BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: MIRENA® IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION	)	MDL Docket No.:_____

MEMORANDUM IN SUPPORT FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE, NASHVILLE DIVISION AND FOR COORDINATION OR CONSOLIDATION OF ALL PRETRIAL PROCEEDINGS PURSUANT TO 28 U.S.C. §1407

Plaintiffs, Brittany S. Smith, Shameka Bridges, Peterson Bridges, Shanika J. Houston, Lauren Hardwick, Emily C. Kellington, Katrina Dawn Copley, Katherine A. Creasy, Jenna Thurmond and Ashley Babich-Zacharias (hereinafter "Movants") respectfully move the Judicial Panel on Multidistrict Litigation ("JPML") for an Order pursuant to 28 U.S.C. §1407, to transfer the currently filed cases identified in the Schedule of Actions, as well as all cases subsequently filed involving similar facts or claims ("tag-along cases") to the United States District Court for the Middle District of Tennessee, Nashville Division, and to consolidate and coordinate all cases for pretrial proceedings before the Honorable John T. Nixon, Senior District Court Judge the United States District Court for the Middle District of Tennessee, Nashville Division.

One of the nine cases identified in the Schedule of Actions (the "Actions") is pending in the district Movants request.[1] Further, Movants request consolidation before the Honorable John

[1] "… about one-half of all open MDLs are comprised of ten of fewer actions." Hon. John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2241 (2008) (internal citations omitted). *See also In re TJX Cos., FACTA Litig.*, 505 F.Supp 2d 1379 (J.P.M.L. 2007) (Coordinating six actions); *In re Wellnx Mktg. & Sales Practices Litig.*, 505 F.Supp 2d 1380 (J.P.M.L. 2007) (Coordinating nine actions); *In re Paxil Prods. Liab. Litig.*, 296 F.Supp 2d 1374 (J.P.M.L 2003) (Coordinating eleven pharmaceutical cases); *In re Air West, Inc. Sec. Litigation*, 384 F Supp 609 (J.P.M.L 1974) (When 2 or more complaints assert comparable allegations against identical defendants based upon similar transactions and events, common factual questions are presumed, and mere fact that divergent legal theories are asserted arising out of same substantive claims and allegations presents no bar to 28 USC § 1407 transfer).

T. Nixon, Senior District Court Judge the United States District Court for the Middle District of Tennessee, Nashville Division, an experienced judge, with the most advanced case, sitting in a central and convenient location. All nine pending Actions name Bayer Healthcare Pharmaceuticals, Inc. (hereinafter "Defendant" or "Bayer") as a Defendant. These Actions all present common factual questions in that all of the plaintiffs' claims arise out of their respective use and personal injuries from Bayer's intra-uterine contraceptive system, commonly known as Mirena® IUS, all of the injuries are related to the release of Levonorgestrel (as contrasted with MDL-2434, which is limited to the migration of the device itself and perforation of or embedment in the cervix or uterine wall), and all of the injuries are related to the increased pressure on the brain caused by the build-up of cerebrospinal fluid.

Plaintiffs seek pretrial consolidation of the proposed Mirena® IUS Levonorgestrel-Related Product Liability Litigation multidistrict litigation ("MDL") at this time because it will serve the convenience of the parties and witnesses, will promote the just and efficient conduct of present and future actions, and will avoid inconsistent rulings in various courts. It is expected that once the due diligence vetting and gathering of medical evidence is completed, there will be hundreds of lawsuits filed throughout the country.

Currently, the undersigned counsel alone has approximately 65 clients who intend to file lawsuits in approximately 40 different jurisdictions arising from injuries substantially similar to the currently pending Actions. *See In re Mid-Air Collision*, 309 F. Supp. 621 (J.P.M.L. 1970) (Where there were at least 38 wrongful death actions arising from airplane collision pending in seven districts, litigation was multidistrict litigation within meaning of 28 USC § 1407). Additionally, Movants' counsel is aware of other attorneys in other jurisdictions who are preparing their respective cases for filing. Therefore, there is a very real risk of conflicting

rulings, including substantial variations in scheduling orders, from the various courts before which these Actions are now and will be pending. In fact, the case currently pending before Senior Judge John T. Nixon in the Middle District of Tennessee is scheduled for trial in September 2016.[2]

In light of continuing, widespread discovery of the relationship between the Mirena® IUS levonorgestrel-releasing product and the injuries at issue in the Actions, and the anticipated substantial new federal courts filings, a coordinated proceeding is both necessary and appropriate.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Common Facts in the Actions Support Transfer.

Mirena® is an intrauterine system (also known as an IUS) that is inserted by a healthcare provider during an office visit. Mirena® IUS is a T-shaped polyethylene frame with a steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as a contraceptive. The federal Food and Drug Administration ("FDA") approved Defendant's New Drug Application for Mirena® IUS in December 2000.

Today, more than 2 million women in the United States use Mirena® IUS. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendant admits "[i]t is not known exactly how Mirena works," but believes that Mirena® IUS may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

The Mirena® IUS is approved to remain in the uterus for up to five (5) years. Mirena®'s IUS label does not sufficiently warn about non-stroke neurological conditions such as

[2] *Katrina Dawn Copley v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 3:14-cv-406 (M.D. Tenn.) (filed February 11, 2014).

pseudotumor cerebri ("PTC"), also known as idiopathic intracranial hypertension ("IIH"). Indeed, Mirena®'s IUS label makes no mention of PTC/IIH, despite a known link between levonorgestrel and PTC/IIH.

Pseudotumor cerebri or idiopathic intracranial hypertension is a condition that develops in the skull when a person's cerebrospinal fluid becomes elevated, causing increased pressure. Fluid builds up in the skull and is not released and absorbed at the proper rate. PTC derives its name from the fact that the condition acts like a tumor but it is not actually a tumor. Patients with PTC or IIH typically develop symptoms of severe migraines or migraine-like headaches with blurred vision, diplopia (double vision), temporary blindness, blind spots, or other visual deficiencies. Visual problems and symptoms frequently are a result of increased pressure on the optic nerve. Patients with PTC or IIH often develop papilledema, or optic disc swelling due to increased intracranial pressure. PTC or IIH patients may also develop a "whooshing" or ringing in the ear, clinically called tinnitus.

PTC or IIH is frequently diagnosed after a lumbar puncture, or spinal tap, is performed which allows a physician to evaluate the level of cerebrospinal fluid in the skull. When patients present with symptoms of PTC or IIH, they often first undergo an MRI, CT scan, and/or other diagnostic radiology tests to rule out an actual tumor or blood clot in the brain. A lumbar puncture is a diagnostic, and sometimes, therapeutic procedure by which a physician inserts a hollow needle into the subarachnoid space in the lumbar area, or lower back of a patient, and draws cerebrospinal fluid ("CSF") from the patient. The collected cerebrospinal fluid is tested to rule out infection or inflammation in the fluid that may be responsible for the elevated pressure. In patients with PTC or IIH, the cerebrospinal fluid is normal. In some cases, a lumbar puncture may provide some immediate relief to a patient suffering from PTC or IIH, but it does not cure to

the condition. Conversely, a lumbar puncture may result in a post-lumbar puncture headache, bleeding or back pain.

Failure to correctly diagnose and treat PTC or IIH may lead to permanent vision loss and even blindness. There is currently no treatment to reverse permanent injury to the optic nerves caused by increased intracranial pressure. Because of this, treatment of PTC or IIH is focused on halting visual loss that has already occurred. Although PTC or IIH is considered reversible in some patients, it may take years before normal pressure is maintained. It also may be irreversible in some cases. PTC or IIH may also recur throughout a patient's lifetime.

In severe cases, therapeutic shunting, which involves surgical insertion of a tube to help drain cerebrospinal fluid from the lower back or from the skull, is recommended. A lumbar-peritoneal shunt ("LP shunt") is commonly used to treat severe cases of PTC/ IIH. An LP shunt involves inserting a tube between vertebrae in the lumbar region of the spine into the subarachnoid cavity. A ventriculo-peritoneal shunt ("VP shunt") may also be used, which involves insertion of a tube through a patient's skull usually behind a patient's ear. Both types of shunting procedures work to relocate excess cerebrospinal fluid to the abdominal cavity, where it can be absorbed. Unfortunately, therapeutic shunting procedures have high failure and revision rates and often require several repeat or revision surgeries. Additionally, a patient's shunt may need frequent adjustment, which may also require surgical intervention, to find the right setting for a particular patient's needs.

It has been estimated that approximately 1-2 people per 100,000 in the United States have PTC or IIH, although reports suggest the prevalence of the disorder is increasing. In 1994, a study found that in females between the ages of 15 to 44, IIH occurred at a rate of approximately

3.3 per 100,000 per year.[3] Despite the rarity of PTC/IIH, upon information and belief, women who use levonorgestrel-containing products, like the Mirena® IUS, more commonly develop the disorder. It is believed that the synthetic hormone released by Mirena® IUS, levonorgestrel, causes or contributes to the development of PTC/IIH, increases the risk of developing PTC/IIH, and/or worsens or exacerbates PTC/IIH. Additionally, because Mirena® IUS is known to cause rapid weight gain in women, the risk of developing PTC/IIH is even greater with Mirena® IUS use.

In 1991, a levonorgestrel-releasing implant called Norplant® became available in the United States, after its manufacturer obtained FDA approval on December 10, 1990. Norplant® was developed by the Population Council and distributed in the United States by Wyeth-Ayerst Laboratories as the "Norplant System." Norplant® consists of a set of six small silicone capsules, each containing 36 mg of levonorgestrel, which are implanted subdermally in the upper arm and effective for five years. Norplant® was estimated to release levonorgestrel initially at about 85 μg/day followed by a decline to about 50 μg/day after nine months and to about 35 μg/day by 18 months with a further decline to about 30 μg/day.

In February 1993, Wyeth submitted a supplemental new drug application to the FDA for the Norplant System, requesting the addition of "idiopathic intracranial hypertension" and other modifications to the PRECAUTIONS section of Norplant System's physician labeling. The supplemental NDA also requested other modifications to the physician labeling and the patient package insert. Wyeth requested expedited review of its supplemental NDA.

On March 26, 1993, the FDA approved the supplemental NDA, including its proposed addition of warnings regarding PTC/IIH to the Norplant System. The new labeling addition

[3] *See* John B. Alder & F.T. Fraunfelder, *Letter to the Editor: Levonorgestrel Implants and Intracranial Hypertension*, 332 New Eng. J. Med. 1720, 1720-21 (1995), available at http://www.nejm.org/doi/full/10.1056/NEJM199506223322519.

included under the PRECAUTIONS section stated:

> "Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care. NORPLANT SYSTEM should be removed from patients experiencing this disorder."

A warning for PTC/IIH was also added to the patient package insert and stated:

> "Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) – An increase in intracranial pressure has been reported in NORPLANT SYSTEM users. Symptoms may include headache (associated with a change in the frequency, pattern, severity, or persistence, of particular importance are those headaches that do not stop) and visual disturbances. Contact your physician or health-care provider if you experience these symptoms. While a causal relationship is unclear, your health-care provider may recommend that the NORPLANT SYSTEM be removed."

By 1995, several reports of women developing PTC or IIH were reported in The New England Journal of Medicine.[4] The authors noted that levonorgestrel may have contributed to the onset of the condition. The authors concluded that until more information became available, patients should be screened for symptoms and the implants should be removed in patients who show increased intracranial pressure. Additional studies concluded the same and noted that IIH/PTC had been reported in Norplant users.[5] By 2001, Norplant®'s label included an entry under the "Warnings" section for "Idiopathic Intracranial Hypertension" that stated:

> Idiopathic intracranial hypertension (pseudotumor cerebri, benign intracranial hypertension) is a disorder of unknown etiology which is seen most commonly in

[4] *See Id*.

[5] *See* Allan J. Coukell & Julia A. Balfour, *Levonorgestrel Subdermal Implants: A Review of Contraceptive Efficay and Acceptability*, 55 Drugs 861, 877 (1998); Karen R. Meckstroth & Philip D. Darney, *Implantable Contraception*, 27 Obstet Gynecol Clin North Am 781, 796 (2000); and Wysowski DK, Green L., *Serious adverse events in Norplant users reported to the Food and Drug Administration's MedWatch Spontaneous Reporting System.*, 85 Obstet Gynecol. 538-42 (1995).

> obese females of reproductive age. There have been reports of idiopathic intracranial hypertension in NORPLANT (levonorgestrel implants (unavailable in us)) SYSTEM users. A cardinal sign of idiopathic intracranial hypertension is papilledema; early symptoms may include headache (associated with a change in frequency, pattern, severity, or persistence; of particular importance are those headaches that are unremitting in nature) and visual disturbances. Patients with these symptoms, particularly obese patients or those with recent weight gain, should be screened for papilledema and, if present, the patient should be referred to a neurologist for further diagnosis and care. NORPLANT (levonorgestrel implants (unavailable in US)) SYSTEM should be removed from patients experiencing this disorder.

Jadelle® or "Norplant® II", which is a two-rod levonorgestrel-releasing implant, also contains similar language under the "Warnings" section of its label. And importantly, Jadelle® is contraindicated in patients with a history of IIH. Jadelle® was approved in the United States in 1996 for up to three years use and in 2002 for up to five years use. However, Jadelle® has never been marketed in the United States. Both the Norplant® and Jadelle® labels included warnings of PTC/IIH specific to informing patients of the disorder.

By the mid-1990s, tens of thousands of lawsuits were filed claiming injuries due to Norplant®. In 1996, the FDA received a "Citizen's Petition before the Food and Drug Administration requesting withdrawal for sale of Norplant®."[6] The petition claimed a number of adverse events were related to Norplant® use, including PTC/IIH. Wyeth pulled Norplant® off the market in June of 2002. Despite a wide body of information available to Defendant regarding the connection between levonorgestrel and PTC/IIH, Mirena®'s IUS label is devoid of any warning regarding PTC or IIH. Because Mirena®'s IUS label is devoid of any warnings of PTC or IIH, once a patient's healthcare provider rules out transient cerebral ischemia or stroke as a cause of symptoms of migraine and/or asymmetrical visual loss, the healthcare provider will not typically know or advise a patient with PTC to remove Mirena® IUS, which causes or contributes to the development and/or progression of PTC/IIH.

[6] *See* http://pop.org/content/norplant-background-a-pri-petition-888.

The United States package labeling for Mirena® IUS does not warn about the injuries at issue in these Actions. The Actions allege that Defendant has a history of overstating the efficacy of Mirena® IUS while understating the potential safety concerns to the detriment of Plaintiffs. All of the Actions similarly allege that the respective Plaintiffs had the Mirena® IUS and that all suffered levonorgestrel-related injuries caused by the increased buildup of cerebrospinal fluid on the brain.

B. Procedural History

On December 13, 2013, Plaintiff, Brittany S. Smith, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Western District of Kentucky.[7] Plaintiff's case was assigned to the Honorable John G. Heyburn II. Subsequently, Bayer filed a Motion to Dismiss Plaintiff's Complaint and Plaintiff filed her Opposition to Bayer's Motion to Dismiss. The motion is still pending at this time.

On January 8, 2014, Plaintiffs, Shameka and Peterson Bridges, along with Plaintiff, Shenika J. Houston, filed personal injury lawsuits against Bayer arising out of Plaintiffs' use of and injury from Mirena® IUS in the United States District Court for the Northern District of Alabama.[8] Plaintiffs' cases were assigned to the Honorable William M. Acker, Jr. Subsequently, Bayer filed a Motion to Dismiss Plaintiff's Complaint and Plaintiffs' filed their Opposition to Bayer's Motion to Dismiss. Judge Acker ruled on the motions to dismiss and ordered the cases to proceed. Defendant answered the Complaints on April 11, 2014. The parties' initial disclosures are due on May 27, 2014. The parties have submitted proposed scheduling orders

[7] *Brittany S. Smith v. Bayer Healthcare Pharmaceuticals Inc.*, Case No. 3:14-cv-6 (W.D. Ky.) (filed December 13, 2013).

[8] *Shameka and Peterson Bridges v. Bayer Healthcare Pharmaceuticals Inc.,* Case No. 2:14-cv-36 (N.D. Ala.) (filed January 8, 2014) and *Shenika J. Houston v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 2:14-cv-35 (N.D. Ala.) (filed January 8, 2014).

and the Court has scheduled an initial case management conference for May 28, 2014.

On January 17, 2014, Plaintiff, Lauren Hardwick, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Western District of Kentucky.[9] Plaintiff's case was assigned to the Honorable John G. Heyburn II. Subsequently, Bayer filed a Motion to Dismiss Plaintiff's Complaint and Plaintiff filed her Opposition to Bayer's Motion to Dismiss. The motion is still pending at this time.

On February 6, 2014, Plaintiff, Emily C. Kellington, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Western District of Virginia.[10] Plaintiff's case was assigned to the Honorable Michael F. Urbanski. Defendant answered the Complaint on May 5, 2014. The parties are in the process of preparing proposed scheduling orders for submission to the Court.

On February 11, 2014, Plaintiff, Katrina Dawn Copley, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Middle District of Tennessee.[11] Plaintiff's case was assigned to the Honorable John T. Nixon. Defendant answered the Complaint on March 12, 2014. The parties filed their proposed case management orders on April 3, 2014. Magistrate Judge E. Clifton Knowles conducted the initial case management conference on April 7, 2014, with appearances from Defendant's national and local counsel as well as Plaintiff's counsel. The parties made their initial disclosures on May 7, 2014. Plaintiff served her first set of discovery requests on

[9] *Lauren Hardwick v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 3:14-cv-82 (W.D. Ky.) (filed January 17, 2014).
[10] *Emily C. Kellington v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 5:14-cv-2 (W.D. Va.) (filed February 6, 2014).
[11] *Katrina Dawn Copley v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 3:14-cv-406 (M.D. Tenn.) (filed February 11, 2014).

May 24, 2014. The Court scheduled a target trial date of September 20, 2016.[12]

On February 20, 2014, Plaintiff, Katherine A. Creasy, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Eastern District of Tennessee.[13] Plaintiff's case was assigned to the Honorable Thomas A. Varlan. Defendant answered the Complaint on May 5, 2014. There has been no subsequent action in the case.

On March 20, 2014, Plaintiff, Jenna Thurmond, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Northern District of Georgia.[14] Plaintiff's case was assigned to the Honorable Orinda D. Evans. Defendant answered the Complaint on April 28, 2014. The parties filed their proposed scheduling orders on May 23, 2014. There has been no subsequent action in this case.[15]

On May 15, 2014, Plaintiff, Ashley Babich-Zacharias, filed a personal injury lawsuit against Bayer arising out of Plaintiff's use of and injury from Mirena® IUS in the United States District Court for the Western District of Kentucky.[16] Plaintiff's case was assigned to the Honorable Thomas B. Russell. Defendant has not yet answered the Complaint or filed a Motion to Dismiss.

Because some courts have ruled on Bayer's Motions to Dismiss, while other courts

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[12] The Court also set a fact discovery cut-off deadline of October 23, 2015 and an expert discovery cut-off deadline of April 25, 2016, along with deadlines for filing dispositive and *Daubert*-related motions on June 8, 2016.

[13] *Katherine A. Creasy v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 3:14-cv-64 (E.D. Tenn.) (filed February 20, 2014).

[14] *Jenna Thurmond v. Bayer Healthcare Pharmaceuticals, Inc.*, Case. No. 1:14-cv-822 (N.D. Ga.) (filed March 20, 2014).

[15] Defendant has, however, served "cross-notices" to various depositions being conducted in the unrelated MDL 2434. However, because discovery has not commenced in most of the Actions, and Plaintiff do not have access to documents to adequately prepare for those depositions, the Plaintiffs have filed "objections" to each of the cross-notices.

[16] *Ashley Babich-Zacharias v. Bayer Healthcare Pharmaceuticals Inc.*, Case No. 5:14-cv-101 (W.D. Ky.) (filed May 15, 2014).

currently have them under advisement, and Bayer has opted to not file Motions to Dismiss in the Tennessee Cases, the Georgia Case, and the Virginia Case, there is a real risk of inconsistent rulings from different district courts regarding the factual sufficiency of the Complaints. Moreover, while Judge Nixon's scheduling order provides for the orderly management of the *Copley* case, including reasonable discovery and briefing deadlines, the Defendant is pushing for much more aggressive discovery cut-off deadlines in the Alabama, Georgia, and Virginia cases – risking premature (and inconsistent) rulings, duplicitous depositions, and other inefficiencies and injustices that may impact the *Copley* case. *See In re Advanced Inv. Mgmt., L.P., Pension Fund Mgmt. Litig*., 254 F. Supp. 2d 1377 (J.P.M.L 2003). (Transfer and centralization of multidistrict litigation actions was considered necessary where it prevented duplicative discovery, inconsistent pretrial rulings, and conserved resources of parties and court); *see also In re TJX Cos., FACTA Litig.*, 505 F. Supp. 2d 1379 (J.P.M.L 2007). Allowing inconsistent scheduling of things such as discovery cut-offs, *Daubert* motions, and dispositive motions in various jurisdictions will ultimately prove to be chaotic, disorderly, expensive and inefficient. Transferring and centralizing these Actions before Judge Nixon, the judge with the most procedurally advanced case, promotes uniform and expeditious treatment, while at the same time conserving valuable judicial resources. *See In re Global Crossing Ltd. Secs. & "ERISA" Litig.*, 223 F. Supp. 2d 1384 (J.P.M.L 2002) (Fifty-seven action pending actions were consolidated in District Court for Southern District of New York, where eighteen constituent actions and eight potential tag-along actions were pending; centralization was necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve resources of parties, their counsel, and the judiciary); *see also In re Progressive Corp. Ins. Underwriting & Rating Practices Litig.*, 259 F. Supp. 2d 1370 (J.P.M.L 2003) (Centralization was necessary to eliminate

duplicative discovery, prevent inconsistent pretrial rulings, and conserve resources of parties, their counsel, and the judiciary). Therefore, transfer is both necessary and appropriate.

II. THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE IS THE IDEAL TRANSFEREE DISTRICT COURT

A. Transfer and Consolidation or Coordination of All Actions Is Appropriate Under 28 U.S.C. §1407.

28 U.S.C. §1407 provides for the transfer of actions to one district for coordinated or consolidated pretrial proceedings where actions pending in different districts involve one or more common questions of fact. 28 U.S.C. §1407(a):

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.

Transfers are authorized where the Panel determines that such transfer will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions. *Id.* The purpose of the multidistrict litigation process is to "eliminate the potential for contemporaneous pretrial rulings by coordinating district and appellate courts in multidistrict related civil actions." *In re Multidistrict Private Civ. Treble Damages Litig.*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968). Coordination is especially important in multidistrict litigations where "the potential for conflicting, disorderly, chaotic" action is greatest. *Id.* at 493.

Transfer of related actions to a single district for pretrial proceedings avoids conflicting pretrial discovery and ensures uniform and expeditious treatment in the pretrial procedures. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1230 (9th Cir. 2006).

Moreover, the Panel "considers that eliminating duplicate discovery in similar cases, avoiding conflicting judicial rulings, and conserving valuable judicial resources are sound reasons for centralizing pretrial proceedings." *See* Hon. John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2236 (2008).

Transfer, coordination and consolidation are appropriate here because many common questions of fact and law exist. Each of the related Actions herein arises from the same or similar nucleus of operative facts (i.e., the levonorgestrel component of the IUS) versus MDL-2434 (which involves migration of the device itself). All of the Actions allege personal injuries caused by the levonorgestrel released from the Mirena IUS® that is manufactured and sold by Bayer. All of the Actions allege that the individual plaintiffs' personal injuries are related to a buildup of cerebrospinal fluid pressure on the brain, causing injuries such as pseudotumor cerebri or idiopathic intracranial hypertension, manifesting as severe migraines or migraine-like headaches with blurred vision, diplopia (double vision), tinnitus, temporary blindness, blind spots, optic nerve swelling (papilledema) or other visual deficiencies.

Plaintiffs in all Actions challenge the safety of the Mirena IUS®, inadequate testing of the Mirena® IUS, and inadequate product warning information about the Mirena® IUS that was given to patients and their healthcare providers. Indeed, their respective Complaints are virtually identical. Accordingly, transfer for coordinated or consolidated pretrial proceedings will serve the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions.

B. The United States District Court For The Middle District Of Tennessee Is The Ideal Forum For Transfer And Consolidation For Coordination.

In selecting the transferee court, according to the MANUAL FOR COMPLEX LITIGATION

(FOURTH) §20.131 (2010), the Panel considers several factors including, but not limited to "where the largest number of cases is pending, where discovery has occurred, where cases have progressed furthest, the site of the occurrence of the common facts, 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) (Centralization of multidistrict litigation in Northern District of Ohio permitted judicial panel to assign case to available transferee judge with successful experience in multidistrict litigation and court equipped to handle litigation).

The United States District Court for the Middle District of Tennessee, Nashville Division, is centrally located geographically and therefore provides economical access to the Court for the parties, the witnesses and their respective counsel. The District Court is located in Nashville, Tennessee and is accessible by most major airlines, including the discount carrier, Southwest Airlines. Many have direct flights to the Nashville International Airport from major cities throughout the United States, with numerous flights daily arriving from and departing to the New York/New Jersey area (where the Defendant is located) and Chicago (where Defendant's National Counsel is located).[17] Lead Counsel for the Plaintiffs/Movants are located in Louisville, Kentucky, approximately two-and-a-half hours by car to Nashville.

Currently, the Middle District of Tennessee has only one pending MDL docket (*In re Aredia & Zometa Prods. Liab. Litig.*, MDL-1760), over which Judge Todd J. Campbell presides.[18] Senior District Judge Nixon, as a senior judge, presumably has a reduced case docket as compared to the other judges within the District. Moreover, he presides over the only case in which discovery has commenced, a trial date has been assigned and briefing deadlines have been

[17] http://www.flynashville.com/flights/Pages/airline-information.aspx
[18] http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-May-15-2014.pdf

set. As such, Senior Judge John T. Nixon of the Middle District of Tennessee, Nashville Division is best-suited to handle this MDL.

C. The Honorable John T. Nixon of the Middle District of Tennessee, Nashville Division is the Ideal Transferee Judge for the Proposed Mirena® IUS Levonorgestrel-Related Product Liability Litigation MDL.

"Ultimately, the Panel's goal is to pair an experienced, knowledgeable, motivated, and available judge in a convenient location with a particular group of cases."[19] Moreover, the "ideal transferee judge is one with some existing knowledge of one of the cases to be centralized and who may already have some experience with complex cases."[20] Further, the "willingness and motivation of a particular judge to handle an MDL docket are ultimately the true keys to whether centralization will benefit the parties."[21]

Senior District Judge John T. Nixon of the Middle District of Tennessee, Nashville Division is an ideal transferee judge for this MDL. Senior District Judge Nixon has served on the federal bench since 1980—serving as the Chief Judge from 1991-1998. Before ascending to the federal bench, he served as a state court judge. Senior District Judge Nixon and his very able Magistrate Judge (Judge E. Clifton Knowles) have prior MDL experience, *see In Re: Nortel Networks Corp. "ERISA" Litigation*, MDL-1537. Based upon their prior MDL experience, their familiarity with the *Copley* Action, and the fact that the *Copley* case is the only action in which discovery has commenced and a trial date has been set, Senior District Judge Nixon and Magistrate Judge Knowles are the ideal team to manage the proposed Mirena® IUS Levonorgestrel-Related Products Liability Litigation MDL.

Alternatively, Senior District Judge William M. Acker, Jr. of the United States District

[19] Hon. John G. Heyburn II, *A View from the Panel: Part of the Solution*, 82 Tul. L. Rev. 2225, 2241 (2008).
[20] *Id.* at 2240.
[21] *Id.*

Court for the Northern District of Alabama (who presides over the next two furthest advanced cases) or Senior District Judge John G. Heyburn II of the United States District Court for the Western District of Kentucky (who also presides over two cases) would be excellent choices as transferee judge for this MDL.

III. CONCLUSION

For the reasons discussed above, Movants respectfully request that the Panel transfer the Actions for coordinated and consolidated pretrial proceedings to the United States District Court for the Middle District of Tennessee, Nashville Division before the Honorable John T. Nixon.

Dated: May 27, 2014

Respectfully submitted,

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