BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BENICAR (AND OTHER OLMESTARTAN DRUGS) PRODUCTS LIABILITY LITIGATION

MDL Docket No. 2606

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

ORAL ARGUMENT REQUESTED

Plaintiffs Roger Deming and Carol Deming (hereafter, "Plaintiffs") respectfully submit this Interested Party Response and Memorandum of Law to the Judicial Panel on Multidistrict Litigation ("the Panel") in response to Plaintiff Annette Johnson's Motion for Transfer of Actions. *See* MDL No. 2606, Dkt. No. 1-1. For the reasons set forth below, Plaintiffs request the consolidation of all actions pending in federal court pursuant to 28 U.S.C. § 1407 alleging injury as a result of ingesting the blood pressure medicine *olmesartan medoxomil*. Plaintiffs further request the Panel grant Plaintiff Johnson's motion to transfer all cases to the United States District Court for the Northern District of Ohio or, the United States District Court for the District of Minnesota. *See* MDL No. 2606, Dkt. No. 52.

NATURE OF THE CASE

A. The FDA has issued significant warnings for blood pressure medicine olmesartan medoxomil.

Olmesartan medoxomil ("olmesartan") is an angiotensin II receptor blocker (ARB) that was approved by the United States Food and Drug Administration ("FDA") on April 25, 2002, for the treatment of hypertension. Defendants have been selling and marketing olmesartan in the

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United States since its FDA approval in 2002. Olmesartan is sold in the United States under the brand names of Benicar[®], Benicar HCT[®], Tribenzor[®], or Azor[®] (collectively referred to as "Benicar products.") Ten years after receiving FDA approval for olmesartan, there were approximately 10.6 million prescriptions dispensed for the Benicar Family in the United States in 2012 alone.^1

However, on July 3, 2013, the FDA issued a Drug Safety Communication and warned that patients ingesting Benicar products could suffer from symptoms of sprue-like enteropathy including "severe, chronic diarrhea with substantial weight loss."² The FDA noted that it may take "months to years after starting olmesartan" for these symptoms to develop, but discontinuation of olmesartan resulted in the clinical improvement of these "sprue-like enteropathy symptoms in *all* patients." (emphasis added).³ In contrast, sprue-like enteropathy was not detected with ARB drugs other than those with olmesartan.⁴

The FDA issued its safety communication after evaluating adverse event reports, published case literature series, and information from FDA's Mini-Sentinel and CMS Medicare database.⁵ The case literature included a Mayo Clinic case series where patients developed diarrhea, weight loss, and villous atrophy while on olmesartan.⁶ As a result, the FDA ordered a warning label change to Benicar products to include severe gastrointestinal injuries as a potential side effect of ingesting the drug.

B. Plaintiffs from across the United States have filed claims against Defendants alleging that ingestion of Benicar products caused severe injuries.

¹ http://www.fda.gov/downloads/Drugs/DrugSafety/UCM359496.pdf, at 1.

 $^{^{2}}$ Id.

³ Id.

Id. 5 *Id*. at 2.

⁶ *Id*. at 3.

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At this time, thirty-three (33) actions alleging Defendants developed, manufactured, and sold Benicar products that caused severe gastrointestinal injuries have been filed in federal courts across the country. The cases were filed in the United States District Courts for the Northern District of Ohio, District of Oregon, Central District of Illinois, Southern District of Illinois, Northern District of California, Central District of California, Southern District of California, Middle District of Louisiana, Eastern District of Louisiana, Eastern District of Minnesota, District of Montana, Southern District of Iowa, District of Arizona, Northern District of Mississippi, Middle District of North Carolina, and Southern District of New York.

These cases are the proverbial tip of the iceberg. There are there are expected to be hundreds if not thousands of people who bring claims against the Defendants for failing to warn them of the true risks of ingesting olmesartan, as well as designing a defective drug. In 2012, approximately 1.9 million patients received a dispensed prescription for olmesartan-containing products.⁷ Unfortunately, many individuals injured by the Benicar products are not diagnosed correctly, at least in part, because their physicians are not aware of the connection between the Benicar products and the symptoms their patients are experiencing. The healthcare community and patients alike are only now becoming aware of the risk in prescribing and ingesting drugs that contain olmesartan.

ARGUMENT

A. Consolidation of the pretrial proceedings of the Olmesartan cases is appropriate in this case given the inevitable duplication of discovery, witnesses and theories of liability involved in each action.

 $^{^{7}}$ *Id*. at 3.

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At the discretion of the Panel, civil actions pending in different federal districts may be transferred to a centralized district. Transfer is appropriate if the Panel determines that consolidation would serve "the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a) (2010). These actions, as well as the thousands of likely future filings contain the same basic facts, the same theories of liability, and the same Defendants. Consolidation in one federal district will promote conservation of judicial resources, avoid potentially endless duplication of discovery, and prevent inconsistent or repetitive rulings. *See e.g., In re Janus Mut. Funds Inv. Litig.*, 310 F. Supp. 2d 1359, 1361 (J.P.M.L. 2004); *In re: Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F. Supp. 2d 1371, 1372 (J.P.M.L. 2007); *In re Fosamax Products Liab. Litig.*, 444 F. Supp. 2d 1347, 1349 (J.P.M.L. 2006). Expert depositions will only be required to be taken once, document production will be centralized and travel will be minimized as Defendants will only have to appear in one location rather than multiple districts around the country. Consolidation in one district will allow the parties to focus their efforts in one forum.

This Panel has routinely recognized that consolidating litigation in one court benefits *both* Plaintiffs and Defendants. Specifically, consolidation strikes a balance between allowing the defendant to conduct discovery only once, and entitling the plaintiff to coordinate their efforts and share their work with other plaintiffs. Recognizing the soundness of this policy, this Panel in *In re Baldwin-United Corp. Litigation*, 581 F. Supp. 739 (J.P.M.L. 1984) noted:

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.

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Id. at 741 (citing *In re Nissan Motor Corporation Antitrust Litigation*, 385 F. Supp. 1253, 1255 (J.P.M.L. 1974)). Consolidation of these actions will save both sides (and the court) countless resources by streamlining the litigation in one forum.

"The Panel has rejected the argument that products liability actions must allege identical injuries to warrant centralization." *In re: Cook Med., Inc., IVC Filters Mktg., Sales Practices & Products Liab. Litig.*, No. MDL 2570, 2014 WL 5318059, at *2 (U.S. Jud. Pan. Mult. Lit. Oct. 15, 2014) (citing *In re: Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F.Supp.2d 1371 (J.P.M.L.2007). Each of the claims filed against Defendants involves the same blood pressure medicine, *olmesartan medoxomil*, and assert similar theories of liability. These theories include: product liability - failure to warn, negligence, product liability - breach of implied warranty, fraud, constructive fraud, and unjust enrichment. Each of these theories of liability can have different applications depending on the rules and laws of an individual forum and the judge who applies these theories. Consolidating the claims will promote a just application of the law for all plaintiffs throughout the country, and would prevent the possibility (and probability) of conflicting rulings from various courts around the country.

Finally, consolidation will aid in the quick dismissal of claims without merit. As held *In re: Lipitor (Atorvastatin Calcium) Mktg., Salespractices & Products Liab. Litig. (No. II)*, "[a]n MDL, after all, gathers all related federal actions before just one judge who, of necessity, acquires an unusually high degree of familiarity with not only the involved parties, counsel, and claims but also the litigation's underlying subject matter. As a result, that judge is uniquely well-positioned to recognize and dispose of spurious claims quickly." *In re: Lipitor (Atorvastatin Calcium) Mktg., Salespractices & Products Liab. Litig. (No. II)*, 997 F. Supp. 2d 1354, 1356 (U.S. Jud. Pan. Mult. Lit. 2014) (internal citations omitted). It is to the benefit of both

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Defendants and Plaintiffs, to have a judge who is extremely familiar with the intricacies of the facts underlying this litigation.

B. Consolidation best serves the combined interests of the Parties in the Northern District of Ohio or in the District of Minnesota.

The filed cases represent a nationwide docket with no district standing out as the geographical focal point. In circumstances like this, the Panel evaluates a number of factors to determine an appropriate district for transfer, including, whether the district has the capacity to handle the litigation and is conveniently located for many parties and witnesses. *In re Motor Fuel Temperature Sales Practices Litig.*, 493 F. Supp. 2d 1365, 1367 (J.P.M.L. 2007). In light of these considerations, Plaintiffs contend transfer to the Northern District of Ohio or the District of Minnesota is appropriate.

1. <u>The Northern District of Ohio</u>

The Northern District of Ohio has the capacity to handle and resolve this litigation. In recent years, the Northern District of Ohio has demonstrated its ability to successfully resolve in numerous products liability cases including, but limited to: *In re: Gadolinium Contrast Dyes Products Liability Litigation*, MDL No. 1909, *In re: DePuy Orthopedics, Inc., ASR Hip Implant Products Liability Litigation*, MDL No. 2197, *In re: Heparin Products Liability Litigation*, MDL No. 2197, *In re: Heparin Products Liability Litigation*, MDL No. 1953, *In re: Ortho Evra Products Liability Litigation*, MDL No. 1742, *In re: Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation*, MDL No. 1535, and *In re: Meridia Products Liability Litigation*, MDL No. 1481. Mass tort litigation contains many complicated and nuanced issue that require highly skilled jurists effectively adjudicate. The consideration suggests the Northern District of Ohio is an appropriate jurisdiction, particularly considering its knowledge, background, and

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experience. Here, the Court past performance handling prior pharmaceutical MDLs will ensure that this litigation will proceed in a timely and efficient manner.

Additionally, the Cleveland division courthouse in the Northern District of Ohio is centrally located for all parties and witnesses, particularly in light of the fact that it is anticipated that such a complex products liability case will unquestionably involve parties and witnesses located in a variety of locations throughout the United States. Traveling to this central location is much more convenient and efficient than traveling to other destinations in the United States. For instance, the Cleveland division courthouse in the Northern District of Ohio is located in Cleveland, which is only twenty minutes from Cleveland Hopkins International Airport in Cleveland, Ohio, allowing for same day travel for regular status conferences and hearings.

2. <u>The District of Minnesota</u>

In re Baycol Products Liab. Litig. (MDL No. 1431), numerous transferee districts were suggested to the Panel with federal cases pending in districts dispersed throughout the country. The Panel noted that there were a number of districts that would be appropriate transferee forums for the litigation. However, the Panel concluded that the District of Minnesota was the appropriate forum because it is a "major metropolitan court that i) is centrally located, ii) is not currently overtaxed with other multidistrict dockets, and iii) possesses the necessary resources, facilities, and technology to sure-handedly devote the substantial time and effort to pretrial matters that this complex docket is likely to require." *In re Baycol Products Liab. Litig.*, 180 F. Supp. 2d 1378, 1380 (J.P.M.L. 2001). The Panel's reasoning for selecting the District of Minnesota in the *In re Baycol Products Liab. Litig*, holds true today.

The District of Minnesota's ability to direct complex consolidated products liability litigation is well established. The Panel has assigned numerous pharmaceutical and medical

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device MDL cases to the District of Minnesota including: *In re Baycol Products Liability Litigation*, MDL No. 1431; *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL No. 1708; *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, MDL No. 1905; *In re Viagra Products Liability Litigation*, MDL No. 1724; *In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, MDL No. 1958; *In re Levaquin Products Liability Litigation*, MDL No. 1943; and *Stryker Rejuvenate & ABG II Hip Implant Prods. Liab. Litig.*, MDL No. 2441. While the District of Minnesota has substantial experience with multidistrict litigation, is not overburdened with multidistrict dockets. In fact, the District of Minnesota only has one MDL with a substantial number of cases pending – In re *Stryker Rejuvenate & ABG II*.

The District of Minnesota also continues to be a district conveniently located for many parties and witnesses. As noted in *Baycol*, the District of Minnesota is a major metropolitan court that is centrally located. Minneapolis-St. Paul International Airport served more than 35 million travelers in 2014 making it the 16th busiest airport in North America.⁸ The airport is less than 10 miles from the federal courthouse in downtown Minneapolis and there is a light rail line that delivers travelers from the airport to the federal courthouse in approximately twenty minutes. Like the Northern District of Ohio, this allows for same day travel for regular status conferences and hearings. In addition, Dr. Joseph Murray, who is a practicing gastroenterologist at the Mayo Clinic in Rochester, Minnesota, is a central factual witness in this litigation. Dr. Murray published the Mayo Clinic study in 2012 referenced above and is also a treating physician for a number of the federal cases filed.

⁸ Minneapolis-St. Paul Metropolitan Airport Web site, located at: <u>https://www.mspairport.com/about-msp/statistics.aspx</u>.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request the Panel to grant Plaintiff Annette Johnson's Motion for Transfer of Actions pursuant to 28 U.S.C. §1407 to the Northern District of Ohio, or to the District of Minnesota.

Respectfully submitted,

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BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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IN RE: BENICAR® (OLMESARTAN) PRODUCTS LIABILITY LITIGATION

MDL No. 2606

PROOF OF SERVICE

I, Michael K. Johnson, hereby certify that pursuant to Panel Rule 4.1, on March 20, 2015,

a true and correct copy of the forgoing INTERESTED PARTY RESPONSE AND

MEMORANDUM OF LAW IN SUPPORT OF TRANSFER OF ACTIONS PURSUANT

TO 28 U.S.C. § 1407 was served upon all interested counsel and/or parties identified below via

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