BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: PROFEMUR HIP IMPLANT PRODUCT LIABILITY LITIGATION	**MDL NO.**

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. §1407

ORAL ARGUMENT REQUESTED

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs Johnny C. Simpson, Elizabeth Simpson, Steven Chadderdon, and Carolyn Chadderdon, ("Movants") bring this motion to transfer all cases to the Eastern District of Arkansas that arise out of claims against Wright Medical Technology, Inc., Wright Medical Group, Inc. (collectively "Wright') and MicroPort Orthopedics, Inc. ("MicroPort") concerning the Profemur total hip implant modular femoral neck when paired with a Profemur total hip implant modular femoral stem. ("Profemur").[1]

The Profemur Modular necks are titanium or cobalt chromium alloy dual modular femoral necks that are coupled with the modular titanium Profemur femoral stems, manufactured, marketed, developed, supplied, labeled, tested, sold and/or distributed by Wright and MicroPort and used in total hip arthroplasty surgeries. The Profemur modular necks have a distal oval male taper which mates with a proximal female taper of the Profemur stems. The design of the taper junction is identical for all of the Profemur modular necks and Profemur modular stems. Movants allege in their complaints that the

[1] After the 2014 purchase of Wright's hip and knee division, MicroPort marketed and distributed the Profemur hip system. In August 2015, MicroPort recalled a part of the Profemur product line due to numerous fractures of the component as a result of fretting and corrosion at the neck stem junction. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=139368

taper of the Profemur modular neck and female bore of the Profemur modular femoral stems were defectively designed and/or manufactured and promote fretting and corrosion at the junction of the modular neck and the femoral stem, which results in personal injury and the need for revision surgery.

Movants are aware of Forty-Two (42) product liability actions involving the modular Profemur femoral hip implant systems pending in Twenty-Five (25) different United States federal district courts, in front of Thirty (30) federal judges, and being prosecuted by more than twenty different law firms.

All of these cases seek damages based upon the same legal theories and operative facts involving the Profemur femoral components. Upon information and belief, more than 25,000 Profemur modular necks and stems have been implanted in patients across the country, so it is inevitable that many more cases involving these components will be filed in federal courts in the coming months. Because all of these pending lawsuits are predicated on common issues of fact, they should be consolidated, coordinated and managed for pretrial purposes through a multidistrict litigation.

The Panel has previously granted motions to transfer cases arising out of defective hip implant systems, *see In Re: Zimmer Durom Hip Cup Products Liability Litigation* (MDL No. 2158); *In Re: DePuy Orthopaedics, Inc., ASR Hip Implant Products Liability Litigation* (MDL No. 2197); *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation* (MDL No. 2244); *In Re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation* (MDL No. 2329); *In Re: Biomet M2a Magnum Hip Implant Products Liability Litigation* (MDL No. 2391); *In Re: Smith & Nephew Hip Implant Products Liability Litigation* (MDL No. 2775), and has granted motions to transfer cases arising out of modular junction corrosion problems present in the Profemur cases. *See In Re:*

Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation (MDL No. 2441); *In Re: Stryker LFIT V40 Femoral Head Products Liability Litigation* (MDL No. 2768) and *In Re: Zimmer M/L Taper Hip Prosthesis Product Liability Litigation* (MDL No. 2859). To promote judicial efficiency and ensure these cases benefit from the cost savings accomplished by coordinated or consolidated pretrial proceedings, Movants respectfully submit this Brief in Support of Plaintiffs' Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407.

II. FACTUAL BACKGROUND

A total hip replacement typically involves implantation of four separate components: a femoral stem, a femoral head, an acetabular liner, and an acetabular shell. The femoral stem in most cases is monolithic, just a single component from the distal point of the femoral stem to the male taper where the femoral head is joined. This creates a single modular femoral system. The Profemur femoral system is dual modular; it consists of a femoral stem designed with a female bore at the proximal body that is joined by press fit during the implanting surgery with the Profemur modular neck. The Wright Medical total hip implant with the Profemur dual modular femoral system has four or five components depending upon whether the acetabular cup is a monoblock metal on metal design or whether the cup consists of a shell and liner.

The Profemur modular necks are made out of titanium or cobalt and chromium alloys. There are a number of different sizes and angles; however, no matter the size, angle, or material, the mating junction between the Profemur stem and Profemur modular neck is designed with the same dimensions with regards to the taper junction. The design intention is that when the male taper of the Profemur modular neck is inserted into the female bore of the Profemur femoral stem, they come into intimate contact. Thus, the stresses inside the

materials keep both components fixed together. The contact area between the inside of the bore of the Profemur femoral stem and the trunnion of the Profemur modular neck is called the taper interface.

The surface of the Profemur modular neck taper is covered by a natural passive film ("passivation layer") consisting of cobalt oxide or titanium oxide which protects against corrosion. Although the taper interface is designed to prevent movement at the junction when assembled, studies have demonstrated that a malfunctioning taper interface can produce micro motion of these components, resulting in a removal of the protective passivation layer ("fretting"), fluid ingress, and subsequent corrosion. This fretting and corrosion can cause the release of cobalt and/or chromium ions, metal debris, and in many cases, fracture of the Profemur modular neck at the taper interface. Fretting wear can result in adverse local tissue reactions, pseudotumor formation, tissue destruction and the need for revision surgery. Catastrophic fracture of the modular neck from fretting corrosion requires emergent medical treatment resulting in revision of some or all of the component parts of the total hip system.

The concern that fretting and corrosion damage could occur at the modular taper of the Profemur modular neck and stem was reported in the early 1990s. Since that time, numerous studies and reports have demonstrated that a malfunctioning or defectively designed taper interface may be susceptible to fretting and corrosion damage resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and/or fracture of the prosthesis and the need for revision surgery.

The Profemur femoral system with the titanium modular neck is a femoral stem/neck component with a taper wedge design constructed from two pieces of Ti-6Al-4V alloy. The

modular neck portion of the stem contains an elliptical taper designed to mate with the corresponding bore taper of the Ti-6Al-4v titanium stem. The male taper of the modular neck contains machine lines that deform when mating with the bore of the femoral stem. This design is an attempt to prevent movement between the modular neck and the bore of the femoral stem.

The Profemur femoral system with the cobalt and chromium modular neck is identical in its design of the taper interface. It is designed to be used with the same Profemur femoral stems as those coupled with the titanium modular neck. The use of cobalt and chromium was marketed as a product line extension to the Profemur system providing greater strength than the Profemur titanium modular neck. This product line extension was in part addressing fretting and corrosion at the taper interface that resulted in catastrophic fracture of some of the Profemur titanium modular necks. In fact, Defendants applied for 510(k) clearance for the Profemur CoCr modular necks through the Food and Drug Administration ("FDA"), naming the Profemur titanium modular necks as a predicate device upon which it relied for clearance.[2]

In order to obtain 510(k) clearance, an applicant must demonstrate that the device is safe and effective by proving substantial equivalence to another legally marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate. Substantial equivalence does not mean the new device must be identical, but equivalence is established with respect to intended use, design, energy use or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable. Here, Defendants represented to the FDA that the Profemur CoCr modular necks are substantially

[2] https://www.accessdata.fda.gov/cdrh_docs/pdf9/K091423.pdf

equivalent to the Profemur Titanium modular necks.

Movants allege that in designing the Profemur modular neck and femoral stem taper, Wright knew or should have known that this taper interface would result in movement between the modular neck component and the bore of the modular stem component resulting in fretting and corrosion, metal ion and debris cast off, and in some instances, fracture of the modular neck component.

III. ARGUMENT

A. Transfer and Coordination of the Profemur Modular Neck Cases is Appropriate and Necessary

28 U.S.C. § 1407 authorizes the Panel to transfer federal civil actions for coordinated or consolidated pretrial proceedings, when (1) the "actions involve one or more common question of fact"; (2) transfer "will be for the convenience of parties and witnesses;" and (3) transfer "will promote the just and efficient conduct of such actions." The purpose of Section 1407 is to "eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation costs, and save the time and effort of the parties, the attorneys, the witnesses, and the courts." Manual for Complex Litigation (Fourth) § 20.131 (2004) (*citing In re Plumbing Fixture Cases*, 298 F. Supp. 484 (J.P.M.L. 1968)). *See also* David H. Herr, Multidistrict Litigation Manual § 5:16 (2010).

Multidistrict litigation serves the purpose of conserving judicial resources and promoting efficiency and consistency. *Illinois Municipal Retirement Fund. v. Citigroup, Inc.*, 391 F.3d 844, 852 (7th Cir. 2004). The objective of the legislation is to provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to assure the 'just and efficient conduct' of such actions. "*Matter of New York City Mun. Sec. Litig.*, 572 F.2d 49, 51 (2d Cir. 1978) (*citing* House Judiciary Committee notes,

H.R. Rep. No. 1130, 90th Cong., 2d Sess., reprinted in 2 U.S. Code Cong. & Admin. News, pp. 1898, 1899-1900 (1968)). Efficient and just management is effected, in part, by eliminating the potential for conflicting contemporaneous rulings by coordinated district and appellate courts. *In re Air Crash off Long Island, N.Y. on July 17, 1996*, 965 F. Supp. 5, 7 (S.D.N.Y. 1997). Multidistrict litigation also promotes inexpensive determination of every action. *In re Nat. Student Mktg. Litig.*, 368 F. Supp. 1311, 1316 (J.P.M.L. 1972).

The Profemur Modular Neck cases are well-suited for centralization under Section 1407. These cases may be pending in district courts from Maine to Oregon, but they share the same basic theories of liability regarding the design, testing, and marketing, and the same basic factual allegations. Although these individual cases may have "some individual issues of fact, this is usually true of product liability cases and medical device cases, in particular." *In re: Cook Med., Inc., IVC Filters Mktg., Sales Practices and Prod. Liab. Litig.* 53 F. Supp.3d 1379, 1380 (J.P.M.L. 2014)(quoting *In re: Cook Med., Inc., Pelvic Repair Sys. Prods. Liab. Litig.* 949 F. Supp2d 1373, 1375 (J.P.M.L. 2013)). "The Panel has rejected the argument that products liability actions must allege identical injuries to warrant centralization." *Id.* at 1381 (citing *In re: Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F. Supp.2d 1371 (J.P.M.L. 2007)). All of the cases will involve the same core document discovery and the same lay and expert witnesses. Transferring these cases pursuant to 28 U.S.C. § 1407 would enhance the convenience and efficiency of this litigation. Declining to transfer would almost certainly lead to inconsistent and conflicting rulings in discovery and other pretrial matters. As set-forth in detail below, these cases are appropriate for transfer and coordination before a single district court.

1. The Profemur Modular Neck Cases Involve Common Questions of Fact and Involve Common Issues for Discovery

Federal civil actions are eligible for transfer pursuant to 28 U.S.C. § 1407 if they involve "common questions of fact" subject to discovery. *See* 28 U.S.C. § 1407(a); *In re Kugel Mesh Hernia Patch Products Liability Litigation*, 493 F.Supp. 2d 1371, 1372-73 (J.P.M.L. 2007). The statute, however, does not require complete identification of common questions of fact to justify transfer. *In re Zyprexa Prods, Liab. Litig.*, 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004).

The cases presented here share a common core of operative facts. All plaintiffs allege that the Profemur modular hip implants with modular stems and necks shared the same design defect that led to a common mechanism of failure and caused similar injuries to each plaintiff, including revision surgery from fracture of the prosthesis, metallosis, adverse local tissue reactions, pseudotumor formation, and/or tissue destruction. While not all plaintiffs suffered the same exact injury or outcome, all injuries are alleged to be attributable to the Profemur modular neck while paired with a Profemur modular stem where the movement between the components caused fretting and corrosion. Although each case may not involve the exact same size or model Profemur, the alleged defect is the same. *In re: Cook Med., Inc., IVC Filters Mktg., Sales Practices and Prod. Liab. Litig.* 53 F. Supp.3d 1379, 1381 (J.P.M.L. 2013) ("The Panel has previously centralized actions involving different models of products made by the same manufacturer where plaintiffs allege a common defect") (citing *In re: MI Windows and Doors, Inc., Prod. Liab. Litig., 857 F. Supp2d 1374(J.P.M.L. 2012); Stryker Rejuvenate and ABG II Hip Implant Prods. Liab. Litig.*, 949 F. Supp.2d 1378, 1379 (J.P.M.L. 2013)).

In addition, each plaintiff alleges Defendants knew or should have known of the

defective nature of these hip implant components, and yet failed to properly warn doctors and patients and failed to timely remove the products from the market when it knew of the dangers associated with these products. Plaintiffs have also asserted the same legal theories of liability, including negligence, failure to warn, strict products liability, defective design and defective manufacturing.

Plaintiffs raise common questions of fact regarding the Profemur modular femoral device combinations, including the following: to what extent these devices caused or will cause harm to patients; when Defendants first learned of the harmful effects caused by these devices; whether, and for how long, Defendants concealed this knowledge from surgeons and physicians and continued to promote sales of these devices; whether Defendants defectively designed and/or manufactured these devices; whether Defendants failed to provide adequate warnings concerning these devices; whether defendants were negligent in their design and/or manufacture of these devices; whether Defendants engaged in fraudulent and illegal marketing practices regarding these devices; and the nature and extent of damages suffered by Plaintiffs as a result of these devices.

Separate, unconsolidated proceedings would increase the cost of litigation for all parties, waste judicial resources, and risk inconsistent rulings on these common questions of fact. For these reasons, Movants respectfully request this Court to consolidate these related actions.

2. Consolidation Prevents Duplicative Discovery

Preventing duplicative discovery favors consolidation. Centralization avoids repetitive discovery and depositions when there are common questions of fact. *See, e.g., In re: Pilot Flying J. Fuel Rebate Contract Litigation (No. II),* 11 F. Supp. 3d, 1351, 1352 (J.P.M.L, 2014). Centralizing also allows Plaintiffs' counsel to coordinate their efforts and

share discovery and the pre-trial workload. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173, F. Supp.2d 1377, 1379 (2001). Small litigations also benefit from consolidation by eliminating duplicative discovery, preventing inconsistent pretrial rulings and conserving the resources of the parties, their counsel and the judiciary. *See In re First Nat'l Collection Bureau, Inc., Tel. Consumer Prot. Act (TCPA) Litig*. 11 F. Supp. 3d 1353, 1354 (J.P.M.L. Apr. 8, 2014).

Substantial duplicative discovery will occur if each of these cases proceeds separately. It is neither cost effective nor efficient for multiple cases to proceed in various courts. Many of the same depositions, documents and discovery will be required in each jurisdiction.

Consolidating benefits both Plaintiffs and Defendants. Pretrial transfer reduces discovery delays and costs for Plaintiffs and allows Plaintiffs to share the pre-trial workload. Defendants are also benefit because depositions of key witnesses will only be required once rather than on dozens of separate occasions. Documents can be produced to one body of plaintiffs, thereby eliminating duplicative discovery as to the common factual issues between the parties. Centralization is necessary to prevent duplicative discovery, lower the overall costs of discovery for all parties, and avoid unnecessary burdens on witnesses.

While Movants anticipate many more filings, even the current number of filed cases would benefit from coordination given the overlapping factual allegations and legal theories of liability.

3. Pretrial Centralization Will Enhance the Convenience of the Litigation as a Whole

Transfer is appropriate when it enhances the convenience of the litigation as a whole. *See e.g. In re Library Editions of Children's Books*, 297 F. Supp. 385, 386 (J.P.M.L. 1968).

As mentioned above, both Plaintiffs and Defendants benefit from consolidation. Pretrial centralization would reduce discovery costs significantly for Defendants. It would also permit Plaintiffs' counsel to coordinate their efforts and share the pretrial workload, thereby reducing costs for each individual plaintiff and her attorneys. Without centralization, Defendants will be forced to hire counsel in multiple districts across the country, respond to similar but invariably slightly different discovery requests, and develop potentially different pretrial litigation strategies. Centralization will permit Defendants to focus their attention and energy on one forum, allow them to respond more quickly and efficiently to Plaintiffs and the transferee court, and enhance the overall efficiency of the litigation. *See, e.g., In re Baldwin-United Corp. Litigation*, 581 F. Supp. 739, 741 (J.P.M.L. 1984) ("[P]rudent counsel will combine their forces and apportion the workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of cost and a minimum of inconvenience to all concerned.").

Centralization will also conserve the precious financial and time resources of the courts. One judge, rather than many, will consider issues related to discovery, privilege, expert witnesses, and other essential aspects of the cases.

In short, transferring the Profemur cases for pretrial coordination or consolidation will make this litigation far more efficient and convenient for everyone involved.

4. Transfer Will Promote the Just and Efficient Conduct of These Actions

Centralization of the Profemur cases promotes the just and efficient conduct of this litigation. Centralization seeks to promote justice and efficiency by eliminating duplicative discovery, preventing inconsistent pretrial rulings, and conserving the resources of the parties, their counsel and the judiciary. *See, e.g., In re Baycol Products Liability Litigation*, 180 F. Supp. 2d 1378, 1380 (J.P.M.L. 2001).

Because every Profemur case asserts the same basic liability allegations, Defendants will likely assert the same defenses to the allegations in each case. With Forty-Two currently filed Profemur cases, and dozens more expected to surface in the near future, it is imperative that there not be conflicting rulings from various courts around the country. Centralization before a single court eliminates the possibility of inconsistent rulings in these cases, thereby preventing different treatment of Plaintiffs under similar legal theories and ensuring the just application of law for all Plaintiffs.

A single transferee court will be in the best position to determine the appropriate resolution of these threshold issues that will affect all actions and that could dramatically simplify the litigation. Movants therefore respectfully request this Court to centralize the Profemur cases to promote the just and efficient conduct of these actions.

B. Transfer to the Eastern District of Arkansas Best Serves Convenience and the Just and Efficient Conduct of These Actions

In determining an appropriate transferee forum, the Panel balances a number of factors, including: the experience, skill and caseload of the parties; location of the witnesses and evidence; and the minimization of costs and inconvenience to the parties. *See, e.g., In re Regents of University of California*, 964 F.2d 1128, 1136 (Fed. Cir. 1992); *In re Wheat Farmers Antitrust Class Action Litig.*, 366 F.Supp. 1087, 1088 (J.P.M.L. 1973); *In re Preferential Drugs Prods. Pricing Antitrust Litig.*, 429 F.Supp. 1027, 1029 (J.P.M.L. 1977); *In re Tri-State Crematory Litig.*, 206 F.Supp. 1376, 1378 (J.P.M.L. 2002); Annotated Manual of Complex Litigation (Fourth) (2004), §20.131, at 303-304.

Movants urge the Panel to transfer the Profemur actions to the Eastern District of Arkansas where these common questions of fact can be efficiently and justly managed by a judge with extensive complex litigation experience. The Eastern District of Arkansas is the

best court to effectively manage a complex products liability case like this one, in part, because of the court's familiarity and experience with the science and damages involved in orthopedic implant product liability cases and Little Rock's close proximity to Memphis, Tennessee, the corporate home of both Wright and MicroPort as well as their corporate witnesses.

In addition, Movants believe that many of the Plaintiffs in this litigation will reside in or have connections to Arkansas, including three plaintiffs who have already filed actions in Arkansas. Also, Little Rock is centrally located in the country.

Although the Eastern District of Arkansas is home to many excellent judges, Movants respectfully request that this litigation be assigned to the Honorable Kristine G. Baker as she is familiar with this litigation and is an immensely qualified judge. Judge Baker currently presides over two Profemur cases and has dealt with the types complex disputes concerning science and discovery that will undoubtedly arise in this litigation. Judge Baker's experience and that of her staff, in managing complex medical device litigation would facilitate the efficient and just prosecution of these related cases.

IV. Conclusion

Transfer and consolidation for pre-trial proceedings of all pending and subsequently filed actions involving the Profemur device combinations would promote the just and efficient prosecution of these actions by allowing national coordination of discovery and other pre-trial matters, prevent duplicative and potentially conflicting pre-trial rulings, reduce the costs of the litigation, and allow cases to proceed more efficiently to trial. For all of these reasons, Movants respectfully request the Panel to enter an order that all such actions be consolidated and transferred to the Eastern District of Arkansas before the Honorable Kristine G. Baker.

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Respectfully submitted,

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