) (dismissed May 2, 2012); *Millman v. Biomet*, No. 1:12-cv-2198 (N.D. Ill.) (dismissed Mar. 27, 2012); *Rehbein v. Biomet Orthopedics, LLC*, No. 12-cv-1247 (D. Md.) (dismissed June 28, 2012); *Williams v. Biomet Orthopedics, LLC*, No. 11-cv-2444 (E.D. La.) (dismissed Mar. 7, 2012). Actions filed in state courts relating to the M^{2}a-Magnum have also terminated. *See, e.g.*, *Strohmeier v. Biomet Orthopedics, LLC*, No. 12SL-CC00114 (Mo. Circuit Court) (dismissed June 26, 2012).

further the purposes of Section 1407 is on the moving party. *See In re G.D. Searle & Co. "Copper 7" IUD Prods. Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980).

Even when one or more common questions of fact exist, the movant must still show that "the inherent disadvantages of Section 1407 transfer" do not "outweigh the benefits [thereof]." *Id.* As a judge of this Panel put it:

> The statutory objectives are not necessarily served by requiring joint pretrial whenever some – even many – questions of fact are common to a large number of cases. . . .
>
> There are a number of inherent inconveniences in transfers for coordinated or consolidated pretrial. Some plaintiffs are temporarily deprived of their choices of forum and some defendants may be forced to litigate in districts where they could not have been sued. Considerable time and trouble are involved in the sheer mechanics of transferring and remanding. After transfer, the process of segregating the pretrial matters which should be remanded for handling by the transferor courts may be time-consuming as well as subject to reasonable disagreement.

In re "East of the Rockies" Concrete Pipe Antitrust Cases, 302 F. Supp. 244, 255 (J.P.M.L. 1969) (Weigel, J., concurring).

ARGUMENT

I. The Magnum Actions Will Require Heavily Individualized Discovery

This Panel has long declined to centralize cases involving common issues when it appeared that plaintiff-specific issues, not common ones, would constitute the bulk of discovery. *See, e.g.*, *In re Wireless Lifestyle Inc.*, MDL No. 2322, 2012 U.S. Dist. LEXIS 12826, at *2 (J.P.M.L. Feb. 3, 2012) ("While there does appear to be some overlap among the actions, the differences among them appear to predominate, and thus centralization would likely hinder the

just and efficient conduct of the litigation, considered as a whole.").[20]

Product-liability cases involving medical devices implanted in the human body are the archetypal category of case where individualized fact issues predominate. As the Sixth Circuit observed, "in medical device products liability litigation . . . the factual and legal issues often *do* differ dramatically from individual to individual because there is no common cause of injury." *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1084 (6th Cir. 1996). The court elaborated:

> Plaintiffs' claims of strict liability, fraudulent misrepresentation . . . , negligent testing, design and manufacture, and failure to warn will differ depending upon the model [of prosthesis] and the year it was issued.
>
> Proofs as to strict liability, negligence, failure to warn, breach of express and implied warranties will also vary from plaintiff to plaintiff because complications with an AMS device may be due to a variety of factors, including surgical error, improper use of the device, anatomical incompatibility, infection, device malfunction, or psychological problems. Furthermore, each plaintiff's urologist would also be required to testify to determine what oral and written statements were made to the physician, and what he in turn told the patient, as well as to issues of reliance, causation and damages.

Id. at 1081; *see also In re N.D. Cal. Dalkon Shield IUD Prods. Liab. Litig.*, 693 F.2d 847, 853-54 (9th Cir. 1982) (noting that in medical-device actions, "individual issues may outnumber

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[20] *Accord In re Ocala Funding, LLC, Com. Litig.*, MDL No. 2362, 2012 U.S. Dist. LEXIS 79495, at *2 (J.P.M.L. June 8, 2012); *In re N.E. Contaminated Beef Prods. Liab. Litig.*, MDL No. 2346, 2012 U.S. Dist. LEXIS 55470, at *1-*2 (J.P.M.L. Apr. 17, 2012); *In re Abbott Labs., Inc. Similac Prods. Liab. Litig.*, 763 F. Supp. 2d 1376, 1376-77 (J.P.M.L. 2011); *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010); *In re Blair Corp. Chenille Robe Prods. Liab. Litig.*, 703 F. Supp. 2d 1379, 1380 (J.P.M.L. 2010); *In re Table Saw Prods. Liab. Litig.*, 641 F. Supp. 2d 1384, 1384 (J.P.M.L. 2009); *In re Victoria's Secret Undergarments/Intimate Apparel Prods. Liab. Litig.*, 626 F. Supp. 2d 1349, 1350 (J.P.M.L. 2009); *In re Shoulder Pain Pump – Chondrolysis Prods. Liab. Litig.*, 571 F. Supp. 2d 1367, 1368 (J.P.M.L. 2008); *In re Penile Implants Prods. Liab. Litig.*, Docket No. 1020, 1994 U.S. Dist. LEXIS 21505, at *2 (J.P.M.L. Sept. 30, 1994); *In re Asbestos Sch. Prods. Liab. Litig.*, 606 F. Supp. 713, 714 (J.P.M.L. 1985); *In re Eli Lilly & Co. "Oraflex" Prods. Liab. Litig.*, 578 F. Supp. 422, 423 (J.P.M.L. 1984); *In re Rely Tampon Prods. Liab. Litig.*, 533 F. Supp. 1346, 1347 (J.P.M.L. 1982); *In re Luminex Int'l, Inc. Prods. Liab. Litig.*, 434 F. Supp. 668, 669-70 (J.P.M.L. 1977); *In re Asbestos & Asbestos Insulation Material Prods. Liab. Litig.*, 431 F. Supp. 906, 909-10 (J.P.M.L. 1977).

common issues" and that common facts are "obscured by individual case histories").

This Panel has sounded the same theme over the years in refusing to consolidate product-liability actions. *See, e.g.*, *Contaminated Beef*, 2012 U.S. Dist. LEXIS 55470, at *1-*2 ("[i]ndividualized issues of causation concerning each plaintiff's injuries appear to predominate"); *Similac*, 763 F. Supp. 2d at 1376-77 ("discovery and motion practice [in each action] may be expected to concern (1) the particular product each plaintiff purchased, (2) any injuries that consumption of the product caused, (3) whether [that unit of product was defective], and/or (4) what advertising or other representations were made to each particular plaintiff"); *Ambulatory Pain Pump*, 709 F. Supp. 2d at 1377 ("individual issues of causation and liability appear to predominate," as product "come[s] in different sizes and designs" and "[p]laintiffs have different medical histories"); *Chenille Robe*, 703 F. Supp. 2d at 1380 ("the litigation will focus to a large extent on individual issues of fact concerning the circumstances of each consumer's injuries"); *Asbestos Insulation*, 431 F. Supp. at 909-10 (accepting argument that "causation is an individual issue," requiring individualized discovery regarding each plaintiff's "physical characteristics" and medical history).[21]

The same is true here. For starters, Biomet's MoM hip-replacement components "come in different sizes and designs." *Ambulatory Pain Pump*, 709 F. Supp. 2d at 1377. Biomet manufactures not just one MoM hip-implant product, but an entire line of MoM products known generally as M^{2}a, each of which has different design features. Some plaintiffs are vague as to

[21] The Panel has declined to centralize product-liability litigations comparable to this one in size – and even much larger – when it found plaintiff-specific discovery would predominate. *See, e.g.*, *Ambulatory Pain Pump*, 709 F. Supp. 2d at 1377 (102 actions and "more than 70 additional related actions"); *Asbestos Insulation*, 431 F. Supp. at 909-10 (103 actions); *Rely Tampon*, 533 F. Supp. at 1347 (92 actions); *Table Saw*, 641 F. Supp. 2d at 1384 (42 actions and "nine additional related actions"); *"Oraflex"*, 578 F. Supp. at 423 (27 actions); *Penile Implants*, 1994 U.S. Dist. LEXIS 21505, at *2 (2 actions and "24 other related actions").

which product in the M²a family they received, so it is not evident that they received an M²a-Magnum product.[22] Even among the remaining plaintiffs, differences predominate. Within the Magnum family, surgeons may choose from two different styles of acetabular cup in a variety of sizes; different styles and sizes of femoral head ("ball"), and different styles and sizes of taper insert. Performance considerations depend on the particular combination of components that was implanted. Moreover, M²a-Magnum products are used with femoral stem components that *do not* belong to the M²a family, and which may be manufactured by other companies.[23] Furthermore, the M²a-Magnum cup component may also be used in *non*-MoM configurations.

As a result, in each Action, much discovery will be spent investigating the particular combination of Biomet and non-Biomet components implanted in each individual plaintiff and which particular component or combination of components – if any – caused the patient's injury.[24] It is likely that different plaintiffs will advance different (and possibly incompatible) theories of defectiveness, depending on the particular combination of components they received.

Discovery in each Action will also delve deeply into the individual plaintiffs' "different medical histories," *Ambulatory Pain Pump*, 709 F. Supp. 2d at 1377, which are crucial to the determination of defect and causation. As described above, hip replacement surgery may fail for various reasons having nothing to do with a design or manufacturing defect in the patient's hip

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[22] For example, the plaintiffs in *Hales* and *Fields* received an unspecified "M2a Hip System." *See Hales* Compl. pmbl., ¶¶ 15-38; *Fields* Compl. pmbl., ¶¶ 15-38. The *Fields* complaint does refer to an *advertisement* for the "M2a-Magnum™ Large Metal Articulation System," but does not claim that the plaintiff *received* that particular product. *Id.* ¶ 24.

[23] For example, the plaintiffs in *Gardner* and *Turner* received a Bi-Metric stem (manufactured by Biomet); the plaintiffs in *Ching*, *Glancey*, *Harris*, *Lane*, *Modrey*, *Morrison*, and *Thomas* received a Taperloc stem (manufactured by Biomet); the plaintiff in *Winningham* received an Alliance X-Series stem (manufactured by Biomet), and the plaintiff in *Napier* received a M/L Taper stem *manufactured by Zimmer*. *See, e.g.*, *Ching* Compl. ¶ 1 n.1; *Glancey* Compl. ¶ 1 n.1; *Morrison* Compl. ¶ 1 n.1; *Thomas* Compl. ¶ 1 n.1; *Winningham* Compl. ¶ 1 n.1; *Napier* Compl. ¶ 1 n.1.

[24] In fact, in *Gardner*, the plaintiff alleges that he received a defective Biomet device in one hip *and* a defective DePuy device in the other. *See Gardner* Compl. ¶ 1.

implant, including surgical error, overweight, activity level, idiosyncratic biological reactions or hypersensitivity, failure to follow instructions, and other patient-specific factors. As a result, individual doctors, surgeons, and other medical providers will be heavily involved in discovery.

Furthermore, because many (if not all) of the Actions allege fraud, misrepresentation, breach of warranty, and like causes of action, discovery will probe the inherently individualized topic of "what advertising or other representations were made to each particular plaintiff" (or her physician). *Similac*, 763 F. Supp. 2d at 1376-77. Similarly, because the Actions allege failure to warn and related causes of action, discovery will focus on what warnings each individual plaintiff (or her physician) received.

In sum, the Magnum Actions involve a host of plaintiff-specific considerations, and discovery in each Action will focus predominantly on those individualized topics. "[T]hus[,] centralization would likely hinder the just and efficient conduct of the litigation, considered as a whole." *Wireless Lifestyle*, 2012 U.S. Dist. LEXIS 12826, at *2.

To the extent the Actions *may* involve overlapping discovery – e.g., design-related documents in Biomet's possession – such documents can be shared among the various plaintiffs without incurring the inefficiencies of consolidation. *See In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig.*, 446 F. Supp. 242, 244 (J.P.M.L. 1978). Biomet will cooperate with plaintiffs' counsel in these efforts. Voluntary cooperation is especially suitable here, because (as discussed below) over half the Actions were filed by a mere five law firms with experience cooperating in existing MoM litigation, and Biomet is represented by the undersigned counsel (with the assistance of local counsel) in every Action.[25]

[25] *See, e.g.*, *In re Boehringer Ingelheim Pharms., Inc.*, 763 F. Supp. 2d 1377, 1378-79 (J.P.M.L. 2011) ("Because plaintiffs in three actions share counsel and [defendant] is represented by common counsel, alternatives to formal centralization, such as voluntary cooperation . . . , appear

II. The Magnum Actions Are At Different Procedural Postures And Are Expeditiously Proceeding Toward Resolution

This Panel has declined to consolidate actions involving common questions of fact when "review of the entire record . . . persuaded [it]" that the actions were "expeditiously [proceeding toward] trial or disposition by other means." *"Copper 7,"* 483 F. Supp. at 1345; *see also In re Telecomm. Providers' Fiber Optic Cable Installation Litig. (No. III)*, 802 F. Supp. 2d 1364, 1365 (J.P.M.L. 2011) (denying consolidation where it appeared "the cases [were] likely on the path to resolution"). Biomet's track record of resolving Magnum Actions "expeditiously" weighs against consolidation. The first lawsuit alleging that the Magnum's MoM design was defective was filed in July 2008; it terminated in summary judgment for Biomet in 2009, and the Eleventh Circuit affirmed in 2011. At least five other Actions have already settled or been dismissed.

As for the still-pending Actions, "[t]he presence of procedural disparities among constituent cases is another factor that can weigh against centralization." *In re CVS Caremark Corp. Wage & Hour Empl't Practices Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010) (denying consolidation where "[a] significant amount of discovery ha[d] already taken place" in one action, whereas "little, if any, pretrial activity ha[d] occurred" in others); *see also Ocala Funding*, 2012 U.S. Dist. LEXIS 79495, at *2 (denying consolidation where "[some] actions [were] at an advanced stage of discovery, whereas discovery ha[d] not yet begun" in others). Among the still-pending Actions, while some are newly filed, others are well-advanced in the discovery process. For example, in *St. Cyr v. Biomet Orthopedics, Inc.*, No. 4:12-cv-00032 (N.D. Tex.), a joint discovery plan has been filed, initial disclosures have been exchanged, requests for production and interrogatories have been propounded and answered by both parties,

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viable."); *In re Rite Aid Corp. Wage & Hour Empl't Practices Litig.*, 655 F. Supp. 2d 1376, 1377 (J.P.M.L. 2009) ("Cooperation [rather than centralization] is particularly appropriate here, where plaintiffs in four of the six actions encompassed by the motion share counsel.").

and preservation and scheduling orders have been entered. In *Faber v. Biomet, Inc.*, No. 12-cv-783 (E.D.N.Y.), a joint protective order has been entered, initial disclosures have been exchanged, requests for production and interrogatories have been propounded and answered by both parties, and the plaintiff's deposition is scheduled for July 25, 2012.[26]

Other Actions have important motions pending. *See, e.g.*, *Chadwick v. Biomet Orthopedics, LLC*, No. 2:12-cv-03136 (D.N.J.) (motion to dismiss); *Gardner v. Biomet, Inc.*, No. 3:12-cv-00130 (S.D. Tex.) (motion to remand and motion to sever); *Abourjilie v. Biomet, Inc.*, No. 2:12-cv-04073 (D.N.J.) (motion to dismiss); *Harris v. Biomet Orthopaedics [sic], LLC*, No. 12-cv-00575 (D. Md.) (motion to remand and motion to dismiss); *Winningham v. Biomet Orthopedics, LLC*, No. 12-CV-0503 (N.D. Cal.) (motion for change of venue). Besides creating further procedural disparities, this raises comity concerns. This Panel has noted its "reluctan[ce] to transfer any action that has an important motion under submission with a court," *In re L. E. Lay & Co. Antitrust Litig.*, 391 F. Supp. 1054, 1056 (J.P.M.L. 1975), and its preference to "permit . . . courts . . . to reach timely decisions on particular issues without abrupt, disconcerting, untimely or inappropriate orders of transfer by the Panel." *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 496 (J.P.M.L. 1968); *see also Telecomm. Providers' Fiber Optic Cable Installation Litig.*, 199 F. Supp. 2d 1377, 1378 (J.P.M.L. 2002) (denying centralization where "a substantial number of . . . dismissal, remand, and other motions . . . [were] pending").

III. This Litigation Is Distinguishable From Other Metal-on-Metal Hip Litigation

Movants note that the Panel has centralized litigation involving several MoM hip devices. *See In re Zimmer Durom Hip Cups Prods. Liab. Litig.*, 717 F. Supp. 2d 1376 (J.P.M.L. 2010) (consolidating 45 actions and 9 related actions); *In re DePuy Orthopaedics Inc., ASR Hip*

[26] In *Turner v. Biomet Orthopedics, LLC*, No. 2:11-cv-02443 (E.D. La.), Biomet has obtained the plaintiff's medical records and intends to take her deposition in late July 2012.

Implant Prods. Liab. Litig., 753 F. Supp. 2d 1378 (J.P.M.L. 2010) (consolidating 8 actions and 105 related actions); *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F. Supp. 2d 1358 (J.P.M.L. 2011) (consolidating 3 actions and 54 related actions); *In re Wright Med. Tech., Inc.*, MDL No. 2329, 2012 U.S. Dist. LEXIS 16410 (J.P.M.L. Feb. 8, 2012) (consolidating 5 actions and 17 related actions).[27]

As an initial matter, in the two *DePuy* proceedings, all (or substantially all) parties, including DePuy, consented to centralization. Biomet's opposition to centralization distinguishes this proceeding. *See In re Discover Card Payment Protection Plan Mktg. & Sales Practices Litig.*, 764 F. Supp. 2d 1341, 1342 (J.P.M.L. 2011) (granting centralization and noting that defendant's consent "add[ed] an element of agreement . . . that was lacking" in similar proceeding where centralization was denied).

In addition, on their face, the Magnum Actions, which involve a broad array of components that share the "Magnum" name, are not comparable to the *Durom* actions, which involve *a single* component – an acetabular cup. *See Zimmer*, 717 F. Supp. 2d at 1378 (finding it "significant" that the actions involved just "a single medical device – the Durom Cup").

Procedural circumstances also distinguish this set of Actions. Biomet's M^{2}a line has been available in the United States for twelve years, and the M^{2}a-Magnum System, in particular, for eight.[28] As a result, the M^{2}a-Magnum litigation, as a whole, is more mature and procedurally diverse than the litigation in prior MoM proceedings. To reiterate: (1) the first Magnum Action

[27] However, the Panel has also *declined* to centralize product-liability actions involving hip prostheses. *See In re Zimmer, Inc. Centralign Hip Prosthesis Prods. Liab. Litig. (No. II)*, 366 F. Supp. 2d 1384, 1385 (J.P.M.L. 2005) (declining to consolidate 22 actions).

[28] By contrast, the MoM products at issue in *Zimmer* and *Wright*, where the defendants contested centralization, had been on the market for only four years and just over two years, respectively, when centralization was granted. *See* **Exhibit M** (FDA 510(k) clearance of Durom acetabular component dated 3/16/2006); **Exhibit N** (FDA premarket approval of Conserve Plus Total Resurfacing Hip System dated 11/18/09).

was filed *over four years ago* and the judgment in Biomet's favor has been affirmed on appeal; (2) other early-filed Magnum Actions have also reached resolution; (3) Biomet has established a track record of resolving Magnum Actions swiftly and effectively; (4) some of the remaining Magnum Actions are at a procedurally advanced stage; and (5) a variety of important motions are pending. None of these considerations was present in the Panel's prior MoM decisions.

More generally, it would be unfair and inappropriate to treat the outcome of this proceeding as predetermined by prior proceedings involving MoM devices. At a recent FDA panel on MoM devices, an expert emphasized: "there is a tendency to lump all metal-on-metal bearings together, but there is a problem with that because it is a very heterogenous group of devices . . . ."[29] As another expert testified, "Not all of these implants are created equal."[30] Because of its unique design, the M^{2}a-Magnum System has a statistically significantly lower revision rate than MoM hip replacements overall, and even has a lower revision rate (though not to a statistically significant degree) than hip replacements generally.[31] Furthermore, a published study found that "metal ion release differs greatly between various [MoM] hip arthroplasty implants" and that the M^{2}a-Magnum had a lower rate of release than devices from manufacturers including DePuy and Zimmer (and the lowest rate of any device in the study).[32]

In conclusion, Movants' motion should be decided on its own facts, and the existence of other MDLs involving MoM hip products should carry no weight.

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[29] Testimony of Joshua J. Jacobs, MD, Prof. and Chairman, Dep't of Orthopedic Surgery, Rush Univ. Med. Ctr., and 1st V.P., Am. Acad. of Orthopaedic Surgeons, http://fda.yorkcast.com/webcast/Viewer/?peid=901726ab91944b158ac705e48664921c1d at 04:35:46.

[30] Testimony of Peter J. Brooks, MD, FRCS, Dep't of Orthopaedic Surgery, Cleveland Clinic, http://fda.yorkcast.com/webcast/Viewer/?peid=901726ab91944b158ac705e48664921c1d at 01:54:50.

[31] *See supra* note 18 and accompanying text.

[32] *See* M. Lavigne et al., *Comparison of whole-blood metal ion levels in four types of metal-on-metal large-diameter femoral head total hip arthroplasty: the potential influence of the adapter sleeve*, J. Bone Joint Surg. Am. May 2011; 93 Suppl. 2:128-36 (abstract at **Exhibit O**).

IV. Movants Appear To Seek Consolidation For Improper Purposes

As the Chair of this Panel has noted, "[t]he Panel is particularly alert . . . to parties who may venture to use the MDL process for some substantive or procedural advantage, and it will act to avert or deflect attempts . . . to 'game' the system."[33] In other words, "where a Section 1407 motion appears intended to further the interests of particular counsel more than those of the statute, we would certainly find less favor with it." *CVS Caremark*, 684 F. Supp. 2d at 1379.[34]

It appears that Movants' counsel (Seeger Salvas) have been angling to create and control an MDL from the very beginning, likely in collaboration with Kaiser & Gornick LLP and Panish, Shea, & Boyle, LLP, the second- and third-most-prolific firms in this matter.[35] Between January 31, 2012 and today, counsel at those three firms – all of whom sit on the plaintiffs' leadership committees in the *DePuy* MDLs[36] – have filed 15 Magnum Actions in the Northern District of California,[37] attempting to create the illusion of a "natural center of gravity" there (Movants' Mem. at 9); however, as described further below, *none of those actions has anything to do with that district*, and litigation in that district would greatly inconvenience their own

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[33] Hon. John G. Heyburn II, *Proceedings of the Tulane Law Review Symposium: The Problem of Multidistrict Litigation: A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2241 (2008) (**Exhibit P**).

[34] *See also In re Louisiana-Pacific Corp.*, MDL No. 2366, 2012 U.S. Dist. LEXIS 82953, at *3-*4 (J.P.M.L. June 11, 2012) (denying consolidation when "circumstances raise[d] the concern that the request to centralize . . . [was] based on considerations that are not entirely consistent with the purposes of Section 1407"); *In re Truck Accident Near Alamogordo*, 387 F. Supp. 732, 734 (J.P.M.L. 1975) (denying consolidation where "it appear[ed] that . . . plaintiffs' ulterior motive for seeking transfer amount[ed] to an attempted misuse of the statute").

[35] *See* **Exhibit Y** (Chart of Law Firms with Most Cases).

[36] *See* Case Management Order #3, *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*. No. 3:11-md-02244-K (N.D. Tex. Jan. 9, 2012) (**Exhibit T**); Case Management Order #3, *In re DePuy Orthopaedics, Inc. ASR Hip Implant Prods. Liab. Litig.*, No. 1:10-md-02197-DAK (N.D. Ohio Jan. 26, 2011) (**Exhibit U**). In addition to the three firms mentioned above, counsel from the other two most prolific firms in this matter, Weitz & Luxenberg and Anapol Schwartz, also serve on the leadership committees in the two *DePuy* MDLs. *See id.*

[37] *See* **Exhibit Y** (Chart of Law Firms with Most Cases).

clients, who hail from as far away as Alaska, Florida, Georgia, Virginia, and Pennsylvania. Gamesmanship is the only logical explanation.

Counsel's motive is no secret. While consolidation is beneficial in appropriate cases, it is well-known that the plaintiffs' bar uses centralization to gin up litigation that would not otherwise (and should not) exist. As a noted drug-and-device-law defense attorney put it:

> Apart from procedural issues, the creation of an MDL proceeding may have a substantive effect on the coordinated litigation. . . . [A]n MDL proceeding takes on a life of its own. Once an MDL is in place, plaintiffs will inevitably file many new complaints. In an MDL, as in the Field of Dreams: "If you build it, they will come."
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> * * *
>
> A second disadvantage of creating a coordinated proceeding is purely one of perception. The perception, however, may influence reality and can cost a client years of litigation and millions of dollars. . . . [W]hen all federal cases are coordinated before a single judge, the judge is likely to perceive a problem with the defendant's product. After all, where there's smoke, there's fire; where there's a mass, there's a tort.
>
> Unfortunately, . . .[t]he [defendant] can no longer hope to prevail simply because it has done nothing wrong. Rather, the MDL process serves only as a mechanism for reaching a settlement.[38]

Even plaintiffs'-side counsel agree: as the "former managing partner of a national plaintiffs' mass tort and class action law firm" wrote, "the publicity of an MDL may attract other lawsuits," and "the more lawsuits the defendant faces, . . . the more pressure it will feel to settle."[39]

Movants' counsel, Kenneth M. Seeger of Seeger Salvas, knows this full well. Sitting on the plaintiffs' executive committee in the *DePuy Pinnacle* MDL,[40] Mr. Seeger watched that

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[38] Mark Herrmann, *To MDL or Not to MDL? A Defense Perspective*, 24 Litigation 43, 45 (Summer 1998) (**Exhibit Q**) (citation omitted).

[39] Ed Konieczny, *Multidistrict Litigation*, *Trust the Leaders*, Issue 21 (Spring 2008) (**Exhibit R**) at 6; *see also* John J. Sullivan, Drug and Device Law, June 26, 2012 (**Exhibit S**) at 2 ("[T]he very existence of a consolidated proceeding encourages more cases. . . .").

[40] *See supra* note 36.

litigation expand from 3 actions (and 54 related actions) at consolidation to *1,472* today. And sitting on a plaintiffs' committee in the *DePuy ASR* MDL,[41] Mr. Seeger saw that litigation mushroom from 8 actions (and 105 related actions) at consolidation to *4,451* now.

Given that (1) only *one* Magnum Action (which ended in judgment for Biomet) was filed before the Panel began consolidating MoM cases, notwithstanding that the M^{2}a-Magnum had been on the market substantially longer than other MoM devices; (2) the M^{2}a-Magnum has not been recalled; and (3) the M^{2}a-Magnum's failure rate and metal-ion-release rate are substantially lower than those of other MoM devices, it is *not* true that "the number of [Magnum Actions] will grow rapidly and that hundreds of [Magnum Actions] will be filed" (Movants' Mem. at 2) – at least, not unless the Panel makes this a self-fulfilling prophecy by creating an MDL.[42] When counsel states that the M^{2}a-Magnum "is the next metal-on-metal hip implant that will benefit from . . . an MDL" (Movants' Mem. at 2), the "benefit" counsel describes would go not to the court system, but to a cadre of highly specialized plaintiffs' attorneys.

V. If The Panel Orders Consolidation, The Northern District of California Is Not An Appropriate Transferee Forum

If the Panel orders consolidation over Biomet's objections, Biomet disputes the appropriateness of the Northern District of California as a transferee forum and proposes the Southern District of New York or the District of New Jersey instead.

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[41] *See id.*

[42] Movants claim that "the FDA has received more than 450 adverse event reports" related to the M^{2}a-Magnum. (Movants' Mem. at 2.) This statistic, if true, is meaningless. Anecdotal reports of this sort lack evidentiary value, as they "do not investigate or explain the mechanism of causation." *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995). The FDA warns that "there is no certainty that the reported [adverse] event . . . was actually due to the product" and that such reporting can be "influence[d]" by "publicity." FDA, Adverse Event Reporting System (AERS) (**Exhibit V**) at 1; *see also DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992), *aff'd*, 6 F.3d 778 (3d Cir. 1993) (noting that adverse event reports "are affected by . . . mass media attention, and are subject to other distortions"); *Hagaman v. Merrell Dow Pharms.*, No. 84-2202-S, 1987 U.S. Dist. LEXIS 6124, at *8 (D. Kan. June 26, 1987) (noting that many reports are "prompted by contemplated or existing litigation").

For starters, although Movants' counsel has created an illusion that the Northern District of California is a "natural center of gravity" in these cases (Movants' Mem. at 9), in reality, that district *has nothing to do with* this matter. Of the pending Magnum Actions, at most *one* (*Jacobs*) may involve a plaintiff from that district.[43] None of the defendants in any Action is from California. None of the research and development of the M²a-Magnum took place in California, and no part of it is manufactured in California.[44] And despite Movants' bald claim that "a large population of M2a Magnum patients live in the Northern District of California" (Movants' Mem. at 9), Northern California has represented only 1.42% of nationwide sales of M²a-Magnum cups (in MoM configurations) in fiscal years 2010-12 (notwithstanding its enormous population).[45] By contrast, New York has represented 6.24% of nationwide sales during this time period (with the majority of those sales in the New York City/Long Island area), and New Jersey has represented 3.52%.[46]

In addition, the Northern District of California is extremely inconvenient for Biomet, the only party all of the Actions have in common. From Biomet's headquarters in Warsaw, Indiana, the only airports within 70 miles are at South Bend and Ft. Wayne, Indiana. According to kayak.com, a leading flight aggregator, the shortest trip from either of those airports to San Francisco is almost 6.5 hours, and the cheapest ticket (for a round trip one month from the date of this writing) is $549. By contrast, flights to New York City airports are as short as 3.5 hours, and fares are as low as $332. Accordingly, the Southern District of New York or the District of

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[43] *See* **Exhibit W** (Chart of Plaintiffs' Home States). The plaintiffs in *Ching* and *Beguin* are also from California, but are from San Diego (in the Southern District) and Shasta County (in the Eastern District), respectively. *See id.*; *Ching* Compl. ¶ 2; *Beguin* Complaint pmbl.

[44] *See* Declaration of Kirk Bailey (**Exhibit G**) ¶¶ 6-8.

[45] *See* Declaration of Matthew Abernethy (**Exhibit X**) ¶ 8.

[46] *See id.* ¶¶ 6-7.

New Jersey (especially its Newark division) are far superior. Furthermore, Biomet Fair Lawn, LP and EBI LLC – two Biomet subsidiaries named in some of the Actions – are based in Fair Lawn, New Jersey and Parsippany, New Jersey, respectively; both are just outside of New York City. And Biomet's national counsel, Patterson Belknap Webb & Tyler LLP, which represents the Biomet defendants in all of the Actions, is located in New York City as well.

Nor is California convenient for the majority of plaintiffs. While three plaintiffs do reside in California (at least two of them outside the Northern District), the remaining plaintiffs reside in Alaska (1), Arizona (1), Arkansas (2), Florida (2), Georgia (1), Idaho (1), Kansas (1), Louisiana (3), Maryland (2), Michigan (1), New Jersey (2), New York (2), North Carolina (1), Ohio (3), Oregon (1), Pennsylvania (4), South Carolina (1), Texas (3), Virginia (3), Washington (1), and Wyoming (1).[47] In other words, just nine plaintiffs live in the western states, while 13 live in the central states, and *18* live in the eastern states. Accordingly, either the Southern District of New York or the District of New Jersey would be more convenient to more plaintiffs than the Northern District of California.

Finally, five Actions are currently pending in New Jersey (*Chadwick*, *Hanson*, *Abourjilie*, *Wade*, and *Lane*), and two in New York (*Konowal* and *Faber*), such that there is already a substantial concentration of litigation in the New York-New Jersey area.[48]

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[47] *See* **Exhibit W** (Chart of Plaintiffs' Home States).

[48] In choosing a transferee district, the Panel sometimes considers where the first-filed and/or most procedurally advanced action is pending. *See, e.g.*, *In re Bank of Am. Credit Protection Mktg. & Sales Practices Litig.*, 804 F. Supp. 2d 1372, 1373 (J.P.M.L. 2011). The Northern District of California contains neither the earliest-filed Magnum Action still pending, *Harris* (D. Md.), nor the most procedurally advanced Actions, *Faber* (E.D.N.Y.) and *St. Cyr* (N.D. Tex.). And while those criteria do not point directly toward Biomet's preferred districts, the courthouse where *Faber* is pending is just two miles from the Southern District of New York's courthouse and 13 miles from the District of New Jersey's Newark courthouse.

CONCLUSION

For the reasons outlined above, the Panel should deny Movants' motion to consolidate the Magnum Actions. In the alternative, the Actions should be consolidated in the Southern District of New York or the District of New Jersey.

Dated: July 19, 2012

Respectfully submitted,

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