BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BENICAR (AND OTHER OLMESTARTAN DRUGS) PRODUCTS LIABILITY LITIGATION	**MDL No. _____**

BRIEF IN SUPPORT OF PLAINTIFF'S MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

ORAL ARGUMENT REQUESTED

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiff Annette Johnson ("Moving Party") brings this motion to transfer all federal cases regarding cases where Plaintiffs ingested Benicar (and other Olmesartan drugs) and allege that they suffered severe gastrointestinal injuries to the Northern District of Ohio.

As this Panel may be aware, 15 lawsuits have been filed in Federal Court and dozens more are anticipated to be filed against Daiichi Sankyo and Forest Lab parties ("Defendants") in the next several weeks.[1] In addition, over 30 lawsuits have been filed in New Jersey state court.[2] All of the lawsuits arise out of Plaintiffs' ingestion of Benicar and they each allege that they suffered severe gastrointestinal injuries.

Benicar (olmesartan) is a blood pressure medication that belongs to the class of drugs known as angiotensin II receptor blockers (ARBs). It received FDA approval for the treatment

[1] A Schedule of Cases is attached hereto as **Exhibit A.**

[2] These 30 New Jersey state court cases involve at least 8 different plaintiff's counsel including: Daniel Nigh of Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor; Rayna Kessler of Robins, Kaplan, Miller & Ciresi; Adam Slater of Mazie, Slater, Katz & Freeman; Steven Teppler of the Abbott Law Group; Paul Rheingold of Rheingold, Valet & Rheingold; Mike Goetz of Morgan & Morgan; Peter Snowdon of Johnson Becker; and Matt Schumacher of Pearson, Randall, Schumacher. These cases have been consolidated in Atlantic County are presided over by the Honorable Nelson C. Johnson.

of hypertension on April 25, 2002. Defendants market olmesartan under the trade names Benicar, Benicar HCT, Tribenzor, and Azor. (These four trade names constitute the list of olmesartan drugs.) On July 3, 2013, the FDA issued a Drug Safety Communication and warned that patients ingesting Benicar and other Olmesartan products could suffer from "severe, chronic diarrhea with substantial weight loss."[3] The FDA advised that after evaluating adverse event reports, published case literature series, and information from FDA's Mini-Sentinel and CMS Medicare assessments they found a "clear association between olmesartan and sprue-like enteropathy." As a result, the FDA ordered a warning label change to Benicar (and other Olmesartan drugs) to include severe gastrointestinal injuries as a potential side effect of ingesting the drug.

Prior to the FDA ordering the warning label change, both the Mayo Clinic and Columbia University published literature indicating the association between Benicar and the severe gastrointestinal injuries suffered by patients included in their studies.[4] Both of these studies also pointed out that with the lack of knowledge that Benicar could potentially cause severe gastrointestinal injuries, the patients in the study were commonly misdiagnosed with Celiac disease, unclassified sprue, autoimmune disease, or a plethora of other conditions that can cause severe gastrointestinal injuries. As a result of not knowing about this association between Benicar and severe gastrointestinal injuries, many treating gastroenterologists and other treating physicians will have misdiagnosed patients and recommended other treatment, when the mere cessation of Benicar could have treated their ailments. Therefore, this litigation will likely include numerous litigants who have been misdiagnosed by their treating gastroenterologists and other treating physicians.

[3] www.fda.gov/Drugs/DrugSafety/ucm359477.htm

[4] *Severe Spruelike Enteropathy Associated With Olmesartan,* Alberto Rubio-Tapia, MD, Margot L. Herman, MD, et. al. (Mayo Clinic Proc. Aug. 2012) and *Villous Atrophy and Negative Celiac Serology: A Diagnostic and Therapeutic Dilemma*, Marisa DeGaetani, MD, Christina A. Tennyson, MD, et. al. (Am. J. Gastroenterology May 2013).

According to the FDA Benicar Drug Safety Communication, in 2012, 10.6 million prescriptions for Benicar were dispensed to approximately 1.9 million patients.[5] Early published literature indicated that severe gastrointestinal injuries may be a rare side effect of ingesting Benicar. Recent studies, however, suggest that this does not appear to be nearly as rare a side effect as was previously thought.[6] A gastroenterology researcher at the Mayo Foundation for Medical Education and Research has been quoted as stating that the patients cited in medical literature as having suffered severe gastrointestinal injuries as a result of ingesting Benicar and other olmesartan drugs are just the "tip of the iceberg".[7] After speaking with many clients who have ingested Benicar and have suffered gastrointestinal injuries, after having reviewed the medical records of these clients and after speaking with many other plaintiff attorneys who represent similarly injured clients, the undersigned counsel also believes that the number of currently filed lawsuits alleging that allege Benicar caused the plaintiffs to suffer severe gastrointestinal injuries after ingesting Benicar are indeed but the tip of the iceberg.

In order to promote efficiency for the parties, the court, and the witnesses, and to avoid inconsistent legal rulings from numerous federal courts, the Panel should transfer the federal civil actions regarding Benicar (and other olmesartan drugs) products liability litigation to the Northern District of Ohio and specifically assign the Honorable Judge Dan Aaron Polster to preside over the litigation.

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[5] www.fda.gov/Drugs/DrugSafety/ucm359477.htm

[6] *Five cases of sprue-like enteropathy in patients treated by olmesartan*, Helene Theophile, Xavier-Richard David, et. al. (Digestive and Liver Disease Journal 2014) states "all cases were observed in a small gastroenterology unit, which suggests that this adverse effect may not be rare" and *Severe Malabsorption Associated With Olmesartan: A French Nationwide Cohort Study*, Mickael Basson, Myriam Mezzarobba, et. al. (AGA Abstracts 2014) found that patients that ingested Benicar for more than 2 years had nearly 10 times the relative risk of being hospitalized for gastrointestinal injuries when compared with ACE Inhibitors, another class of blood pressure medications.

[7] http://www.medpagetoday.com/Cardiology/Hypertension/40278, quoting Margot Herman, MD.

ARGUMENT

A. STANDARD FOR TRANSFER AND CONSOLIDATION

28 U.S.C. § 1407 directs the Judicial Panel on Multidistrict Litigation to transfer federal civil actions for pretrial coordination or consolidation when: (1) the cases involve "common questions of fact," (2) the transfer is convenient for the parties and witnesses; and (3) the transfer "promote[s] the just and efficient conduct" of the cases. 28 U.S.C. § 1407(a). The general purpose of § 1407 is to "eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation costs, and save the time and effort of the parties, the attorneys, the witnesses, and the courts." *In re: Plumbing Fixture Cases*, 298 F. Supp. 484 (J.P.M.L. 1968). Upon a motion for transfer, the Panel considers factors including "the progress of discovery, docket conditions, familiarity of the transferee judge with the relevant issues, and size of the litigation." *In re: Phenylpropanolamine (PPA) Products Liability Litigation*, 460 F.3d 1217, 1230 (9th Cir. 2006). Also, when there is a significant state court docket regarding similar facts and theories of liability as the Federal cases that are proposed to be consolidated, this factor weighs in favor of consolidation as "[c]reation of an MDL likely will make it easier to coordinate, as needed, pretrial proceedings in both the state and federal cases, because there will now be just one judge handling the latter." *In re: Lipitor (Atorvastatin Calcium) Marketing, Salespractices and Products Liability Litigation (No. II)* 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014) (citing *In re: Plavix Mktg., Sales Practices & Prods. Liab. Litig. (No. II)*, 923 F. Supp. 2d 1376, 1378-79 (J.P.M.L. 2013).

After a case is consolidated to multidistrict litigation, "[c]oordination of so many parties and claims requires that a district court be given broad discretion to structure a procedural framework for moving the cases as a whole as well as individually, more so than in an action involving only a few parties and a handful of claims. *Id.* at 1231-1232.

B. TRANSFER AND CONSOLIDATION ARE APPROPRIATE IN THIS MATTER

1. THESE CASES RAISE COMMON QUESTIONS OF FACT AND INVOLVE COMMON ISSUES FOR DISCOVERY

One factor to consider for transfer and consolidation pursuant to 28 U.S.C. § 1407 is whether they involve "common questions of fact" subject to discovery. *In re: Kugel Mesh Hernia Patch Products Liability Litigation*, 493 F. Supp. 2d 1371, 1372-73 (J.P.M.L. 2007). That factor is clearly met here. The Benicar and other olmesartan drug cases currently pending, and future filings will ultimately share countless issues of fact and discovery, including:

(1) Whether and to what extent Benicar and other olmesartan drugs have caused, or will cause, harmful effects in patients that ingested Benicar including but not limited to severe dehydration, severe malabsorption, rapid and substantial weight loss, chronic diarrhea, vomiting, significant abdominal pains, acute renal failure, and/or accelerated aging as a result of the body's inability to adequately absorb food and water over a period of months or years;

(2) When Defendants first learned of the connection between Benicar and other olmesartan drug usage and the foregoing harmful effects caused by ingesting Benicar and other olmesartan drugs;

(3) Whether, and for how long, Defendants concealed any such knowledge from prescribing physicians and physicians treating patients' gastrointestinal injuries;

(4) Whether Defendants defectively designed and/or manufactured Benicar and the other olmesartan drugs;

(5) Whether Defendants failed to provide adequate warnings and instruction concerning the usage and side effects of Benicar and other olmesartan drugs;

(6) Whether Defendants were negligent in their design and/or manufacture of Benicar and the other olmesartan drugs;

(7) Whether Defendants engaged in fraudulent and illegal marketing practices including, but not limited to, making unsubstantiated claims regarding the effectiveness and superiority of Benicar and the other olmesartan drugs; and

(8) The nature and extent of past and future damages suffered by Plaintiffs as a result of ingesting Benicar and the other olmesartan drugs.

Separate, unconsolidated pretrial proceedings in the federal cases that have been and will be filed would greatly increase the costs of this litigation for all parties, waste judicial resources, and create a significant risk of inconsistent rulings on these common questions of fact.

2. PRETRIAL CENTRALIZATION OF THE BENICAR AND OTHER OLMESARTAN DRUG PRODUCTS LIABILITY CASES WILL ENHANCE THE CONVENIENCE OF THE LITIGATION AS A WHOLE

Transfer and consolidation is also appropriate when it enhances the convenience of the litigation as a whole. *In re: Library Editions of Children's Books*, 297 F. Supp. 385, 386 (J.P.M.L. 1968). Defendants and Plaintiffs both benefit from pretrial centralization. Pretrial centralization would reduce discovery requests and costs significantly for Defendants. Pretrial centralization also permits Plaintiffs' counsel to coordinate their efforts and share the pretrial workload, which reduces each individual counsel's costs. In addition, Pretrial centralization allows Defendants to work with one consolidated set of discovery requests and filings from Plaintiffs' counsel in federal cases, rather than negotiating with various counsel and courts across the country. Pretrial centralization will also allow Plaintiffs and Defendants to concentrate their attention and energy on one federal forum, allowing Plaintiffs and Defendants to respond more quickly and effectively to opposing counsel and the transferee court, enhancing the overall efficiency of the litigation. *In re: Baldwin-United Corp. Litigation*, 581 F. Supp. 739, 741

(J.P.M.L. 1984). Centralization will conserve financial resources of the courts as one federal judge, rather than many federal judges will resolve issues related to discovery, expert witnesses, and other common issues between the cases. Finally, centralization of the federal cases will make it easier for the New Jersey state court judge (and potential future state court judges) to coordinate with one federal judge, as opposed to attempting to coordinate with multiple federal judges across the country.

Briefly stated, transferring the Benicar and other olmesartan drug cases for pretrial coordination or consolidation will make this litigation much more efficient and convenient for all parties involved.

C. THE NORTHERN DISTRICT OF OHIO IS THE PREEMINENT TRANSFEREE FORUM TO EFFICIENTLY OVERSEE THE FEDERAL BENICAR AND OTHER OLMESARTAN DRUG PRODUCT LIABILITY CASES

Moving Party respectfully urges the Panel to transfer the Benicar and other olmesartan drug product liability cases to the Northern District of Ohio where they can be efficiently and justly managed by a court with extensive experience in multidistrict litigation, particularly in the area of products liability drug and medical device cases. The Panel balances a number of factors in determining the transferee forum, including: the experience, skill and caseloads of the available judges; the number of cases pending in the jurisdiction; the convenience of the parties; the location of the witnesses and evidence; and the minimization of cost and inconvenience to the parties. *See In re: Preferential Drugs Prods. Pricing Antitrust Litig.*, 429 F.Supp. 1027, 1029 (J.P.M.L. 1977); *In re: Tri-State Crematory Litig.*, 206 F.Supp. 1376, 1378 (J.P.M.L. 2002); and *In re: Lipitor (No. II)*, 997 F. Supp. 2d at 1357. Of the factors the Panel considers when determining the transferee forum, the judicial experience, the number of pending cases and available resources, the minimization of cost and convenience of the parties, and the location of the witnesses and evidence weighs heavily in favor of the Northern District of Ohio.

The Northern District of Ohio is well-versed in handling multidistrict litigations and specifically, handling drug and medical device products liability cases. The Northern District of Ohio has brought about successful resolution in several drug products liability cases including but limited to: *In re: Gadolinium Contrast Dyes Products Liability Litigation*, MDL No. 1909, *In re: DePuy Orthopaedics, Inc., ASR Hip Implant 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. 1401, and *In re: Meridia Products Liability Litigation*, MDL No. 1481. The Northern District of Ohio has brought about successful resolution, at least in part, for all of the major litigations and therefore is ready,willing, and able to take on another major drug products liability MDL. The Northern District of Ohio's knowledge, background, and experience will ensure that this litigation will proceed in a timely and efficient manner.

Currently, nine of the fifteen filed federal cases are filed in the Northern District of Ohio. Moving Party expects several more federal cases to be filed in the Northern District of Ohio in the next couple of months. The number of cases currently pending in a given District is an appropriate factor in determining the transferee forum. *See* David F. Hen, Multidistrict Litigation Manual § 6:8 (2010). The remaining six cases not before the Northern District of Ohio are spread across five different District Courts with no Court presiding over more than two Benicar or other olmesartan drug case. Since most of the currently filed cases are filed in the Northern District of Ohio, this location will also be convenient for the plaintiffs involved in those cases and also other case specific witnesses such as treating physicians and the plaintiffs' spouses or other relatives.

Specifically, Moving Party asks that these cases be transferred to the Cleveland division in the Northern District of Ohio. The Cleveland-Akron-Canton, OH Combined Statistical Area

had a population of over 3.5 million and is ranked as the country's 15th largest CSA.[8] Cleveland's Carl B. Stokes Federal Courthouse is within convenient proximity to Cleveland Hopkins International Airport, and Cleveland itself is likewise geographically convenient and accessible for the Defendants, Plaintiffs, and the numerous medical fact, and other expert witnesses who will be involved in this litigation. As a major metropolitan area, Cleveland has significant and ample hotel capacity, all within easy walking distance of the courthouse.

D. WITHIN THE NORTHERN DISTRICT OF OHIO, THE CONSOLIDATED CASE SHOULD BE ASSIGNED TO THE HONORABLE JUDGE DAN AARON POLSTER

The Benicar litigation will involve scientific evidence and testimony in a number of fields, and the duration, complexity and scale of discovery may be comparable to the *Gadolinium* litigation, over which the Honorable Judge Dan Aaron Polster successfully presided. Counsel for Moving Party has experience litigating the *Gadolinium Contrast Dyes Products Liability Litigation* (MDL 1909) before Judge Polster and believes that the Honorable Judge Polster would bring the same evenhandedness and efficiency to the Benicar litigation. In *Gadolinium*, Judge Polster masterfully guided the parties to a resolution of over 700 cases. The *Gadolinium* MDL has all but concluded, with only two pending cases. Undersigned counsel respectfully submits that there is now room on Judge Polster's docket for another complex MDL involving drug litigation. In *Gadolinium*, the defendants' counsel initially requested that the Gadolinium consolidated cases be transferred to Judge Polster. As such, Judge Polster has been requested by both Plaintiffs' and Defendants' counsel to preside over a drug products liability MDL and Moving Party believes that Judge Polster is uniquely positioned to help the parties expedite the

[8] Metropolitan and Micropolitan Statistical Areas".*Statistical Abstract of the United States*. United States Census Bureau.

litigation with a fair and just result. Judge Polster is already the assigned judge of record in a pending Benicar case. (*Kuhn v. Daiichi Sankyo, Inc., et al*, case number 1:14-cv-02781)

In addition, Judge Polster successfully presided over MDL 2066, *In Re: Oral Sodium Phosphate Solution-Based Product Liability Litigation*. Judge Polster received the initial transfer order of this case on June 23, 2009 and, as reflected by that docket, the Master Settlement Agreement order was entered in less than one year's time, on June 15, 2010.

A graduate of Harvard College and Harvard Law School who served for over 20 years as a trial attorney for the US Department of Justice, Antitrust Division, Judge Polster has now been on the federal bench since 1998. He possesses impeccable credentials and has the demonstrated ability to oversee this complex litigation.

CONCLUSION

For the aforementioned reasons, Moving Party respectfully requests that the Panel order coordinated or consolidated pretrial proceedings for the Benicar (and other olmesartan drugs) products liability litigation, and respectfully requests that the Panel transfer these cases to the Northern District of Ohio with the Honorable Judge Dan Aaron Polster assigned to preside.

Respectfully submitted,

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