BEFORE THE UNITED STATES JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: STRYKER REJUVENATE AND ABG II HIP IMPLANT PRODUCTS LIABILITY LITIGATION	**MDL NO.: 2441 ORAL ARGUMENT REQUESTED**

INTERESTED PARTY RESPONSE AND MEMORANDUM OF LAW IN SUPPORT OF TRANSFER, COORDINATION, AND CONSOLIDATION PURSUANT TO 28 U.S.C. § 1407

PRELIMINARY STATEMENT

Plaintiff Stephanie Teoli ("Plaintiff") respectfully submits this Interested Party Response and Memorandum of Law to the Judicial Panel on Multidistrict Litigation ("the Panel") seeking consolidation of all actions pending in federal court pursuant to 28 U.S.C. § 1407 alleging injury as a result of the recalled Stryker Rejuvenate and ABG II Modular hip stems. For the reasons set forth below, Plaintiff requests the Panel enter an order granting Plaintiffs' Robert Davis and Christine Wilkinson's Motions for Centralization and Transfer of actions. (MDL No.2441, Dkt. No. 1-1 & Dkt. No. 4-1). However, Plaintiff respectfully requests that the Panel utilize the MDL experience and resources of the District Court of New Jersey and transfer all cases to the District of New Jersey before the Honorable Susan Davis Wigenton.

FACTUAL BACKGROUND ABOUT STRYKER REJUVENATE AND ABG II MODULAR HIP IMPLANT STEMS AND THE RECALL

The Stryker Rejuvenate and the ABG II are both modular stem systems that are comprised of two component parts: (i) a titanium femoral stem and (ii) a cobalt-chromium neck. See image A. These stems have two modular

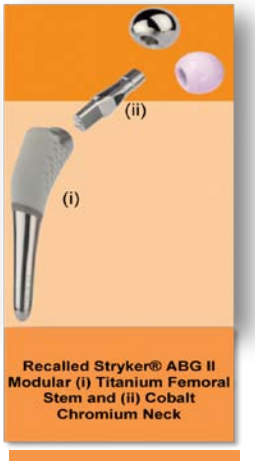

Image A

juncture points, one where the neck and the stem meet and the other where the neck and the ball meet. Traditional stems are not modular; the stem and the neck are all one piece. These modular stem systems were intended to offer surgeons more intra-operative options when it came to neck and stem length and to provide patients enhanced stability. Both the Rejuvenate modular stem and the ABG II modular stem systems consisted of various length stems and necks to allow surgeons to customize the fit and account for various anatomical differences. See Image B.

Image B

In both the Rejuvenate and the ABG II systems the stems are made from TMZF titanium and the modular necks are made from cobalt and chromium.

Both the Rejuvenate and the ABG II have the same dual modular neck junctures, the failure of which was the reason for the recall. Both of these Stryker stems were recalled the same day and for the same reason stating:

> Stryker initiated a voluntary recall of its Rejuvenate Modular and ABG II modular-neck hip stems in June 2012. This voluntary recall was initiated due to potential risks associated with modular-neck stems. These risks include the potential for fretting and/or corrosion at or about the modular-neck junction, which may result in adverse local tissue reaction, as well as possible pain and/or swelling, in or around your hip.

http://www.aboutstryker.com/modularneckstems/. The recall was directly related to the failed design of the modular-neck stem. While there are some differences in the shape of the part of these stems that gets inserted into the femur bone, they both have the same innovative modular neck design. This modular neck design is causing fretting and/or corrosion at the modular junctures. The failure/defect in the Rejuvenate and the ABG II stems are identical.

In September 2007 Stryker received 510k clearance for its first Stryker Modular Hip System. See K071082. It was described as being composed of a modular stem with a modular

neck intended for cementless, press-fit application. Id. Femoral heads and acetabular cups are not part of these systems. The Modular Stem was designed to be used with the Stryker femoral heads, bipolar and compatible acetabular components. Id. The basic design of the stem was described as similar to the then available Wright Medical Profemur Total Hip Modular Neck System, which as also been the subject of a recall due to fretting and corrosion at the modular neck junction. The current Rejuvenate Modular Stem is the result of two line extensions in 2008 and 2009 where the combined head/neck length options were extended. See K081044 and K092561. In 2009 Stryker also received FDA clearance for the ABG II Modular Hip Stem which was also described as a hip stem comprised of a modular stem with a modular neck intended for cementless, press-fit application and was designed for use with available compatible Stryker femoral heads, bipolar and acetabular components – the same description as the Rejuvenate Modular Stem. See K092406. The innovativeness behind the design for both of these hip implant stems was the modular neck juncture.

On January 24, 2011 Plaintiff Stephanie Teoli underwent a right total hip replacement at which time she received a Stryker ABG II modular hip implant stem, which was implanted in her femur bone as part of the hip replacement system. As a result of testing positive for heavy metal ions, worsening of pain symptoms and an MRI revealing adverse local tissue reaction Ms. Teoli underwent a revision surgery on August 8, 2012. At the time of the revision, it was discovered that there was significant corrosion of the ABG II device at the modular neck juncture. On April 1, 2013, Plaintiff initiated suit in Federal Court in the District of New Jersey, the Newark Division. No Discovery or initial disclosures have been produced in this case as it was recently filed.

CENTRALIZATION AND TRANSFER OF THE STRYKER REJUVENATE AND ABG II MODULAR HIP IMPLANT STEMS IN THE SAME MDL IS APPROPRIATE AND NECESSARY

In addition to the reasons set forth in Plaintiff, Robert Davis', Reply Brief in Support of Plaintiff's Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407, this MDL should include both the Rejuvenate and the ABG II implant stems because they have almost identical design characteristics that raise common factual issues. See Pltfs Reply Brief, Doc. 30, filed March 25, 2013. Of the 57 filings, there are currently four known ABG II cases pending in various district courts, and the number is expected to grow exponentially as there were over 9,000 ABG II devices recalled less than a year ago. It is expected that at this early stage there would be less ABG II cases filed. This is relatively proportionate to the ratio of recalled devices considering over 43,000 Rejuvenate devices were recalled. This litigation will be comprised of thousands of Rejuvenate and ABG II cases that all failed as a result of the same defective modular neck design.

This Panel has expanded a number of medical device MDLs to include more than one product where there were similar design characteristics and they raised common factual issues. Recently, in another hip implant product MDL, In re: Biomet M2a Magnum Hip Implant Products Liability Litig., this Panel ruled to expand the MDL to include an earlier generation device, the M2a-Taper because it shared sufficient questions of fact to merit inclusion in the MDL proceedings. See Transfer Order, MDL No. 2391, Doc. 394 Filed 4/1/2013. Although the two Biomet cups are two different designs, one modular and the other monoblock, they had similar characteristics thereby creating overlapping factual issues. Similarly, in the NexGen MDL, this Panel decided to expand that litigation to include an entirely different component that had a similar characteristic as the other components in the MDL. See In re: Zimmer NexGen

Knee Implant Products Liability Litigation, MDL No. 2272, Doc. 781. The new component was part of the same product line, involving the same manufacturer and had the same key "flex" characteristic as the other components, thereby raising similar questions of fact. This decision was based on the fact that there was substantial overlap between the Flex articular surface and the components already in the MDL. See, In re: Zimmer NexGen Knee Implant Products Liability Litigation, MDL No. 2272, Doc. 781 ("It may be, for example, that many of the same Zimmer personnel were involved in the development, design, manufacture, regulatory approval process, or marketing of not only the components identified in our centralization order but also the flex articular surface at issue in Colbert, and thus including the action in the MDL will result in significant efficiencies.").

The inclusion of the ABG II in this MDL would make it no different than so many other MDLs involving medical devices that often include various devices/products in order to properly effectuate the purpose of U.S.C. § 1407. As this Panel has ordered in the past, MDL treatment is proper where various options are available from within a single product line. In In re: Kugel Mesh Hernia Patch Prods. Liab. Litig., 493 F. Supp. 2d 1371, 1372 (J.P.M.L. 2007), the various and different products that were subject to the MDL included, but are not limited to, the Bard Composix Mesh, Bard Kugel Hernia Patch, and the Bard Ventralex Hernia Patch. In the Kugel Mesh MDL, the thirteen actions that were part of the MDL all involved various models of hernia patches that were manufactured and sold by various Defendants. Id. Even though the models of the hernia patches were different and multiple Defendants were involved, the Panel still included all thirteen of the actions in the MDL, stating, "all actions can [ ] be expected to share factual questions." Id. The related factual questions involved the "design, manufacture, safety, testing, marketing, and performance" of the hernia patches. Id. The JPML stated that "transfer under

Section 1407 does not require complete identity or even a majority of common factual or legal issues as a prerequisite to transfer." Id. at 1373-74. Although multiple products were involved, centralization of all the actions was still "necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary." Id. at 1372. In the instant case, the devices at issue are manufactured by the same company, have the same alleged defective modular neck design, same mode of failure, as well as the same signature injuries. Moreover, they were both the subject of the same recall for the same reason – their modularity - the related factual questions are undeniable. They share the same factual questions regarding design, safety, manufacturing, and performance.

As this Panel is well aware, other orthopedic device MDLs include devices with varying technical characteristics. In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation, MDL No. 2244, is a perfect example. This Panel approved the application for MDL status regarding Pinnacle hip implants involving varying, interchangeable components all from within the same product line. The Pinnacle hip devices consist of a variety of sizes, various acetabular cup designs, and a variety of cup liners both metal and polyethylene, all of which are interchangeable parts of the same product line - Pinnacle. The Pinnacle line includes not only various metal-on-metal designs, but also metal-on-polyethylene designs. With this knowledge, this Panel ordered all configurations within the Pinnacle Hip line to be included in the MDL. See In re: DePuy Orthopedics, Pinnacle Hip Implants Prods. Liab. Litig., 787 F.Supp.2d 1358, 1360 (J.P.M.L. 2011). Specifically, the Panel stated "[a]t this early stage of the litigation, we will not limit the scope of this MDL docket. The transferee judge can further refine the issues and closely scrutinize the arguments of the parties regarding the inclusion of metal-on-metal and other configurations." Id. In Pinnacle the JPML was faced with a MDL that included

multiple products, some of which failed for different reasons, but because of the overlapping factual issues the Panel relied on "[t]he transferee' judge's ability to streamline pretrial proceedings in all actions, while simultaneously directing the appropriate resolution of all claims." Id. This prospective MDL is no different than the Pinnacle MDL. In fact, the most critical factual issues involved in this litigation are identical for both the Rejuvenate stem and the ABG II stem - the defective modular design, which was the same in both stems. In both of these stems, the defective design is causing fretting and corrosion between the modular neck and stem. Since both the Rejuvenate and the ABG II are made from the same materials - TMZF Titanium and cobalt-chromium, the fretting of these materials is causing the damages and metal poisoning. All factual issues relating to the design, research, testing, marketing, and the recall of the modularity characteristic of both the stems will significantly overlap, if not be identical. Although there are some design differences in the shape of the stems, the shape of the stems does not appear to contribute to the failure. Moreover, even if the differences in the shapes of these two stems did become factual issues in and of themselves, the MDL judge would have the flexibility to formulate an appropriate trial plan to accommodate any differences.

As Plaintiffs have already set forth, MDLs frequently involve products with varying design characteristics, some of which are issues in the litigation that are addressed through the use of different discovery tracks. Although the Rejuvenate and the ABG II are not identical products, their subtle and nuanced design differences, do not appear to be a factual issue in this litigation at this early stage. Certainly, these differences do not preclude the inclusion of the ABG II Modular stem in this MDL. Although the Panel does not require identical questions of fact but merely overlapping questions of fact, at this stage in the litigation the questions of fact in the ABG II stem cases are identical to the questions of fact in the Rejuvenate stem cases.

THE DISTRICT OF NEW JERSEY IS THE PREEMINENT TRANSFEREE FORUM TO EFFICIENTLY MANAGE THE STRYKER REJUVENATE AND ABG II MODULAR HIP IMPLANT STEMS LITIGATION

Plaintiff respectfully urges the Panel to transfer these actions to the District of New Jersey, and specifically to the Honorable Susan D. Wigenton, who is the presiding Judge in the *Teoli* matter. It is well-established that the District of New Jersey is highly-versed in handling multidistrict litigations as there are currently 16 pending MDLs in the District of New Jersey. It has successfully and efficiently managed multiple complex product MDLs including the Zimmer Durom Hip Cup Products Liability Litigation and the Fosamax Products Liability Litigation. The Court's experience in managing large scale mass tort litigations will undoubtedly ensure efficient and appropriate oversight that will be central for an action of this magnitude.

In determining an appropriate transferee forum, the panel balances a number of factors, including: the experience, skill and caseloads of the available judges; number of cases pending in the jurisdiction; convenience of the parties; location of the witnesses and evidence; and the minimization of cost and convenience to the parties. See, e.g., In re Regents of University of California, 964 F.2d 1128, 1136 (Fed. Cir. 1992); In re Tri-State Crematory Litig., 206 F.Supp. 1376, 1378 (J.P.M.L. 2002); Manual for Complex Litigation (Fourth) (2010), § 20.131, at 221. Of the factors the Panel considers when determining the transferee forum, experience, available resources, and convenience to the parties weigh heavily in favor of transferring all related cases to the District of New Jersey.

While there are a number of eminently qualified judges serving the District of New Jersey, if transferred to New Jersey, Plaintiff respectfully requests that the litigation be assigned to the Honorable Susan D. Wigenton. Judge Wigenton's comprehensive experience, including presiding over the Zimmer Durom metal-on-metal hip implant cases, makes her an excellent

choice to oversee this proposed MDL. See In re Zimmer Durom Hip Cup Prods. Liab Litig., 717 F.Supp.2d 1376 (J.P.M.L. 2010). Judge Wigenton managed to quickly create a successful settlement program resulting in the resolution of 113 of the 188 total actions filed; only 75 cases remain. In light of her success in resolving the bulk of the Durom Cup litigation so efficiently and given the experience she gained presiding over a similar hip litigation MDL, she clearly possesses unique knowledge and expertise with the type of product and injuries at issue in this case.

In addition, Judge Wigenton undoubtedly gained still greater knowledge regarding this Defendant's products and other hip implant systems when she presided over Howmedica Osteonics Corp v. Depuy Orthopaedics, Inc., Case No. 2:11-cv-06498-SDW-MCA, in a case regarding patent infringement of an acetabular cup system that is part of a hip implant.[1] Based upon Judge Wigenton's experience and results from the Zimmer Durom MDL and specifically in conjunction with her familiarity with this Defendant's products, Judge Wigenton is the superior choice to ensure an efficient MDL.

Judge Wigenton has more than thirteen years of experience as a jurist, including nearly seven years of experience as a federal judge. Before her appointment to the District of New Jersey in 2006, Judge Wigenton served as a U.S. Magistrate Judge for the United States District for the District of New Jersey from 2000 to 2006. Prior to her judicial appointments, Judge Wigenton practiced privately as a lawyer in Middletown, New Jersey for twelve years.[2] Before that, she served as a public defender for Asbury Park from 1989-1993.[3] Outside of the courtroom, Judge Wigenton was formerly the Chair of Monmouth County District Ethics

[1] See http://www.iniplaw.org/2011/11/howmedica-osteonics-corp-and-s.html
[2] See http://www.uscourts.gov/JudgesAndJudgeships/BiographicalDirectoryOfJudges.aspx
[3] See http://tri.gmnews.com/news/2008-10-30/front_page/022.html

Committee and served as the Chair of the Civil Justice Reform Act Committee for the Federal Courts in the District of New Jersey.[4]

Judge Wigenton has also been recognized for her hard work and experience by her community. In 2003 she was recognized by the Monmouth Council of Girl Scouts at the Annual Women of Distinction Dinner. In addition to such recognition, Judge Wigenton was honored with the Professionalism Excellence Award by the organization.[5] In 2010, Judge Wigenton was awarded for her commitment to social justice by the Thurgood Marshall College Fund Awards of Excellence dinner.[6] In 2012, Judge Wigenton was recognized by the New Jersey Women Lawyers Association for her exceptional achievement on the bench.[7]

Finally, Judge Wigenton is located in the Newark Division, which is a convenient and affordable location for both parties. The Newark International Airport is minutes from the Federal Court House and easily accessible by means of public transportation. It is also a central hub for multiple airlines, providing direct flights throughout the day to destinations across the U.S. Also, Newark train station is a major hub for Amtrak trains for the entire Eastern Seaboard and would provide easy access to and from major cities along the eastern coast. Further, Defendant Stryker's corporate headquarters is located in Mahwah, New Jersey, thereby making the District of New Jersey a convenient location for the Defendants.

Most significantly, there is state coordinated litigation in the State of New Jersey before the Honorable Brian R. Martinotti of Bergen County, which is about 30 minutes from Newark,

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[4] See http://www.jtbf.net/index.php?src=directory&view=biographies&srctype=detail&refno=183

[5] See http://votesmart.org/public-statement/15686/tribute-to-mary-pat-angelini-alice-j-guttler-the-honorable-susan-d-wigenton-and-theresa-i-seitz

[6] See http://localtalknews.com/newark/community/200-stephen-adubato-mayor-cory-booker-john-farmer-paula-dow-susan-wigenton-honored-by-thurgood-marshall

[7] See http://www.njwla.org/wp-content/uploads/2012-Gala-press-release.pdf

NJ. The proximity between the State Court Judge and the MDL Judge would uniquely allow for State and Federal cooperation or coordination and easily allow for joint hearings. As many of the same counsel are involved in the state and federal litigation this will also allow the parties to conserve resources and reduce costs consistent with the intent of Section 1407. Further, given the proximity of the defendant, many witnesses will be located in New Jersey and many of the depositions will occur in New Jersey as well.

Accordingly, Plaintiff respectfully requests the Panel transfer these cases to the District of New Jersey with the Honorable Susan D. Wigenton assigned to preside.

CONCLUSION

For the reasons set forth above, Interested Party Plaintiff, Stephanie Teoli, respectfully requests this Panel consolidate all current and future Rejuvenate and ABG II modular-neck system cases and designate the District of New Jersey as the transferee forum with The Honorable Susan D. Wigenton presiding. In the alternative, Moving Party requests that this Panel designate the Northern District of Illinois or the Eastern District of Pennsylvania as the transferee forum.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2013, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will deliver the document to all counsel of record.

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