BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: SMITH & NEPHEW HIP IMPLANT PRODUCTS LIABILITY LITIGATION	)	MDL Docket No.:_____

BRIEF IN SUPPORT OF MOTION FOR TRANSFER OF ACTIONS TO THE DISTRICT OF MARYLAND PURSUANT TO 28 U.S.C. §1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS (ORAL ARGUMENT REQUESTED)

INTRODUCTION

Plaintiffs Sarah Crews, Alberto Grazia, Marla Hand, Cynthia Kruse, Lori LeBlanc, Heidi Marion, Sidney Rand and Steven Zingler (hereinafter "Movants"), bring this motion to transfer all 31 of the pending cases that arise out of the Birmingham Hip Resurfacing ("BHR") and R3 metal-on-metal liner ("R3") to the United States District Court for the District of Maryland.

The BHR and the R3 are components in "metal-on-metal" hip implant systems made by Smith & Nephew, Inc. Similar metal-on-metal hip systems have been the subject of widespread mass tort litigation in recent years. The Panel previously granted motions to transfer cases involving six other metal-on-metal hips. MDL 2158, In re: Zimmer Durom Hip Cup Products Liability Litigation; MDL 2197, In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation; MDL 2144, In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation; MDL 2329, In re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation; MDL 2391, In re: Biomet M2a Magnum Hip Implant Products Liability Litigation; MDL 2441, In re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation. Movants request that the Panel follow the same approach taken in these

other six proceedings, and consolidate pending Smith & Nephew cases involving the BHR and R3 devices for the sake of judicial efficiency and economy.

FACTUAL AND PROCEDURAL BACKGROUND

The BHR and R3 are medical devices used in metal-on-metal hip replacement surgery. The BHR consists of a femoral head component and a hemispherical acetabular cup that is made in a range of 12 sizes. The cup fits into the patient's hip socket, or acetabulum, and then rubs against the femoral head during articulation (movement) of the patient's hip joint. Both components are made of cobalt and chromium metal alloys. The BHR may be used as part of a hip resurfacing, or it may be combined with a femoral stem in a total hip arthroplasty. The U.S. Food and Drug Administration ("FDA") approved the BHR for sale in the U.S. on May 9, 2006, through the Premarket Approval ("PMA") process for Class III medical devices. The R3 system consists of a femoral head and cup, with a metal acetabular liner separating the two components. These two devices share a similar mechanism of failure, and the FDA initially approved the R3 to be used as part of the BHR system. Smith & Nephew recalled the R3 in June 2012 due to high failure rates. The company later withdrew the BHR device from the U.S. market in June 2015 due to similar high failure rates, particularly in women and in patients with smaller hip joints.

The problems associated with the BHR and the R3 liner are similar to the injuries caused by other metal-on-metal hip devices, which have been well documented starting with the August 2010 recall of the DePuy ASR device. Data compiled by the National Joint Registry of England and Wales show the BHR has a seven-year revision rate of 11.76 percent, well above the normal acceptable failure rate for a device of this type. Similar data compiled by the National Joint Replacement Registry of Australia in 2015 show the BHR has a ten-year revision rate of 14.5 percent for women. Other studies place the failure rate for women as high as 26 percent.

Movants expect that dozens of additional cases involving the BHR and R3 will be filed in the future as adverse events continue to be reported to the FDA, and more patients experience device failure.[1] Smith & Nephew continued selling its metal-on-metal hips for years even after most of its competitors recalled or withdrew similar devices from the U.S. market in 2010 and 2011. There are currently 31 cases involving the BHR and R3 devices pending in 22 different districts, with 32 different law firms involved. Most cases were filed in the last 12 months, and discovery has been limited due to arguments about the extent to which the cases are subject to express or implied pre-emption under the framework of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1976. Consequently, most cases remain in the early stages of discovery and none have proceeded to trial. The oldest filed case is in the District of Maryland (October 2014). Other older cases are pending in the Southern District of West Virginia (December 2014), the District of Utah (July 2015) and the Northern District of Illinois (October 2015).[2]

These cases will benefit from consolidated proceedings, as they involve common factual and legal issues. Consolidation of other metal-on-metal hip cases has proven to be an efficient and cost-effective tool to resolve products liability litigation where a single manufacturer is connected to hundreds or even thousands of similar claims. For example, there are currently 1,452 actions pending in MDL 2197 for the DePuy ASR device, compared to 9,929 total actions

[1] In its 2012 post-marketing annual report to the FDA, Smith & Nephew disclosed 356 reportable complaints for the BHR alone between March 1, 2011, and February 29, 2012. The following year, it disclosed 380 reportable complaints between April 1, 2012, and April 1, 2013.

[2] All currently pending cases are listed in the attached Schedule of Actions. The oldest case in West Virginia is *Raab v. Smith & Nephew, Inc.*, 2:14-cv-30279. The oldest Maryland case is *Williams v. Smith & Nephew, Inc*., 1:14-cv-03138. The oldest Illinois case is *Laverty v. Smith & Nephew, Inc*., 1:15-cv-09485. The Utah case is *Marion v. Smith & Nephew, Inc*., 1:15-cv-00096.

historically.[3] Likewise, there are 455 actions pending in MDL 2391 involving Biomet metal hips, compared to 2,642 total actions historically.[4] Finally, there are 1,794 actions pending in MDL 2441 involving Stryker metal hips, compared to 3,356 historically.[5]

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). 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." *Id.* 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

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[3] MDL Statistics Report – Distribution of Pending MDL Dockets by Actions Pending (Dec. 15, 2016) available at http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Actions_Pending-December-15-2016.pdf

[4] *Id.*

[5] *Id.*

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.). Transfer under 28 U.S.C. §1407, however, does not require complete identity or even a majority of common factual or legal issues as a prerequisite to transfer. *In re Rembrandt Techs., L.P.*, 493 F. Supp. 2d 1367, 1369 (J.P.M.L. 2007).

Consolidation also saves time, effort, and financial resources of the judiciary and the parties, and lowers the possibility of inconsistent rulings from parallel proceedings. *See in re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, 883 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012); *In re DePuy Orthopaedics, Inc.*, 753 F. Supp. 2d 1378, 1379 (J.P.M.L. 2010) ("Centralization under Section 1407 will eliminate duplicate discovery, prevent inconsistent trial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and the judiciary").

B. TRANSFER AND COORDINATION IS APPROPRIATE BECAUSE THE SMITH & NEPHEW BHR AND R3 CASES RAISE COMMON QUESTIONS OF FACT

Movants all claim injuries from prosthetic metal-on-metal hip devices manufactured by Defendant. Questions common to all of these suits arise from the underlying facts and course of conduct alleged in each complaint. Specifically, Smith & Nephew's actions relating to the design, manufacture, sale, testing, regulatory compliance, marketing, advertising, promotion,

and/or distribution of the BHR and/or R3 form the basis of each lawsuit. Such common questions include:

1) Whether and to what extent Smith & Nephew complied with the terms of the PMA granted by the FDA for the BHR device in 2006.
2) Whether Smith & Nephew failed to warn and/or adequately warned patients and their physicians about the known health risks, including premature failure, posed by the BHR and R3 devices;
3) Whether Smith & Nephew intentionally, deliberately, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed, or suppressed material and important information from the FDA regarding the true and known risks of the BHR and R3 devices;
4) Whether and to what extent the BHR and R3 devices have caused, or will cause, toxic levels of cobalt and chromium in the bodies of patients implanted with the devices, and causing other symptoms including pain, adverse local tissue reaction, pseudotumor, bone and tissue necrosis, metallosis, and other symptoms leading to revision surgery.
5) Whether and to what extent Smith & Nephew defectively designed and/or manufactured the BHR and R3 devices.
6) Whether Smith & Nephew engaged in fraudulent and illegal marketing practices, including but not limited to making unsubstantiated claims regarding the superiority of the BHR and R3 devices compared to similar devices, even after those similar devices were recalled or pulled from the U.S. market.

Movants all allege injuries caused by the metal-on-metal articulation of their hip devices. While there are design differences between the BHR and R3, the same pre-emption issues tied to their shared PMA are expected to be at the heart of this litigation, especially in the early stages of discovery. Thus, many of the same custodians and regulatory experts will be deposed for both devices, and document production will substantially overlap. Furthermore, this Panel has in the past agreed to consolidate metal hip cases where a single defendant — notably Biomet and Stryker — made multiple metal hip devices, so long as they shared common facts related to their regulatory and marketing histories.[6] Nonetheless, if the Panel decides not to consolidate the BHR and R3 cases together in the same MDL, movants respectfully request that the Panel consolidate only the BHR cases under 28 U.S.C. §1407. All but three of the currently pending related cases, including all claims related to movants' cases, involve the BHR only.[7]

C. THE SMITH & NEPHEW BHR AND R3 CASES SHOULD BE TRANSFERRED TO THE DISTRICT OF MARYLAND.

The District of Maryland is home to *Williams*, the oldest filed case in the attached Schedule of Actions, having been filed more than two years ago in October 2014.[8] *Williams* also is among the most advanced cases in terms of discovery, and the presiding judge, Hon. Catherine C. Blake, already is familiar with key issues related to Smith & Nephew's metal-on-metal hip devices. Notably, she evaluated and ruled upon PMA preemption issues in *Williams* in August

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[6] *In re Stryker Rejuvenate & ABG II Hip Implant Prods. Liab. Litig.*, No. MDL No. 2441, 2013 U.S. Dist. LEXIS 86004, at *1 (consolidating cases involving the Rejuvenate and ABG II femoral stems in a single MDL); *see also Price v. Biomet, Inc.,* No. 3:14-cv-275-RLM-CAN, 2016 U.S. Dist. LEXIS 14929, at *2 (N.D. Ind. Feb. 8, 2016) (noting that, "(i)n April 2013, the Judicial Panel on Multidistrict Litigation expanded the docket to include the M2a-Taper, adding its customary caveat that the transferee judge is free to employ separate tracks for the different devices, or even make a suggestion of remand.").

[7] On information and belief, the three cases involving the R3 liner on the attached Schedule of Actions are as follows: *LaFountain v. Smith & Nephew Inc*, 3:14-cv-1598, *Tipsord v. Smith & Nephew, Inc.*, 1:16-cv-1339, and *Cochran v. Smith & Nephew, Inc*., 1:16-cv-01121.

[8] *See Williams Compl.*, Exhibit A.

2015 and she recently accepted a second BHR case, *Twigg*.[9] Judge Blake has been an Article III judge for more than two decades, and she has presided over at least two other MDLs. She recently presided over MDL 2294, a patent infringement case filed in 2011 that appears to have been resolved as of June 2016.[10]

Maryland also is located conveniently on the East Coast, and Baltimore is a short flight from Smith & Nephew's domestic headquarters in Memphis and its headquarters in the United Kingdom. Thus, as a transferee court, Maryland appears to meet many of the criteria in the MANUAL FOR COMPLEX LITIGATION (FOURTH) §20.131 (2010), including "… where discovery has occurred, where cases have progressed furthest, … where the cost and inconvenience will be minimized, and the experience, skill, and caseloads of available judges." *See also in re Commer. Money Ctr., Inc. Equip. Lease Litig.*, 229 F. Supp. 2d 1379 (J.P.M.L 2002).

Movants are open to alternative venues for consolidation. The Southern District of West Virginia is home to *Raab*, the second-oldest currently pending case and arguably the most advanced in discovery. The same district is home to two other BHR cases, *Starcher* and *Lewis*. A third possible venue is the Northern District of Illinois, home to *Laverty* and *Hand*, both assigned to Judge Matthew Kennelly, who presides over MDL 2545, *In re Testosterone Replacement Therapy Products Liability Litigation.* If Judge Kennelly is unable to assume a second MDL, there are other jurists in the Northern District of Illinois who are familiar with Smith & Nephew BHR device litigation and related pre-emption issues.[11]

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[9] *Austin Davis Twigg, IV, v. Smith & Nephew, Inc.*, 1:17-cv-256 (assigned to Judge Blake on January 31, 2017).

[10] *In re: Webvention LLC ('294) Patient Litigation*, MDL 2294. The only other MDL pending in the District of Maryland is *In re: KBR, Inc., Burn Pit Litigation*, MDL 2083.

[11] Judge James B. Zagel presided over Barbara Comella, et. al. v. Smith & Nephew, Inc., 1:13-cv-01850; Judge Joan Humphrey Lefkow presided over Stephen Tillman v. Smith & Nephew, Inc., 1:12-cv-4977; and Judge Robert W. Gettleman presided over Cheryl Elmore, et. al. v. Smith & Nephew, Inc., 1:12-cv-8347. All three of these cases were later dismissed by agreement of the parties.

Other possible venues for an MDL include the District of Utah, home to the fourth-oldest case (*Marion*), the District of Colorado, home to two recently filed cases (*Kruse* and *Hunt*), and the Southern District of Mississippi, home to a BHR case that is fully briefed on the pre-emption issue (*Switzer*). Some cases involving the BHR and R3 have been consolidated in state court in Shelby County, Tenn., the U.S. headquarters for Smith & Nephew. However, relatively few cases remain pending in Shelby County. Importantly, on information and belief, no BHR or R3 cases have been removed to the Western District of Tennessee, and no such cases have been filed or are pending in the Western District of Tennessee.

CONCLUSION

For the reasons described above, Movants Sarah Crews, Alberto Grazia, Marla Hand, Cynthia Kruse, Lori LeBlanc, Heidi Marion, Sidney Rand and Steven Zingler request that the Panel transfer cases involving the BHR and R3 devices to the District of Maryland, United States District Court, or to a suitable alternative transferee court pursuant to 28 U.S.C. §1407.

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Respectfully submitted,

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