

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

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

**MDL No. 2606**

**REPLY IN SUPPORT OF PLAINTIFF’S MOTION FOR TRANSFER OF ACTIONS  
PURSUANT TO 28 U.S.C. § 1407**

Plaintiff Annette Johnson hereby replies to Defendants’ Brief in Response and Opposition to Plaintiff’s Motion for Transfer and Coordination under 28 U.S.C. § 1407.

Defendants argue that consolidation is unnecessary because the litigation is “driven by a small number of Plaintiffs’ counsel before a few courts.”<sup>1</sup> Actually, there are 16 different plaintiffs’ law firms involved in 24 federal Benicar lawsuits. No one firm or group of firms is driving the litigation; Defendants have no evidence to the contrary. And the number of federal courts before whom these cases are pending is not “a few.” The number is 13: 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, Eastern District of Louisiana, Northern District of Alabama, District of Minnesota, District of Montana, Southern District of Iowa, and Southern District of New York.

Defendants also think that the universe of Benicar lawsuits is small—and hence there is no need for an MDL—because “[t]he condition [sprue-like enteropathy] has been reported as rare and was previously unreported in the medical literature in association with” Benicar medications.<sup>2</sup> This thinking is misguided. The reason the condition has until now been reported

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<sup>1</sup> Defs. Brief in Opp., pg. 1.

<sup>2</sup> Id. at 3.

as rare is because the association between Benicar and sprue-like enteropathy was only recently discovered.

The association was not discovered until 2012, when the Mayo Clinic published the results of the first study that examined the association between olmesartan usage and severe gastrointestinal injuries.<sup>3</sup> This study was the first time the public had any warning that ingesting olmesartan drugs can cause severe gastrointestinal injuries. The Mayo Clinic study reported 22 patients suffering from olmesartan-induced gastrointestinal injuries. By late 2012, one of the study's authors, Margot Herman, M.D., had identified a total of 60 probable cases of severe sprue-like enteropathy.<sup>4</sup> Dr. Herman believes "it is the tip of the iceberg."<sup>5</sup>

In May 2013, Columbia University authors published a case series that cited 16 additional patients who had pathological findings of villous atrophy, which is the wearing away of the part of the lower intestine that helps a person absorb nutrients, as a result of olmesartan usage.<sup>6</sup> At Digestive Disease Week in May 2014, Dr. Mezzaroba reported 218 individuals who were hospitalized with a discharge diagnosis of intestinal malabsorption. She found that patients who ingested olmesartan for more than 2 years were nearly 10 times more likely to be hospitalized for intestinal malabsorption injuries as compared to other blood pressure medications. For many olmesartan users, the damage has been done; fortunately, the medical community's increased scrutiny of olmesartan has brought this issue to the attention of gastroenterologists and has given them the tools to accurately diagnose their ailing patients.

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<sup>3</sup> *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).

<sup>4</sup> <http://www.medpagetoday.com/MeetingCoverage/ACG/35498>.

<sup>5</sup> Id.

<sup>6</sup> *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).

These injuries are therefore not nearly as rare as Defendants suggest, and many more lawsuits are anticipated to be filed on behalf of individuals suffering gastrointestinal injuries after ingesting olmesartan. Indeed in the month and a half since Plaintiff's motion for transfer was filed (December 18), nine additional lawsuits were filed in federal court.

Plaintiffs' counsel filed a motion for consolidation because consolidation is in the best interest of all parties. Whether this litigation is consolidated or not, it will grow substantially, not because non-meritorious claims will be filed, but because olmesartan use is widespread and because the associated risk of gastrointestinal injuries is significant. This litigation will require consolidation if the parties have any hope of resolving their cases in a just and efficient manner.

Nevertheless, Defendants argue that because the cases "have different procedural postures and are at various stages of discovery and pretrial activities," an MDL will require Defendants "to start over before a different judge."<sup>7</sup> But an MDL would not wipe the slate clean. In an MDL, the parties will get the benefit of the work already completed, and going forward the new work—depositions, motions practice, etc.—will be done in a coordinated fashion. Moreover, the fact that the cases are in different procedural places militates *in favor* of consolidation, since it would avoid the risk that different judges will make different rulings on the same questions or order duplicative discovery. Allowing the cases to proceed at different paces before different judges in different courts would invite the very chaos MDLs are designed to avoid.

Another factor supporting transfer and consolidation is that this litigation is similar to the *Xarelto* litigation,<sup>8</sup> which was consolidated, and quite different from the *Cymbalta* litigation,<sup>9</sup> which wasn't—and which Defendants rely on in their brief. In the *Xarelto* litigation, "there

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<sup>7</sup> Defs. Brief in Opp., pg. 6.

<sup>8</sup> *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 171957.

<sup>9</sup> *In re Cymbalta (Duloxetine) Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 170732.

[we]re over two dozen involved plaintiffs’ firms....”<sup>10</sup> In the *Cymbalta* litigation, only two firms represented the plaintiffs in all the federal cases at the time of the Panel hearing; the Panel reasoned that the low number of plaintiff’s counsel “suggests that informal coordination with respect to the remaining discovery, as well as other pretrial matters, should be practicable.”<sup>11</sup>

Like the *Xarelto* litigation,<sup>12</sup> this litigation involves key foreign defendants. The parent company of the Daiichi Defendants, Daiichi Sankyo, Ltd., a Japanese corporation, has been named in several of the Benicar lawsuits and most likely will eventually be named in nearly all Benicar lawsuits. Daiichi Sankyo Ltd. researched, developed, and manufactured Benicar in Japan, where it is based. Many important documents and witnesses are located in Japan and a large number of documents will likely be in Japanese and will need to be translated. The *Xarelto* litigation also involved a key foreign defendant—Bayer Pharma AG, who was partially responsible for research, development, and manufacturing of Xarelto. Just as the Panel noted in *Xarelto*, the Benicar discovery that is located in a foreign country makes effective informal coordination “unlikely.”

Also like the *Xarelto* litigation, and unlike the *Cymbalta* litigation, the Benicar litigation is still in its infancy. Of the 24 Benicar federal cases currently filed, only two have even begun document production. The remaining 22 have not had any document production or depositions take place. The majority of federal cases have not entered *any* preliminary discovery orders, such as a protective order, ESI order, or case management order. In addition, Defendants have only produced a handful of documents from the Forest Defendants and they have not produced any documents from the Japanese Daiichi company.

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<sup>10</sup> *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 171957 at \*3.

<sup>11</sup> *In re Cymbalta (Duloxetine) Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 170732 at \*2-3.

<sup>12</sup> *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 171957 at \*3.

Currently, approximately forty cases have been filed in New Jersey state court and have been consolidated before the Honorable Nelson Johnson in the Superior Court of Atlantic County. The New Jersey state court litigation is in its infancy as well. While the first New Jersey state court actions involving Benicar were filed in February 2014, the first case management conference with Judge Nelson was only recently held (in November 2014). Some law firms have filed lawsuits in both the state court of New Jersey and in various federal court jurisdictions; however, the majority of plaintiff law firms have exclusively filed cases in either New Jersey state court or federal court. The Panel has ruled that when there is a significant state court docket with cases related to 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.”<sup>13</sup>

In *Cymbalta*, the Panel considered the advanced state of the litigation for three cases in ruling against consolidation.<sup>14</sup> One case had completed discovery and had entered the dispositive motion practice stage and the other two had discovery deadlines ending within days of the Panel’s order. Unlike the *Cymbalta* litigation, none of the Benicar cases have discovery deadlines before the Panel hearing date. Only two of the cases have had any document production and Defendants have produced only a small fraction of the millions of pages of documents that are ultimately expected to be produced. Like *Xarelto*, and unlike *Cymbalta*, the Benicar litigation is only in its infancy.

As for venue, the Northern District of Ohio is the best option because it has the judicial resources necessary to handle a large MDL, is conveniently located, making travel for the parties

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<sup>13</sup> *In re: Lipitor (Atorvastatin Calcium) Marketing, Salespractices and Products Liability Litigation (No. II)* 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014).

<sup>14</sup> *In re Cymbalta (Duloxetine) Prods. Liab. Litig.*, 2014 U.S. Dist. LEXIS 170732 at \*2-3.

more efficient, and is the venue most of the plaintiffs' law firms find suitable. As noted, 16 different plaintiffs' law firms are already involved in the Benicar litigation. Nine of the plaintiffs' law firms filed a motion with the Panel asking for a specific transferee forum. Four of those nine requested the Northern District of Ohio as their first choice; no other jurisdiction had more than one plaintiffs' law firm requesting it as their first choice.

In addition, the plaintiffs' firms recognize the experience that the Northern District of Ohio has in litigating drug MDLs and the experience that the Honorable Judge Dan Aaron Polster has in litigating a drug MDL with a large number of individual plaintiffs (MDL 1909, Gadolinium Contrast Dyes Products Liability Litigation). Even Defendants agree that the Northern District of Ohio is an appropriate venue, as they have selected it as their second choice.

Although Defendants requested the District of New Jersey as their first choice, not a single Benicar case has been filed in the District of New Jersey. An MDL is normally only transferred to a district that has a related case pending: "the Panel looks for an available and convenient transfer forum, usually one that...has a related action pending on its docket." Manual for Complex Litigation, Fourth, § 22.33. *See, e.g., In re Lupron Mktg. & Sales Practices Litig.*, 180 F. Supp. 2d 1376, 1378 (J.P.M.L. 2001). Since no Benicar case has been filed in the District of New Jersey, the cases should not be transferred there; rather, they should be transferred to Defendants' second choice and the choice of the plurality of plaintiffs' law firms—the Northern District of Ohio.

For these reasons, Plaintiff respectfully requests that the Panel grant the Motion for Transfer and Coordination under 28 U.S.C. § 1407 and transfer the Benicar (and other olmesartan drugs) products liability litigation to the Northern District of Ohio with the Honorable Judge Dan Aaron Polster presiding.

Respectfully submitted,

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