

**BEFORE THE UNITED STATES  
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION**

**IN RE: ELMIRON (Pentosan Polysulfate )  
Sodium) PRODUCTS LIABILITY ) MDL Docket No.: \_\_\_\_  
LITIGATION )**

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS’  
MOTION TO TRANSFER ACTIONS TO THE DISTRICT OF NEW  
JERSEY PURSUANT TO 28 U.S.C. § 1407 FOR CONSOLIDATED  
PRETRIAL PROCEEDINGS**

**I. PRELIMINARY STATEMENT**

Movants SHERRY DOBBINS AND JAMES DOBBINS (collectively, “Plaintiffs”)<sup>1</sup>, who are Plaintiffs in one of 24 civil actions pending in the United States District Court for the District of New Jersey before the Honorable Brian R. Martinotti<sup>2</sup> (as identified in the Schedule of Actions annexed hereto), submit this Memorandum of Law in support of their Motion to Transfer and centralize all currently filed cases listed in the annexed Schedule of Actions (“the Actions”), as well as any subsequently filed cases involving common questions of fact (“tag-along actions), for coordinated or consolidated pretrial proceedings before Judge Martinotti in the District of New Jersey pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation (“Panel”).

Your undersigned’s law firm represents the aforementioned Plaintiffs in their case pending in the District of New Jersey,<sup>3</sup> who are seeking recovery against Defendants JANSSEN

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<sup>1</sup> *Sherry Dobbins and James Dobbins v. Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica Inc. f/k/a Ortho-McNeil Janssen Pharmaceuticals, Inc.; Janssen Ortho LLC; Janssen Research & Development, LLC f/k/a Johnson & Johnson Pharmaceutical Research & Development L.L.C.; Ortho-McNeil Pharmaceuticals, LLC, Johnson & Johnson Company; Teva Branded Pharmaceutical Products R&D, Inc.; and Teva Pharmaceuticals USA, Inc.*; Case No- 3:20-cv-09530 (D.N.J.)

<sup>2</sup> Upon information and belief, Judge Brian R. Martinotti sits in both the Trenton Division and the Newark Division.

<sup>3</sup> Our office currently represents and is investigating claims on behalf of over 100 additional potential plaintiffs.

PHARMACEUTICALS, INC. f/k/a, JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN ORTHO LLC; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC; ORTHO-MCNEIL PHARMACEUTICALS, LLC; JOHNSON & JOHNSON COMPANY; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; and TEVA PHARMACEUTICALS USA, INC. (hereinafter referred to as “Defendants”), for personal injuries caused by its pharmaceutical drug Elmiron. At all relevant times, Defendants created, designed, developed, manufactured, labeled, promoted, marketed, distributed and/or sold Elmiron and/or were responsible for introducing it into the stream of commerce.

In addition to the 24 cases filed in the District of New Jersey, all of which have been assigned to Judge Martinotti, there are 39 additional personal injury actions filed in 10 different federal courts across the country related to Elmiron (for a total of 63 actions filed in 11 federal courts). It is anticipated that the number of filed cases both before Judge Martinotti<sup>4</sup> as well as those being filed in other federal district courts will continue to increase. It is estimated that there are likely a few thousand potential Elmiron cases to be filed. Given the volume of actions filed and the overlapping nature of the facts and issues involved, Plaintiffs respectfully submit that transfer, centralization, consolidation and coordination of all Elmiron actions into one multidistrict litigation (“MDL”) pursuant to 28 U.S.C. § 1407 is undoubtedly warranted.

A MDL would be the most efficient and most appropriate course of action for the Panel because it would: (1) promote the just and efficient conduct of these actions; (2) prevent inconsistent pretrial rulings and duplicative discovery; and (3) conserve the resources of the

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<sup>4</sup> As noted below, because a majority of Defendants are citizens and residents of New Jersey with their principal places of businesses within New Jersey, non-resident plaintiffs can properly file in New Jersey federal court.

judiciary, the parties and their counsel.

To this end, Plaintiffs respectfully request an Order be entered by the Panel consolidating and coordinating the Actions, as well as any future tag-along actions, and further transferring said actions to the United States District Court for the District of New Jersey before the Honorable Brian R. Martinotti.

## **II. FACTUAL CLAIMS ABOUT ELMIRON**

Elmiron is a pharmaceutical prescription drug approved by the United States Food and Drug Administration (“FDA”) in September 1996 for the relief of pain or discomfort associated with interstitial cystitis – a chronic bladder condition affecting millions of people, mainly women. Interstitial cystitis causes increased bladder pressure, bladder pain, and at time even pelvic pain. Approved since 1996, Elmiron remains the only oral drug approved for this indication in the United States.

Prior to its approval in 1996, Defendants conducted pre-approval clinical studies, and, it appears that during these studies, vision-related adverse events, including optic neuritis, amblyopia, and retinal hemorrhage, were reported. Following Elmiron’s approval in 1996, Defendants received multiple Adverse Event Reports (hereinafter referred to as “AERs”), both in the United States and internationally, detailing injuries associated with the drug, including serious visual symptoms and/or damage, but Defendants did nothing with these AERs.

Recently, beginning in or about Spring of 2018, medical reports and findings have been published by reputable medical clinics, including the Emory Eye Center, Kaiser Permanente and Harvard, in which the safety of the drug has been called into question. Specifically, these reports and findings strongly support that Elmiron use can cause unusual retinal pigmentary changes or

maculopathy not resembling any other type of retinal disease.<sup>5</sup> Additionally, these reports and findings demonstrated that Elmiron-related maculopathy continues to evolve after drug cessation and may pose a long-term threat to central vision.<sup>6</sup>

Despite adverse event information obtained during Elmiron's preclinical trials, AERs received after Elmiron was approved by the FDA and/or the overwhelming body of research and literature discussed above, Defendants did not update the Elmiron U.S.A. label to include a warning regarding retinal pigmentary changes and to recommend initial and periodic retinal screening both during and following Elmiron use until June 16, 2020.<sup>7</sup> By contrast, Defendants had updated its labels in Canada and Europe in 2019 to include warnings regarding pigmentary maculopathy.<sup>8</sup>

It is increasingly clear that Defendants neglected to provide sufficient warning of the adverse events associated with Elmiron. Furthermore, Defendants' marketing of these drugs as a

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<sup>5</sup> Pearce WA, et al. *Re: FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials: Future Direction for Research*. J Urol 2018;200(5):1122-1123; Pearce WA, et al. *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium*. Ophthalmology. 2018 May 22; Foote, et al. 2019. *Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary Changes and Vision Loss*. AUA 2019 Abstract MP47-03; Hanif AM, et al. *Strength of Association between Pentosan Polysulfate and a Novel Maculopathy*. Ophthalmology. 2019 Oct;126(10):1464-1466; Hanif A, et al. *Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A Multicenter Study*. JAMA Ophthalmol. 2019;137(11):1275-1282; *More Evidence Linking Common Bladder Medication to a Vision-threatening Eye Condition.* AAO Press Release. Oct. 12, 2019; Vora RA, et al. *Prevalence of Maculopathy Associated with Long-Term Pentosan Polysulfate Therapy*. Ophthalmology. 2020 June;127(6):835-836; Schaal, S. and Hadad, A. *Qualitative and Quantitative Analysis of Pentosan Polysulfate Sodium Retinal Toxicity Demonstrates a Dose-Response Curve.* AAO PA068 – 2019; Jain N, et al. 2019. *Association of macular disease with long-term use of pentosan polysulfate sodium: findings from a US cohort*. Br. J. Ophthalmol. 2019 Nov 6.

<sup>6</sup> Huckfeldt R, et al. *Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium*. Ophthalmic Surgery, Lasers & Imaging Retina. 2019;50(10):656-659; Shah, R., et al. *Disease Course in Patients With Pentosan Polysulfate Sodium-Associated Maculopathy After Drug Cessation*. JAMA Ophthalmology. July 9, 2020.

<sup>7</sup><https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2277#>

<sup>8</sup><https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch/health-product-infowatch-october-2019.html#elmiron>

[https://www.ema.europa.eu/en/documents/scientific-conclusion/elmiron-h-c-psusa-00010614-201812-epar-scientific-conclusions-grounds-variation-terms-marketing\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-conclusion/elmiron-h-c-psusa-00010614-201812-epar-scientific-conclusions-grounds-variation-terms-marketing_en.pdf)

safe and effective medication to relieve the pain and discomfort associated with interstitial cystitis without proper warnings was negligent and irresponsible given that the dangers associated with Elmiron far outweighed any purported benefit the drug may have.

Defendants' failure to adequately warn of the potential dangers associated with Elmiron prevented the medical community and the general public from making informed decisions about prescribing and/or using Elmiron, and likely thousands of individuals suffered adverse events due to their use of Elmiron. Upon information and belief, it is estimated that thousands individuals experienced serious ocular injuries, including but not limited to retinal pigmentary changes and/or maculopathy, as a direct and proximate result of using and ingesting Defendants' Elmiron. Many of these injured individuals have filed or will be filing lawsuits against Defendants.

### III. ARGUMENT

#### A. MULTIDISTRICT CENTRALIZATION IS APPROPRIATE FOR THESE CASES ONLY IN THE PROPER VENUE

Under 28 U.S.C. § 1407, the Panel *may* consolidate numerous cases if the moving party sufficiently demonstrates that (1) the lawsuits contain common questions of fact, (2) consolidation would best serve the convenience of the parties and witnesses, and (3) consolidation promotes just and efficient conduct of such actions. *See* 28 U.S.C. § 1407. Plaintiffs respectfully submit that the Elmiron Actions meet the statutory requisites for the Panel's determination that centralization is warranted.

Indeed consolidation of these actions to one district court for pre-trial proceedings is the most appropriate course of action for this Panel to take because the factors for centralization have been demonstrated, and, thus, centralization and coordination of pretrial proceedings against Defendant is warranted.

First, each of the related Elmiron actions against Defendants allege very similar, if not

virtually identical, causes of action and contain the same allegations about Elmiron and the propensity of Elmiron to cause serious injuries, including retinal pigmentary changes and/or maculopathy. These actions are based upon the same or substantially similar underlying facts: (1) Elmiron can cause retinal pigmentary changes and/or maculopathy as supported by, among other things, the growing medical literature; (2) Defendants negligently created, designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed and sold Elmiron to the public, including the Plaintiffs in the respective actions and caused their alleged injuries; (3) Defendants knew or should have known of the dangers and defects associated with Elmiron; (4) Defendants failed to warn the of the dangers and defects associated with Elmiron; and (5) all Plaintiffs suffered grave ocular injuries as a result of using Defendant's defective Elmiron.

In response to these common allegations, Defendants will likely deny that its Elmiron can cause the alleged injuries and will oppose and offer alternative explanations regarding plaintiffs' allegations regarding these injuries, the defective warnings, and of course Defendants' conduct.<sup>9</sup> These defenses also involve common questions of facts and law that overlap and are common to all plaintiffs and Defendants, and, therefore, centralization is appropriate.

To illustrate further, Plaintiffs submit that these related actions will collectively involve common questions against Defendants, *inter alia*, in the following topic areas:

- whether Defendant's Elmiron had a dangerous design defect;
- whether Defendants knew that the Elmiron had a dangerous design defect;
- whether Defendants knew that the Elmiron was unsafe and/or dangerous in that could cause ocular injuries, such as retinal pigmentary changes and/or maculopathy;

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<sup>9</sup> Given the nature of the recent 2020 U.S. warning, which itself warns of the injuries alleged in these actions, the fact that the injuries alleged are now contained in said warning should carry little weight in Defendants efforts against refuting causation. Similarly, the fact that these warnings were issued in other countries over a year before being issued in the U.S., does not help Defendants liability or notice defenses.

- whether Defendants knowingly sold defective Elmiron to the public, including the respective Plaintiffs, thereby causing them to suffer ocular injuries, such as retinal pigmentary changes and/or maculopathy;
- whether Defendants knew that its representations regarding Elmiron were false;
- whether Defendants adequately instructed users of Elmiron or their physicians regarding the dangers associated with Elmiron;
- whether Defendants' misrepresentations about of Elmiron caused plaintiffs and other users to suffer from ocular injuries, such as retinal pigmentary changes and/or maculopathy; and
- generally, what Defendants knew about Elmiron (e.g., pertaining to safety and efficacy) and when they knew it.

Second, centralization before one MDL court would prevent inconsistent judicial rulings, would eliminate duplicative discovery, would be more convenient to the parties, witnesses and their counsel, and would conserve the resources of the judiciary, the parties and their counsel. *See, e.g., In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, 330 F.Supp.3d 1378, 1379 (J.P.M.L. 2016) (highlighting that consolidation will eliminate duplicative discovery; prevent inconsistent pretrial rulings on *Daubert* issues and other pretrial matters; and conserve resources); *see also In re MLR, LLC, Patent Litig.*, 269 F.Supp.2d 1380, 1381 (J.P.M.L. 2003) (noting that consolidation before a single transferee judge allows for consideration of “all parties’ legitimate discovery needs while ensuring that common parties and witnesses are not subjected to discovery demands which duplicate activity that has already occurred or is occurring in other actions.”)

Indeed, because the actions alleging injuries as a result of Elmiron are based upon substantially similar, if not identical, allegations, the parties will likely address similar issues in discovery, and in some cases identical issues, especially those involving plaintiffs’ injuries and Defendant’s misrepresentations upon which they relied. *See In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 148 F. Supp. 3d 1383, 1385 (J.P.M.L. 2015) (transfer under

§ 1407 was appropriate where related actions shared factual issues related to allegations of injuries from a defective warming system); *see also In re Actos Prods. Liab. Litig.*, 840 F. Supp. 2d 1356 (J.P.M.L. 2011) (granting consolidation of claims involving a pharmaceutical drug where: (1) the actions involved common questions of fact regarding whether the drug could cause cancer and whether defendants concealed their knowledge of the risk and failed to provide adequate warnings; and (2) centralization would eliminate duplicative discovery, prevent inconsistent pretrial rulings and conserve the resources of the parties, their counsel and the judiciary); *see also In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F.Supp.3d 1402 (J.P.M.L. 2014) (granting consolidation where issues concerning the development, manufacture, regulatory approval, labeling and marketing of a pharmaceutical drug were common to all actions and highlighting that centralization would eliminate duplicative discovery, prevent inconsistent pretrial rulings and conserve the resources of the parties, their counsel and the judiciary.)

Lastly, as noted above, the need for centralization is evidenced by the fact that there are already 63 similar Elmiron actions on file in 11 district courts around the country, with more cases coming regularly, all of which will ultimately result in separate scheduling orders and many other duplicative pretrial practices being done, should a MDL not be created. It would be inefficient and uneconomical to have any sort of informal coordination of these separate proceedings that are pending in different district courts, before different judges, and/or on different scheduling tracks, in large part because of the sheer number of cases at issue. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014) (granting centralization after previously denying centralization noting that the number of involved actions, districts and judges had grown considerably to over 226 actions, 40 districts and 100 judges such that it would be highly difficult, if not impossible, to coordinate effectively on an informal basis);

*see also In re Xarelto*, 65 F. Supp. 3d at 1404 (rejecting informal coordination argument finding that “the considerable growth in the litigation over the past few months” which included 51 actions pending in 22 districts demonstrated that informal coordination would not be practicable or effective); *see also In re Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 3d 1378, 1379-1380 (J.P.M.L. 2015) (rejecting a defendant’s argument that informal coordination was superior to consolidation pursuant to 28 U.S.C. § 1407 noting that there were already 78 actions pending in 38 districts and, even if additional actions were not filed, the number of actions pending, involved districts and involved counsel warranted centralization).

Here, it is estimated that there will likely be thousands of Elmiron actions filed throughout the country. MDL centralization of such related actions was instituted precisely for the purpose of avoiding the myriad of issues that would result were these cases to proceed individually through pretrial proceedings. These well-recognized benefits of MDL centralization include: (1) avoiding inconsistent rulings, (2) avoiding duplicative discovery, (3) avoiding the increased burden and expense on the parties, their counsel, witnesses and the judiciary; and (4) promoting efficiency, judicial economy and significant financial savings. *Supra*; *see also* Manual for Complex Litigation, Fourth Edition, 2004 (“Manual”) Section 20.13 (Transfer pursuant to 28 U.S.C. 1407 is appropriate when the Panel determines that transfer “will be for the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions”); *see also e.g.* Manual Section 20.11 (when cases are pending in the same federal court and involve common questions of fact, consolidation is warranted when it reduces cost and delay and does not increase the burden on the parties).

Thus, for the sake of uniformity, economy and efficiency, Plaintiffs respectfully submit that centralization of all Elmiron actions is warranted and appropriate under the circumstances.

**B. THE MOST APPROPRIATE VENUE FOR THIS LITIGATION IS THE DISTRICT OF NEW JERSEY**

Assuming centralization is appropriate – which we submit that it is – the question presented then becomes one of determining the proper venue for transfer of these cases. To this end, Plaintiffs herein submit that the most appropriate venue for this litigation would be the United States District Court for the District of New Jersey, before Judge Brian R. Martinotti.

**a. The District of New Jersey Currently has 24 Actions Pending**

As identified above and in the annexed Schedule of Actions, there are currently 24 actions filed in the District of New Jersey and they have all been assigned to one judge – Judge Martinotti. This factor lends support to the District of New Jersey as an appropriate venue for this MDL. See *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 787 F. Supp. 2d 1355 (J.P.M.L. 2011)(transferring to the District of New Jersey noting that nearly 2/3 of the pending actions were already there before a single judge); see also *In Re DePuy Orthopaedics, Inc.*, 753 F.Supp.2d 1378, 1380 (J.P.M.L. 2010)(transferring to the Northern District of Ohio because, among other things, several potential tag-along actions were already pending there).<sup>10</sup>

**b. Judge Martinotti has the Experience to Oversee this MDL and Appears Interested in So Doing**

Upon information and belief, the Panel looks to interested, experienced jurists to ensure that any given MDL will be managed in an efficient manner that is beneficial to all parties and

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<sup>10</sup> While there are also a significant number of cases filed in the Eastern District of Pennsylvania, it appears that these cases have been assigned to three different judges and a review of the docket sheets associated with these cases reveals that most of the actions appear to be proceeding at a different and non-uniform pace, which is in contrast to the progress that Judge Martinotti has made regarding all of the cases in New Jersey which are all before His Honor and which are all moving in a consolidated fashion.

witnesses involved. To this end, Judge Martinotti is an experienced mass tort jurist who appears interested in “steer[ing] this MDL on a prudent course,” – a proposition expressed by the Panel in prior Orders. See *In re DePuy Orthopaedics, Inc.*, 753 F.Supp. 2d 1378 (J.P.M.L. 2010)(identifying the late Judge David A. Katz as an experienced transferree judge); *In re Mirena IUD Prods. Liab. Litig.*, 938 F.Supp.2d 1355 (J.P.M.L. 2013)(identifying the late Judge Cathy Seibel as an experienced transferree judge); *In re Vigara (Sildenafil Citrate) Prods. Liab. Litig.*, 2016 LEXIS 47256 (J.P.M.L. 2016)(identifying Judge Richard Seeborg as an experienced transferree judge); *In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, 883 F. Supp. 2d 1355 (2012)(identifying Judge David R. Herndon as an experienced transferree judge); *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F. Supp. 3d 1402 (J.P.M.L. 2014)(identifying Judge Eldon E. Fallon as an experienced transferree judge); *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380 (J.P.M.L. 2004)(identifying Judge Jack B. Weinstein as an experienced transferree judge).

As the Panel may be aware, prior to being appointed to the federal bench in 2016, Judge Martinotti served as a judge of the Superior Court of New Jersey for approximately 14 years (2002 to 2016), and in August 2009 he was appointed as one of only three judges in New Jersey to oversee mass tort cases. In holding this position on the state court bench, Judge Martinotti oversaw and managed numerous mass tort litigations, including *In Re Zelnorm Litigation* (Case No. 280); *In Re Stryker Trident Hip Implant Litigation* (Case No. 285); *In Re Yaz, Yasmin, Ocella Litigation* (Case No. 287); *In Re Pelvic Mesh/Gynecare Litigation* (Case No. 291); *In Re DePuy ASR Hip Implant Litigation* (Case No. 293); *In Re Stryker Rejuvenate and ABG II Hip Modular Stem Litigation* (Case No. 296); and *In Re Mirena Litigation* (Case No. 297). Each of the aforementioned mass torts over which he presided in state court had a sister MDL, and therefore he worked and cooperated well with the federal judges overseeing those MDLs.

Following his appointment to the federal bench in 2016, Judge Martinotti presided over *In re Invokana (Canagliflozin) Products Liability Litigation* (MDL-2750), a MDL created in December 2016 and one which is now resolved, primarily through settlements and dismissals. Recently, Judge Martinotti was assigned another small MDL – *In re: Allergan Biocell Textured Breast Implant Products Liability Litigation* (MDL-2921). This MDL was created in 2019 and is relatively small in relation to other medical device/pharmaceutical MDLs; as there are still under 300 cases filed. In addition, there are significant dispositive motions, including but not limited to preemption motions, which could be dispositive of the entire litigation, and if not, dispositive of some significant legal issues thereby further narrowing its already small size.

In sum, between his time on the state court bench, which included his assignment to and oversight of numerous mass tort actions (and therefore having the opportunity to work with many different MDL judges), and his four years on the federal bench, Judge Martinotti has gained exceptional experience overseeing mass tort litigations. This experience coupled with his judicial leadership and availability to litigants, Plaintiffs submit, would make him an excellent choice to oversee this MDL.

**c. It Appears Judge Martinotti is Interested in this Litigation**

In addition to his experience, it also appears that Judge Martinotti is interested in managing and overseeing this litigation.

This interest is evidenced by the fact that Judge Martinotti has held two case management conferences with the Elmiron litigants, and a third is set for October 7, 2020. In leading up to and following these conferences, he has displayed an eagerness to move these cases forward with a focused eye towards having the parties engage in negotiating the necessary foundational case management orders that typically are entered in most products liability MDLs. In so doing, he has

directed the parties to address these foundational concepts through proposed orders, stipulations and other agreements, which have obviated the need for Rule 12 and other motion practice at this time. He has also set and maintained regular conferences for all litigants to participate in, telephonically and through video conferencing.

Some highlights of the foundational orders the Court has encouraged the parties to address and/or that have been already entered include:

- CMO 2, which includes the parties Rule 26(a)(1) initial disclosures being suspended and waived except that a Master Initial Disclosure be filed by Defendants;
- CMO 2, which requires disclosure of related filed Elmiron cases be made to a Plaintiff designee for tracking and notice purposes;
- A Protective Order; and
- A directive to the Defendants to produce the New Drug Application (“NDA”) for Elmiron.

Judge Martinotti has also maintained “pressure” on the parties to address other foundational case management orders, including those to address preservation of documents, an electronically stored information order, as well as an order to address access to medical records via authorizations and plaintiff fact sheets. *See e.g.* CMOs 1, 2 and 3 entered in *Dobbins v. Janssen Pharmaceuticals, et al*, 3:20-cv-09530 (DNJ)[Docs 19, 20 and 23] as well as entered in all other 23 District of New Jersey Elmiron-related actions.

Judge Martinotti’s guidance and work in moving these cases along, many of which were filed after other Elmiron actions in other jurisdictions were filed, evinces an experienced, able, and interested jurist, who, Plaintiffs respectfully submit, should be permitted to continue to oversee this litigation as a MDL. Indeed, Judge Martinotti’s knowledge base for the necessary foundational groundwork cannot be understated, as he will bring both his pragmatic approaches

and his significant mass tort judicial experience to all facets of this MDL as the litigation matures; precisely as he has done already by getting the parties to engage in a fast, measured and systematic manner, almost as if he is managing a MDL already.

In sum, Judge Martinotti clearly has exceptional experience overseeing mass tort litigations, and given the judicial leadership exhibited to date in the consolidated Elmiron actions currently pending before him, it appears that he is an interested jurist in overseeing and managing these cases a MDL.

**d. The Respective Caseload and History of Speedy and Effective Resolution Favors the District of New Jersey**

The District of New Jersey would also be an efficient location for these cases. The District of New Jersey currently has only twelve MDLs before it with six of them located in Trenton. As to the two assigned to Judge Martinotti, the first one, *In Re: Invokana (Canagliflozin) Products Liability Litigation* (MDL-2750), is over, with virtually all cases resolved, such that no status conferences, in person or telephonic, have even been held in over seven months. With respect to *In re: Allergan Biocell Textured Breast Implant Products Liability Litigation* (MDL-2921), as noted above, this MDL is approximately one year old and appears very small as there are still under 300 cases filed in the MDL. Additionally, upon information and belief, there have been monthly conferences, even in the face of the COVID-19 situation, underscoring Judge Martinotti's keen ability to manage his docket and complex cases.

As such, Judge Martinotti likely has the necessary time to devote to a new MDL and, particularly in light of the fact that he has already been very engaged in setting the 24 actions before him on an organized course, he certainly has the experience and skill to effectively manage a MDL, as well as the seeming interest to do so given the significant time he has already devoted to the parties in assisting in resolving both their issues and the foundational issues of this case.

Thus, he should undoubtedly be a strong candidate to oversee this litigation.

While New Jersey, like many other districts, are short on judges and other resources according to judicial statistics, each District of New Jersey judge had only approximately 1,069 civil filings for the 12-month period ending on June 30, 2020, and the average length of time from filing to disposition was an extremely efficient 9.8 months, and 39.4 months to see a case through trial.<sup>11</sup> Given the efficiency of the District of New Jersey, it would serve as a very appropriate transferee forum. Of course, the highly engaged nature of Judge Martinotti supports this argument as well.

**e. The District of New Jersey is a Convenient and Easily Accessible Venue**

In the past, the Panel has often shown preference for consolidation in the district which is convenient for the parties and witnesses. While, in general, travel and convenience may likely be less of a persuasive factor given the current COVID-19 world in which we find ourselves, Plaintiffs submit that selecting a MDL venue that is home to a defendant during the pandemic should be a factor for the Panel to consider. In this case, a majority of the Defendants are citizens and residents of New Jersey and have their principal places of business located in New Jersey. Therefore, to the extent travel for hearings is needed and to the extent a hybrid remote deposition process is utilized, having many of the witnesses in the state of the MDL will only serve the convenience of the litigants and the witnesses in these challenging times, without having to worry about inter-state travel, where quarantining for 14 days (or some other similar time frame) might become mandated again.

Further, while convenience of the parties and witnesses may be less of an issue in the current COVID-19 world, it is important to note that Judge Martinotti has shown the ability to

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<sup>11</sup> [https://www.uscourts.gov/sites/default/files/data\\_tables/fcms\\_na\\_distprofile0630.2020.pdf](https://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile0630.2020.pdf) (last accessed September 11, 2020). Notably, these statistics are efficient even during the COVID-19 pandemic.

effectively, efficiently and continuously manage his docket during these unprecedented times. Specifically, as to the Elmiron litigation, he has held both telephonic conferences and Zoom conferences with the litigants. To this end, while the “convenience” factor for travel may be less of a factor, the convenience and accessibility of the Court itself, and particularly Judge Martinotti, cannot be understated. Again, Judge Martinotti has shown his willingness to be available to meet the needs of the litigants and to advance the case.

Of course, if we are fortunate to being traveling again soon because the situation surrounding the COVID-19 pandemic has improved, the District of New Jersey remains an extremely convenient location for all parties, witnesses and their counsel as it is easily accessible from anywhere in the United States. Trenton is located just 36 miles from Philadelphia, Pennsylvania and is easily accessible by train or car. In this regard, Philadelphia International Airport offers multiple non-stop and one-stop flights. Further, Trenton is within a reasonable traveling distance from one of the country’s largest airports, Newark Liberty International Airport, which also offers multiple non-stop and one-stop flights. Similarly, Trenton is within a reasonable traveling and/or commuting distance from other regional and international airports, including the airports in Atlantic City and New York. Of course, because Judge Matinotti also sits in Newark, his proximity to New York City and the travel access that is provided by New York City furthers and significantly supports the convenience of this district, and Judge Martinotti in particular.

Accordingly, travel to the District of New Jersey will conserve the resources of the parties and witnesses, when compared with other venues that may be proposed and is, therefore, the appropriate forum for this MDL.

**f. Defendants Have a Long Standing History of Supporting the District of New Jersey**

Defendants, in particular Johnson & Johnson (“J&J”), have repeatedly taken the position

that the District of New Jersey is an easily accessible and convenient location for MDLs, especially for them since their principal places of business are located in New Jersey. To illustrate, in *In Re Xarelto Products Marketing and Sales Practice Litigation* (MDL-2592), Defendants J&J and Janssen advocated for centralization in the District of New Jersey and argued that:

- (1) the District of New Jersey was better suited to meet the goals of any MDL proceeding, over the venues advocated by the plaintiffs;
- (2) the District of New Jersey was a convenient location that had sufficient available resources to handle an MDL proceeding;
- (3) the District of New Jersey should be considered a strong candidate for transfer since Defendants had their principal places of business located there and, thus, the District of New Jersey offered a distinct advantage of proximity to many witnesses and documents;
- (4) the District of New Jersey is located in a major metropolitan area that can accommodate counsel and courthouses; and
- (5) the relative congestion of the District of New Jersey's docket weighed in favor of transfer to the District of New Jersey.

(Attached hereto as Ex. A is a copy of said Response Memorandum.)

Similarly, regarding the *Invokana* MDL, in advocating for not only the District of New Jersey, but also Judge Martinotti, Defendants J&J and Janssen advanced the same points as identified above, but also argued, as Plaintiffs do here, that:

- (1) the District of New Jersey generally and Judge Martinotti specifically have significant experience handling multidistrict litigation involving pharmaceutical and medical device products liability actions;
- (2) Judge Brian Martinotti has extensive experience handling large and complex pharmaceutical MDLs;
- (3) Judge Martinotti exhibits the attributes required for a transferee judge;
- (4) Judge Martinotti had already brought his significant case management skills to bear in the cases pending before him and had demonstrated his willingness and motivation to justly and efficiently manage this litigation; and

(5) Transfer was appropriate because the largest number of cases were pending in the District of New Jersey.

(Attached hereto as Ex. B is a copy of said Response Memorandum.)

Likewise, Defendant J&J has consistently advocated for the District of New Jersey in other mass tort MDLs. See e.g. *In Re DePuy Orthopaedics, Inc. ASR Hip Implant Products Liability Litigation*, MDL No. 2197 [Doc 8]; *In Re Ethicon, Inc. Women’s Pelvic Repair Products Liability Litigation*, MDL No. 2327 [Doc. 42-1]; *In Re Johnson & Johnson “Baby Powder” and “Shower to Shower” Marketing, Sales Practices and Products Liability Litigation*, MDL No. 2738 [Doc. 38]; *Levaquin Products Liability Litigation*, MDL No. 1943 [Doc. 4]; ]; *In Re Propulsid Products Liability Litigation*, MDL No. 1355 [Doc. 4]; and *In re Panacryl Sutures Products Liability Litigation*, MDL No. 1959 [Doc. 5].<sup>12</sup>

While we recognize that positions change and neither the Defendants nor their counsel are bound to the position they advocated in the aforementioned MDL’s, centralization of this MDL to the District of New Jersey is as appropriate now as it was then – perhaps more so given the unique experience of Judge Brian Martinotti, the advanced posture of the cases before him as well as his leadership role in the cases to date, and the volume of cases already filed in the District of New Jersey.

### **III. CONCLUSION**

For the foregoing reasons, Plaintiffs herein respectfully request that the Panel grant the present motion for consolidation and centralization via a multidistrict litigation to the District of New Jersey, before Judge Brian R. Martinotti; and grant such other and further relief as it may deem just and appropriate under the circumstances.

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<sup>12</sup> Of course, many of these MDLs were ultimately not sent to the District of New Jersey.

Dated: September 23, 2020

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