BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. _____ **BRIEF IN SUPPORT OF MOTION OF PLAINTIFFS FOR TRANSFER OF ACTIONS TO THE NORTHERN DISTRICT OF CALIFORNIA OR THE SOURTHERN DISTRICT OF NEW YORK PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS** **ORAL ARGUMENT REQUESTED**

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs Leyda Ching and Diane Winningham ("Moving Parties") bring this motion to transfer all cases that arise out of the Biomet M2a Magnum hip implant ("M2a Magnum") to the Northern District of California or the Southern District of New York.

The M2a Magnum is what is referred to as a "metal-on-metal" implant. Traditional hip implants consist of a metal ball rotating within a polyethylene plastic cup. On the other hand, a metal-on-metal hip implant consists of a metal ball rotating within a metal cup. The failure of "metal-on-metal" hip implants has been the subject of significant media attention and litigation over the last two years.

The Panel already has granted motions to transfer cases arising out of four similar metal-on-metal hips. In June 2010, the Panel transferred MDL 2158, *In re: Zimmer Durom Hip Cup Products Liability Litigation* to the Honorable Susan D. Wigenton in the

District of New Jersey. Six months later, in December 2010, the Panel transferred MDL 2197, *In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation* to the Honorable David A. Katz in the Northern District of Ohio. Following the DePuy ASR consolidation, in May 2011, the Panel transferred *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation* to the Honorable James E. Kinkeade in the Northern District of Texas. Most recently, in March 2012, the Panel transferred MDL 2329, *In re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation* to Judge William S. Duffey, Jr. in the Northern District of Georgia.

The Biomet M2a Magnum is the next metal-on-metal hip implant that will benefit from consolidated pretrial proceedings though an MDL. As of May 31, 2012, the FDA has received more than 450 adverse event reports related to the M2a Magnum hip implant. As these hundreds of injured patients begin to file lawsuits, the federal courts are starting to see an increasing number of new M2a Magnum cases. Moving Parties are aware of nine cases that have been filed in six different district courts across the country. Moving Parties anticipate that the number of cases will grow rapidly and that hundreds of M2a Magnum cases will be filed in federal courts.

To promote judicial efficiency and ensure that the M2a Magnum cases benefit from the cost savings accomplished by consolidated pretrial proceedings, the Moving Parties request that the M2a Magnum cases be transferred to the Northern District of California or the Southern District of New York for multidistrict pretrial proceedings.

FACTUAL BACKGROUND

The Biomet M2a Magnum is a total hip replacement system. A total hip replacement is used to replace the body's natural joint with an artificial one. Traditionally, these artificial joints consisted of a metal ball that rotated within a ***plastic cup***. But recently some orthopedic companies—including Biomet Orthopedics, LLC, DePuy Orthopaedics, Inc., and Wright Medical Technology, Inc.—launched new hip replacement systems that consisted of metal balls rotating within ***metal cups***. This subset of total hip replacements is referred to as "metal on metal" hip implants.

Metal-on-metal hip implants are now failing at an alarmingly high rate, especially when compared to the traditional metal-on-plastic implants. Two years ago, in August 2010, DePuy Orthopaedics, Inc. recalled its ASR and ASR-XL metal-on-metal hips because of the high number of reported failures of the implant. More recently, in March 2012, the National Joint Registry of England and Wales published an article in the prominent British medical journal, *The Lancet*, that indicted all metal-on-metal hip implants like the Biomet M2a Magnum. The National Registry's article concluded that "analysis of National Joint Registry data provides unequivocal evidence that metal-on-metal stemmed prostheses are associated with higher failure rates than other types. . . ."[1] The National Registry also stated that:

> Metals have been shown to be toxic to many organs including the lungs, kidneys, and brain and can disseminate throughout the body after [total hip replacement.] Furthermore, there is now strong evidence that cobalt and

[1] Alison J. Smith, et al., Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales, *The Lancet*, Volume 379, Issue 9822, Pages 1199 - 1204, 31 March 2012.

> chrome are genotoxic and can signal across biological barriers at concentrations produced after [total hip replacement.] *Id*.

Not surprisingly, many of the patients who were injured by metal-on-metal hip implants have filed lawsuits in federal courts. As of May 14, 2012, the Panel has transferred 5,411 cases to the four existing MDLs that involve metal-on-metal hip implants:[2]

Multidistrict Litigation	**Cases Transferred**
MDL 2158, *In re: Zimmer Durom Hip Cup Products Liability Litigation*	151
MDL 2197, *In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation*	4,034
MDL 2244, *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*	1,194
MDL 2329, *In re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation*	32

The Biomet M2a Magnum is the latest in this string of metal-on-metal hip implant failures. To date, the FDA has received at least 450 complaints involving the M2a Magnum.[3] These failures seem to be increasing rapidly. For example, in the first five months of 2012 alone, the FDA received 159 reports of adverse events related to the M2a Magnum.

[2] MDL Statistics Report – Distribution of Pending MDL Dockets, May 14, 2012. (http://www.jpml.uscourts.gov/sites/jpml/files/Pending%20MDL%20Dockets_By%20District_May-2012.pdf)

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

Both of the Moving Parties, Diane Winningham and Leyda Ching, had Biomet M2a Magnum hip implants that failed. As a result of the failure of their hip implants, both Ms. Ching and Ms. Winningham had to undergo complex, painful, and risky surgical procedures to remove the M2a Magnum hip implant and replace it with a new one. Ms. Ching and Ms. Winningham both filed lawsuits in the Northern District of California in San Francisco. A copy of Moving Parties' Complaints is attached to this Motion to Transfer.

In their Complaints, the Moving Parties allege causes of action for strict product liability, negligence, breach of implied warranty, and breach of express warranty. Moving Parties allege, among other things, that the M2a Magnum is defective because it was improperly designed and manufactured and because it was not accompanied with adequate warnings. They also allege that Defendants have known about the defects and dangers of the M2a Magnum for several years and have actively concealed that knowledge from physicians that purchase these devices for implantation in their patients. As a result of the defects in the M2a Magnum, Moving Parties have suffered physical injuries (including the need for a painful surgery to remove and replace the implant), pain, suffering, and emotional distress, and economic damages including lost wages and medical expenses.

Moving Parties are aware of seven other similar lawsuits involving the M2a Magnum that have been filed in six district courts across the country. A copy of the Complaints in each of these cases is attached to this Motion. In each of these Complaints, the plaintiff's allegations are almost identical to those in Moving Parties'

Complaints. For example, each of the plaintiffs allege that he or she had the M2a Magnum implanted in his or her body, and that the M2a Magnum failed and caused the plaintiff injuries and damages. Each Complaint states causes of action for product liability, negligence, and breach of warranty.

Moving Parties anticipate that a large number of additional M2a Magnum cases will be filed in federal courts across the country. The number of adverse events reported to the FDA that involve the M2a Magnum is approaching 500, and is increasing rapidly with time. These adverse event reports suggest that the pace of new filings alleging defects with the M2a Magnum will be similar to the four other metal-on-metal hip implants that the Panel has transferred. At the time the motion to transfer was filed in MDL 2197, *In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation*, there were only eight cases filed. Now more than 4,000 cases have been transferred to the ASR MDL. Similarly, at the time the motion to transfer was filed in MDL 2244, *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*, there were only three cases filed. Now more than 1,100 cases have been transferred to the Pinnacle MDL.

Like the other four metal-on-metal MDLs, the M2a Magnum cases will benefit from consolidated proceedings. As is discussed below, these cases involve several common issues or fact that would best be resolved by one Judge. Consequently, Moving Parties request that the Panel transfer the M2a Magnum cases to either the Northern District of California or the Southern District of New York.

ARGUMENT

A. STANDARD FOR TRANSFER AND COORDINATION

Multidistrict litigation is designed "to 'promote the just and efficient conduct' of 'civil actions involving one or more common questions of fact' that are pending in different districts." *In re: Phenylpropanolamine (PPA) Products Liability Litigation*, 460 F.3d 1217, 1229 (9th Cir. 2006), *quoting* 28 U.S.C. § 1407(a)). Upon a motion for transfer, the Judicial Panel on Multidistrict Litigation "analyzes each group of cases in light of the statutory criteria and the primary purposes of the MDL process to determine whether transfer is appropriate." *In re PPA Products Liability Litigation*, 460 F.3d at 1230. It considers factors including "the progress of discovery, docket conditions, familiarity of the transferee judge with the relevant issues, and the size of the litigation." *Id*., *citing* Multidistrict Litigation Manual § 5.16.

On the specific issue of whether to centralize litigation in a single district, the Panel considers the convenience of the parties and witnesses, the number of related actions, and the complexity of common questions of fact. Cf. *In re DaimlerChrysler Corp. Seat Belt Buckle Products Liability Litigation*, 217 F.Supp.2d 1376, 1377 (Judicial Panel on Multidistrict Litigation 2002) (considering these factors and determining that centralization was not warranted.) Once a case goes into multidistrict litigation, "[c]oordination of so many parties and claims requires that a district court be given broad discretion to structure a procedural framework for moving the cases as a whole as well as individually, more so than in an action involving only a few parties and a handful of claims." *In re PPA Products Liability Litigation*, 460 F.3d at 1231-32. This requires that

the district court "be able to 'uncomplicate matters'" and that counsel "'collaborate with the trial judge from the outset in fashioning workable programmatic procedures, and thereafter alert the court in a timely manner as operating experience points up infirmities warranting further judicial attention.'" *Id*., *quoting Massaro v. Chesley* (*In re San Juan Dupont Plaza Hotel Fire Litig.*), 111 F.3d 220, 229 (1st Cir.1997.)

B. TRANSFER AND COORDINATION IS APPROPRIATE BECAUSE THE M2A MAGNUM CASES RAISE COMMON QUESTIONS OF FACT

The defective nature of the M2a Magnum has and will give rise to numerous "civil actions involving one or more common questions of fact." 28 U.S.C. § 1407(a). Among the common questions of fact are:

(1) Whether and to what extent the M2a Magnum has caused, or will cause, harmful effects in patients that received the device including but not limited to physical injury, pain and suffering, swelling, severe inflammation of surrounding tissue and bone, metallosis, toxic levels of cobalt and chromium metal, an inability to walk and other lack of mobility, and the need for revision surgery to remove the defective M2a Magnum with the attendant risks of complications and death from surgery;

(2) When Defendants first learned of the connection between the M2a Magnum and the foregoing harmful effects caused by the devices;

(3) Whether, and for how long, Defendants concealed this knowledge from physicians that purchased the devices for surgical implantation in their patients and the public;

(4) Whether Defendants defectively designed and/or manufactured the M2a Magnum;

(5) Whether Defendants failed to provide adequate warnings and instruction concerning the M2a Magnum;

(6) Whether Defendants were negligent in their design and/or manufacture of the M2a Magnum;

(7) Whether Defendants engaged in fraudulent and illegal marketing practices, including but not limited to making unsubstantiated claims regarding the superiority of the M2a Magnum as a hip replacement system in order to market the M2a Magnum to physicians and the public; and

(8) The nature and extent of damages suffered by Plaintiffs as a result of the M2a Magnum.

Separate, unconsolidated pretrial proceedings in the cases that have been and will be filed would greatly increase the costs of this litigation for all parties, waste judicial resources, and create a significant risk of inconsistent rulings on these common questions of fact.

C. THE COORDINATED M2A MAGNUM CASE SHOULD BE TRANSFERRED TO THE NORTHERN DISTRICT OF CALIFORNIA OR SOUTHERN DISTRICT OF NEW YORK

The Northern District of California has already become a natural center of gravity for the litigation involving the M2a Magnum. Three of the nine pending cases are filed in the Northern District of California, more than any other district. And because a large population of M2a Magnum patients live in the Northern District of California, several more cases are likely to be filed in this district.

Moving Parties both filed their cases in the Northern District of California in January 2012. In the six months since these cases were filed, several significant pretrial proceedings have occurred. In the case filed by Diane Winningham, the Court has already entered a scheduling order that sets discovery deadlines and a trial date on December 16, 2013. The parties worked cooperatively to submit a Stipulated Protective Order allowing the parties to produce confidential documents to each other, and the Court entered the parties' proposed Protective Order in June 2012. Plaintiffs also have submitted to defendants proposed orders governing the production of Electronically Stored Information and the preparation of privilege logs. The parties also have exchanged preliminary disclosures, and plaintiff has served defendants with comprehensive preliminary discovery, consisting of 179 specific requests for the production of documents.

The three Judges in the Northern District of California who are currently handling M2a Magnum cases all have significant experience handling complex multidistrict cases of this nature. The Honorable Claudia Wilken currently is presiding over *Hale v. Biomet Orthopaedics, LLC* (N.D. Cal. No. 12-CV-3081). Judge Wilken is the incoming Chief Judge of the Northern District of California, and she has successfully managed MDL 1819, *In re: Static Random Access Memory (SRAM) Antitrust Litigation*, a case that resulted in a class settlement that is currently pending before Judge Wilken. The Honorable Jeffrey S. White is presiding over *Winningham v. Biomet Orthopaedics, LLC* (N.D. Cal. No 12-00503). Judge White is successfully managing MDL No. 2264, *In re: Google Inc. Android Consumer Privacy Litigation*, a multidistrict litigation that was

assigned to him last year. Finally, the Honorable Samuel Conti is presiding over *Ching v. Biomet Orthopaedics, LLC* (N.D. Cal. No. 12-CV-00502). Judge Conti, who is on senior status, is currently managing MDL 1917, *In re: Cathode Ray Tube (CRT) Antitrust Litigation*.

The Northern District of California offers many advantages that would promote efficient pretrial proceedings in this case. Most importantly, the Northern District of California has several Judges who are experienced in handling complex multidistrict litigation of this nature and have proven their ability to efficiently resolve complex cases. The Defendants have retained experienced counsel in the San Francisco office of Reed Smith LLP, a well-known law firm that specializes in complex medical device cases and has a proven track record of representing companies in multidistrict litigation. Likewise, counsel for several of the plaintiffs who have filed M2a Magnum cases are based in San Francisco.

The Southern District of New York also offers several advantages as a transfer venue. One of the M2a Magnum cases (*Konowal v. Biomet, Inc., et al.*) is pending in the Southern District of New York in Manhattan. Like the Northern District of California, the Southern District of New York has several judges who are experienced in handling mass tort cases of this nature.

Both the Northern District of California and the Southern District of New York are conveniently located so that parties and counsel from across the country can easily travel to any pretrial proceedings. Both the New York metropolitan area and the San

Francisco metropolitan area are easily accessible, have multiple airports, several hotels, plenty of meeting space, and all of the business services that are needed by counsel.

For these reasons, Moving Parties request that the Panel transfer cases involving the M2a Magnum to either the Northern District of California or the Southern District of New York.

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By /s/ Kenneth M. Seeger

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LIST OF EXHIBITS

Exhibit	Case Captions	Civil Action No.
Exhibit 1	*Leyda Ching v. Biomet Orthopedics LLC, Biomet, Inc., and Biomet, LLC*	N.D. California, No. 12-CV-0502
Exhibit 2	*Diane Winningham v. Biomet Orthopedics LLC, Biomet, Inc., and Biomet, LLC*	N.D. California, No. 12-CV-0503
Exhibit 3	*Patrick D. Hales and Melinda Hales v. Biomet Orthopedics LLC, Biomet, Inc., and Biomet, LLC*	N.D. California, No. 12-CV-3081
Exhibit 4	*Vincent Pizzitolo v. Biomet Orthopedics, LLC*	E.D. Louisiana, No. 2:12-cv-00521
Exhibit 5	*Lana Turner v. Biomet Orthopedics, LLC, and Touro Infirmary*	E.D. Louisiana, No. 2:11-cv-02443
Exhibit 6	*John Harris v. Biomet Orthopedics, LLC, Biomet, Inc., Mid-Atlantic Medical LLC d/b/a Biomet Med Atlantic*	D. Maryland, No. 24-C-12-000048
Exhibit 7	*William Konowal and Julieanne Konowal v. Biomet, Inc., Biomet, LLC, and Biomet Orthopedics, LLC*	S.D. New York, No. 12-CIV-4342
Exhibit 8	*Nan Faber v. Biomet New York, Inc., Biomet, Inc., EBI, LLC, and Biomet Orthopedics, LLC*	E.D. New York, No. 1:12-cv-00783-CAM-MDG
Exhibit 9	*Carole St. Cyr, and Eugene St. Cyr v. Biomet Orthopedics, Inc., Biomet, Inc., and Biomet Manufacturing Corp.*	N.D. Texas, No. 4:12-cv-00032-Y