BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: POWER MORCELLATOR LITIGATION	MDL No. _____

BRIEF IN SUPPORT OF MOTION OF PLAINTIFFS ROBIN L. BARNETT; EVA C. GALAMBOS AND JOHN T. GALAMBOS; ARTHUR T. JOHNSON, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF JONEL ROLLINS DAVIS-JOHNSON, DECEASED; JENNIFER A. SANDERS AND RANDALL L. SANDERS; RUTHANN AND DARYL SMITH; AND CARLA AND JOE WHITEHEAD FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF KANSAS, PURSUANT TO 28 U.S.C. § 1407, AND JPML RULE 7.2, FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Plaintiffs in six of the twenty-two actions pending in sixteen United States District Courts listed on the Schedule of Actions (collectively "Plaintiffs"), respectfully submit this memorandum of law in support of their motion, pursuant to 28 U.S.C. § 1407, and JPML Rule 7.2, to centralize twenty-two related federal actions, and any subsequently filed related actions, before the Hon. Kathryn H. Vratil in the United States District Court for the District of Kansas for coordinated pretrial proceedings. The actions are product liability suits in which Plaintiffs assert claims against Defendants and others alleging that the use of a Power Morcellator during a laparoscopic hysterectomy or myomectomy for the removal of uterine fibroids can cause the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroids.

PRELIMINARY STATEMENT

Plaintiffs request coordination of the federal Power Morcellator actions in a multidistrict litigation ("MDL") because: **(i)** the complaints all assert product liability claims against Defendants based on allegations that the use of a Power Morcellator device during a laparoscopic hysterectomy or myomectomy for the removal of uterine fibroids can and did cause the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroids; **(ii)** the actions involve common questions of fact, including the issue of general causation, that is, whether the use of a Power Morcellator device is capable of causing the injuries alleged; **(iii)** transfer to a single district will be convenient for the parties and witnesses and will promote the just and efficient conduct of the litigation; and **(iv)** absent transfer and coordination, the parties and courts will face the burden and expense of needlessly duplicative discovery, pretrial proceedings and possible inconsistent pretrial rulings. The creation of an MDL at this time is appropriate because there are already twenty-two similar actions pending in sixteen different federal district courts, all in the preliminary stages of litigation, and additional actions are expected to be filed in, or removed to, federal court in the future.

In addition, Plaintiffs request that the MDL be assigned to the Hon. Kathryn H. Vratil in the U.S. District Court for the District of Kansas, an experienced judge in a highly accessible district where one of the actions is currently pending, and where the court has the requisite resources and expertise, including a prior record of managing MDL's.

STATEMENT OF FACTS

In the United States, it is estimated that 650,000 women a year will undergo a surgical myomectomy or hysterectomy for the management of symptomatic uterine fibroids. In conventional non-Power Morcellator hysterectomies, the woman's entire uterus is removed essentially intact and in conventional myomectomies the uterine fibroids are removed essentially intact and the women's uterus is left intact.

However, in the last two decades, laparoscopic procedures with electric Laparoscopic Power Morcellator devices to remove uterine fibroids or other tissue, have increasingly replaced traditional open abdominal surgical hysterectomies, myomectomies and laparotomies.

Laparoscopic Power Morcellators are electronically powered medical tools with spinning blades that shred, grind, and core tissue into smaller pieces or fragments so the tissue can be removed through small incisions or extraction "ports" in the abdomen. The Laparoscopic Power Morcellator device is designed with a grasper that pulls the tissue up against the sharp rotating blades, severing the shredded tissue from the rest of the large mass and continuously pulling cut portions of tissue up through the extraction tube. The morcellator's spinning blade shreds the tissue masses at a high velocity and can disperse cellular particles from the shredded tissue throughout the abdomen during surgery.

During electronic tissue morcellation, morcellated fragments can be left in the abdomino-pelvic cavity, or attach to surrounding organs (such as the loops of the bowel), and cancerous cells can travel to remote areas of the body through the vasculature or lymphatic system. Once disseminated in the body, morcellated fragments can become implanted in the surrounding tissue or organs, and begin to grow.

When tissue fragments escape into the abdomino-pelvic cavity and seed in other tissue or organs, complications can arise months or years after the surgery.

As a result, the use of a Laparoscopic Power Morcellator can spread, upstage or worsen a women's occult cancer, changing the stage of the cancer from an early stage cancer into a much higher stage cancer and significantly worsening a women's prognosis.

Power Morcellators have been widely promoted by the Defendants as an effective means of removal of uterine fibroids.

Power Morcellators have been linked to several severe medical disorders including, but not limited to, causing the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroids. Evidence linking the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroid and similar injury risks were not disclosed to or shared with the public, including Plaintiffs, by any Defendant. Instead, Defendants' strategy beginning in the early 1990's has been to aggressively market Power Morcellators by falsely misleading potential users about the products and by failing to protect users from serious dangers which Defendants knew or should have known could result from the use of these products.

On or about April 17, 2014, the Food and Drug Administration ("FDA") issued a Safety Communication Notice and Quantitative Assessment to inform health care providers and the public that "based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of woman with uterine fibroids." On November 24, 2014, the FDA issued an updated FDA Safety Communication regarding Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy.

> The update estimated approximately 1 in 350 women undergoing hysterectomy and myomectomy for the treatment of fibroids is found to have unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma. At this time, there is no reliable method for predicting or testing whether a women with fibroids may have a uterine sarcoma. If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's long-term survival.

Id.

Between early 2014 and the present, Plaintiffs filed twenty-two lawsuits in federal district courts in California, Colorado, Florida, Georgia, Kansas, Louisiana, Maryland, New Jersey, New York, Pennsylvania, South Carolina, Tennessee and Wisconsin alleging Defendants, and others, failed to adequately warn that the use of these electronic surgical devices during laparoscopic uterine surgery could cause the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroids, and that the Plaintiffs were injured as a result. In each case, the Plaintiffs' claim that Defendants failed to adequately warn that the use of a Power Morcellator could cause the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroids, and that the Plaintiffs were injured as a result. Two cases are currently pending in the Eastern District of California (*Kateian and Nielson*); one case is pending in the Northern District of California (*Salem-Robinson*); one case is pending in the District of Colorado (*Minihan*); one case is pending in the Southern District of Florida (*Kotis*); one case is pending in the Northern District of Georgia (*Galambos*); one case is pending in the District of Kansas (*Shafer*); one case is pending in the Eastern District of Louisiana (*Phillips*); one case is pending in the District of Maryland (*Caradori*); two cases are currently pending in

the District of New Jersey (*Smith and Whitehead*); one case is pending in the Northern District of New York (*Bobletz*); one case is pending in the Western District of New York (*Leuzzi*); two cases are pending in the Eastern District of Pennsylvania (*Burkhart and Johnson*); one case is pending in the Middle District of Pennsylvania (*Sanders*); four cases are pending in the District of South Carolina (*Gourdine, Ostrander, Watkins and Phillips*); one case is pending in the Middle District of Tennessee (*Schroeder*); and one case is pending in the Western District of Wisconsin (*Barnett)*.

The moving Plaintiffs are unaware of any other Power Morcellator-related lawsuits pending in any other federal court. However, upon information and belief, several additional actions have been filed in several state courts around the country. Given the widespread use of Power Morcellators and the harm they cause, it is likely that additional similar actions will be filed in or removed to federal courts in the future.

ARGUMENT

I. Transfer and Pretrial Coordination of These Related Actions Will Promote the Goals of 28 U.S.C. § 1407

Transfer and coordination of these related actions in a single court is appropriate and will promote the goals of 28 U.S.C. § 1407. Transfer under Section 1407 is appropriate where: **(i)** "civil actions involving one or more common questions of fact are pending in different districts"; **(ii)** transfer and coordination "will promote the just and efficient conduct of such actions"; and **(iii)** transfer and coordination will serve "the convenience of parties and witnesses." 28 U.S.C. § 1407(a). As set forth below, each of these criteria is satisfied here.

A. The Actions Involve Common Issues of Fact

The Power Morcellator actions share a substantial overlap of factual issues. Each alleges that the use of a Power Morcellator caused the dissemination and upstaging of occult cancer or the development of recurrent parasitic fibroids, and other injuries; and that Defendants failed to adequately warn of such risks. The actions involve the same categories of Plaintiffs: patients who had a Power Morcellator used during a laparoscopic hysterectomy or myomectomy for the removal of uterine fibroids and were injured.

Plaintiffs also assert similar causes of action, including negligence, strict liability – design defect, and strict liability - failure to warn. Some cases involve other, similar claims, including but not limited to: breach of express warranty, breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, violations of states consumer protection statutes and loss of consortium. Defendants contest Plaintiffs' allegations and assert that there is no scientific basis for claiming a causal connection between Power Morcellator use and the injuries alleged. It is clear that discovery relating to medical causation, the adequacy of product testing and warnings, and marketing will overlap across the cases, as will Defendants' anticipated challenges involving Plaintiffs' ability to satisfy the requirements of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Although the actions present certain individualized factual issues, "Section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization." *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F. Supp. 2d 1376, 1378 (J.P.M.L. 2010); *accord In re Denture Cream Prods. Liab. Litig.*, 624 F. Supp. 2d 1379, 1381 (J.P.M.L. 2009). Instead, where, as here, the underlying factual and legal allegations are sufficiently similar, "[t]ransferee judges have demonstrated the ability to accommodate common

and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits." *In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 597 F. Supp. 2d 1377, 1378 (J.P.M.L. 2009). Courts have applied this dual discovery approach in a number of recent product liability actions involving pharmaceutical products. *See, e.g.*, *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 655 F. Supp. 2d 1343, 1344 (J.P.M.L. 2009); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 655 F. Supp. 2d 1346, 1346 (J.P.M.L. 2009); *In re Vioxx*, 360 F. Supp. 2d at 1353-54.

B. Coordination Will Promote the Just and Efficient Management of Pretrial Proceedings in the Actions

Because they share common questions of fact and implicate overlapping discovery and expert and dispositive issues, coordination of these actions before a single judge will provide the most efficient approach to managing the cases at this time.

In each of the twenty-two pending actions, Plaintiffs are seeking or will seek much of the same discovery from Defendants, including documents and deposition testimony related to the testing, design, labeling, marketing, and safety of Power Morcellators. Coordinating the actions before one judge at this early stage will allow the parties and the court to address this overlapping discovery in an organized manner and avoid the potentially very costly duplication of efforts and judicial resources that would be required if the cases were to continue to proceed on separate schedules and in separate courts.

Indeed, this Panel has consistently recognized that Section 1407 coordination is a preferred way to manage individual lawsuits that raise similar questions regarding a Defendant's development, design, and testing of a particular prescription medication or device. *See, e.g.*, *In*

re A. H. Robins Co. "Dalkon Shield" IUD Prods. Liab. Litig., 406 F. Supp. 540, 542 (J.P.M.L. 1975); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 793 F. Supp. 1098, 1100 (J.P.M.L. 1992); *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 844 F. Supp. 1553, 1554 (J.P.M.L. 1994); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366, 1367 (J.P.M.L. 2003); *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1381-82 (J.P.M.L. 2004); *In re:* ***DePuy*** *Orthopaedics, Inc., ASR Hip Implant Prods. Liab. Litg.,* 753 F.Supp.2d 1378 (J.P.M.L. 2010); *In re:* ***DePuy*** *Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litg.,* 787 F.Supp.2d 1358, 1360 (J.P.M.L. 2011).

Coordination is also appropriate here to avoid potentially inconsistent pre-trial rulings on the same or similar issues and the uncertainty and confusion that would result. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, MDL No. 2272, 2011 WL 3563293, at *1 (J.P.M.L. Aug. 8, 2011) ("Centralization under Section 1407 will eliminate duplicative discovery, [and] prevent inconsistent pretrial rulings on *Daubert* and other pretrial issues . . ."); *In re Transocean Tender Offer Sec. Litig.*, 415 F. Supp. 382, 384 (J.P.M.L. 1976) ("[T]he likelihood of motions for partial dismissal and summary judgment in all three actions grounded at least in part on [a common issue] makes Section 1407 treatment additionally necessary to prevent conflicting pretrial rulings and conserve judicial effort.").

C. Coordination Will Serve the Convenience of Witnesses and Parties

For many of the same reasons that coordination will promote the just and efficient management of the actions at this time, it will also serve the convenience of the witnesses and parties. In particular, coordinating and streamlining discovery will minimize unnecessary

duplication, travel, and other expenses, and allow the parties to conserve, and more effectively focus, their resources in litigating these actions. As this Panel has noted:

> Since a Section 1407 transfer is for pretrial proceedings only, there is usually no need for the parties and witnesses to travel to the transferee district for depositions or otherwise. Furthermore, the judicious use of liaison counsel, lead counsel and steering committees will eliminate the need for most counsel ever to travel to the transferee district. And it is most logical to assume that prudent 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.

In re Baldwin-United Corp. Litig., 581 F. Supp. 739, 740-41 (J.P.M.L. 1984) (citations omitted).

In sum, coordination of these actions is appropriate because it would "eliminate duplicative discovery, prevent inconsistent pretrial rulings . . . and conserve the resources of the parties, their counsel and the judiciary." *In re Temporomandibular Joint (TMJ) Implants*, 844 F. Supp. at 1554.

II. Coordination in the United States District Court District of Kansas Is Appropriate

At this point in the litigation, transferring the Power Morcellator cases to the Hon. Kathryn H. Vratil in the United States District Court for the District of Kansas would best serve the purposes of 28 U.S.C. § 1407.

The Panel considers a variety of factors in determining where to transfer related cases, including the locations of pending cases; the location of the defendant; and the resources of the potential transferee districts and courts. *See, e.g., In re Cintas Corp. Overtime Pay Arbitration Litig.,* 444 F.Supp. 2d 1353, 1355 (J.P.M.L. 2006).

While Judge Vratil does not currently preside over a Power Morcellator case, there exists no restriction preventing the JPML from assigning her the Power Morcellator MDL. In

accordance with 28 U.S.C. §1407, there is no prohibition from assigning an MDL to a judge who is not assigned any of the transferee cases. Specifically, all that is stated is, "[s]uch coordinated or consolidated pretrial proceedings shall be conducted by a judge or judges to whom such actions are assigned by the judicial panel on multidistrict litigation." 28 U.S.C. §1407(b). Furthermore, when the JPML chooses to centralize a multidistrict action, it possesses broad discretion to select a transferee judge. There exists no articulated or promulgated method used by the JPML panel in assigning a judge to an MDL. The JPML has assigned judges to MDL's based on experience (*See*, *e.g.*, *In re Trasylol Products Liability Litig.,* 545 F. Supp. 2d 1357 (J.P.M.L. 2008), "we are assigning this litigation to a jurist who has the experience to steer this litigation on a prudent course."); *In re Conagra Peanut Butter Prods. Liab. Litig.*, 495 F. Supp. 2d 1381, 1382 (J.P.M.L. 2007) ("we are selecting a jurist experienced in multidistrict litigation to steer this matter on a prudent course."); *In re Wellnx Mktg. & Sales Practices Litig.*, 505 F. Supp. 2d 1380, 1381 (J.P.M.L. 2007) the JPML noted that the judge assigned the MDL was an "experienced MDL transferee judge to steer this litigation on a prudent course).

Consideration of the current pending cases weighs in favor of transfer to the Hon. Kathryn H. Vratil in the United States District Court for the District of Kansas.

A. The District of Kansas Is an Appropriate Forum for the Power Morcellator Cases

The District of Kansas would be a suitable forum for this MDL as the Court is centrally located for Plaintiffs and Defendants who reside throughout the country. The Defendant manufacturers of these devices reside in over 11 states in every region of the country with no manufacturer of a Power Morcellator device having the same principal place of business in the same state as another.

The District of Kansas has one of the least crowded dockets across the country and was the 54th-busiest U.S. District Court (out of 94 District Courts) by pending cases in the 12-month

period ending December 31, 2014.[1] The 10th Circuit also has one of the least crowded dockets of the Circuit Court of Appeals ranked 10th of eleven in pending cases in the 12-month period ending December 31, 2014. [2] It is important that the District Court be able to handle an MDL with the potential for hundreds of cases as the parties anticipate in the Power Morcellator litigation. There already is a pending Power Morcellator case filed in the District of Kansas, which is one of the twenty-two Power Morcellator cases filed in the U.S. federal courts to date.

Judge Vratil has experience presiding over Multi-District Litigations, including two which are currently assigned to her. She has worked with a number of Magistrate Judges who would be available to assist her with the Power Morcellator MDL including the two Magistrate Judges that assist her in the two MDL litigations she is currently presiding over. MDL dockets can include hundreds of cases where none or few plaintiffs are residents of the designated district court.

Lastly, the Kansas City, Kansas courthouse of the District of Kansas where Judge Vratil presides is a 20 minute drive from Kansas City International Airport in Kansas City, Missouri. This airport is accessible via several major hubs – Chicago, Dallas, Atlanta, and Denver. From Chicago O'Hare International alone, there are over twenty non-stop flights to Kansas City, Missouri each business day. That means that from virtually anywhere in the country, one can take a non-stop to Chicago and then, delayed or not, almost immediately take a short 1 hour, 40 minute flight to Kansas City. For attorneys practicing in an MDL, ease of travel is extremely important. For every trip out of Kansas City, lawyers will be to the airport and through security in literally 30 minutes from when they leave the courthouse. Kansas City International Airport

[1] http://www.uscourts.gov/Statistics/FederalCourtManagementStatistics/district-courts-december-2014.aspx

[2] http://www.uscourts.gov/Statistics/FederalCourtManagementStatistics/district-courts-december-2014.aspx

has at least 8 major car rental companies and multiple hotels are conveniently located within a 3 mile radius of the Kansas City courthouse with daily rates averaging less than $200. The Kansas City Downtown Marriott hotel has over 980 guest rooms, the Kansas City Convention Center attached to the hotel, business center, multiple conference rooms, fitness center, pool and restaurants starting at $169 per night.

In sum, the Honorable Kathryn H. Vratil and the United States District Court for the District of Kansas are well-equipped to handle and manage these actions, and would be an excellent choice for this MDL. Each of the major factors, docket, experience and convenience, are clearly met.

B. Judge Vratil Has the Skill and Experience to Supervise the Power Morcellator MDL

Judge Kathryn H. Vratil was confirmed to the United States District Court for the District of Kansas in 1992 following her nomination by former president George H.W. Bush. With this appointment, Judge Vratil became the first woman appointed to the United States District Court for the District of Kansas.

Judge Vratil graduated with a Bachelor of Arts from the University of Kansas, in 1971, where she later was inducted into the Emily Taylor Center for Women & Gender Equity at the University of Kansas Women's Hall of Fame. She received her Jurist Doctor ("J.D.") from the University of Kansas School of Law in 1975, where she was a member of the Order of the Coif. After receiving her J.D., from 1975-1978, Judge Vratil served as a law clerk to Hon. Earl E. O'Connor, U.S. District Court, District of Kansas, and it was his seat to which she was appointed to in 1992 when he took senior status. During the fourteen years before her appointment to the District of Kansas, Judge Vratil worked in private practice for the law firm of Lathrop &

Norquist (presently Lathrop & Gage LLP); a Kansas City, Missouri based civil defense firm. Judge Vratil was a partner in the litigation practice group specializing in commercial and business litigation. In 1990-1992, she took a position as Municipal Judge for the City of Prarie Village, Kansas.

Since her appointment, Judge Vratil has served as a justice of the Court and the District's Chief Judge from January 2008 to April 2014. She has participated on multiple regional and national judicial committees, including the Judicial Panel on Multidistrict Litigation, the Judicial Conference of the United States Committee on the Administrative Office, a member of the Board of Directors of the Federal Judicial Center, a member of the Federal Judicial Center Committee on District Judge Education, the U.S. District Court for the District of Kansas Bench Bar Committee, a Fellow of the American Bar foundation, and former president of the Earl E. O'Connor Inn of Court.

Judge Vratil served on the Judicial Panel on Multidistrict Litigation from February 2, 2004 to October 15, 2013, and was Acting Chairman from 2012 to 2013. She has been assigned two MDL cases by the JPML, including *In Re: Monsanto Company Genetically-Engineered Wheat Litig.*, 2:13-md-247, and *In Re: Motor Fuel Temperature Sales Practices Litig.*, 2:07-md-1840. Judge Vratil's skills and experience qualify her to preside over the Power Morcellator litigation.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request an Order transferring the actions identified in the accompanying Schedule of Actions, as well as any cases subsequently filed involving facts or claims to the Hon. Kathryn H. Vratil in the United States District Court for the District of Kansas for pretrial coordination and granting such other and further relief as the Panel may deem just and proper.

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Respectfully submitted,

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