BEFORE THE
UNITED STATES JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: BENICAR (AND OTHER MDL OLMESARTAN DRUGS) PRODUCTS LIABILITY LITIGATION	§ § § § §	MDL No. 2606

DEFENDANTS' BRIEF IN RESPONSE AND OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER AND COORDINATION UNDER 28 U.S.C. § 1407

[ORAL ARGUMENT REQUESTED]

I. INTRODUCTION

Defendants Daiichi Sankyo, Inc. and Daiichi Sankyo U.S. Holdings, Inc. ("Daiichi U.S. Defendants"), and Forest Research Institute, Inc., Forest Pharmaceuticals, Inc. and Forest Laboratories, LLC ("Forest Defendants") (collectively "Defendants") hereby respond to and oppose Plaintiffs' Motion to Transfer 15 personal injury actions involving the alleged use of 3 different prescription olmesartan medications to a Multi-District Litigation ("MDL") proceeding pursuant to 28 U.S.C. § 1407.

An MDL proceeding is unnecessary here and will not promote the just and efficient conduct of this litigation as required by 28 U.S.C. § 1407. As this Panel has repeatedly recognized, informal coordination, where possible, is preferred to a formal centralized proceeding. As outlined in detail below, the olmesartan litigation involving Benicar®, Benicar® HCT and Azor® is driven by a small number of Plaintiffs' counsel before a few courts, and involves cases that will turn on highly individualized, case-specific legal and factual issues that are not susceptible to common proof. Defense counsel is already informally coordinating common discovery in these actions before a handful of courts to maximize efficiencies. Creating an MDL proceeding will only add to the burden, expense and uncertainty of this litigation, and would prejudice Defendants as these actions would have to start anew before a different court.

Benicar®, Benicar® HCT and Azor® are in a class of hypertensive medications known as Angiotensin II Receptor Blockers (ARBs) that are designed to help patients achieve an optimal blood pressure to reduce the risk of heart disease and stroke. ARBs have been on the market for 20 years, and there has never been a request for an MDL proceeding or mass filings involving Benicar®, Benicar® HCT or Azor® or for any other ARB. Plaintiffs' claims allegedly arise out of a new and reportedly rare intestinal disorder known as "sprue-like enteropathy." Plaintiffs' assertion that dozens of more cases could potentially be filed in the future is not reflected in the record, or the medicine, and is based on pure speculation. This Panel's prior decisions have considered the existing docket of pending actions, and not the possibility that more may be filed in the future. These are circumstances that weigh decidedly in favor of informal coordination of the current inventory of cases without an MDL proceeding. While Defendants do not believe an MDL proceeding is appropriate, if this Panel is inclined to transfer cases to an MDL proceeding based on the current record, they respectfully request that the Panel transfer the actions to the District of New Jersey. The Daiichi U.S. Defendants and Forest Defendants have principle places of businesses in New Jersey, and many documents and witnesses are located in New Jersey. The District of New Jersey also is the best venue to facilitate federal-state coordination, as there are 39 actions currently consolidated for pretrial discovery and pending in New Jersey state court before the Hon. Nelson C. Johnson in Atlantic City.

For these and the reasons set forth below, Defendants respectfully request that Plaintiffs' Motion to Transfer and Coordinate be denied, or in the alternative that any MDL proceeding be assigned to one of several judges in the District of New Jersey.

II. BACKGROUND

A. High Blood Pressure and Olmesartan Medications

Millions of Americans suffer from high blood pressure. Often called the "silent killer", high blood pressure is a chronic and common disease that if left untreated increases the risk of heart disease and stroke. Benicar®, Benicar® HCT and Azor® are blood pressure medications

in a class of medications known as ARBs, which were first sold in the United States nearly twenty years ago.[1]

Benicar®, otherwise known as olmesartan medoxomil, was approved for sale by the U.S. Food and Drug Administration ("FDA") on April 25, 2002, and is available in 5 mg, 20 mg and 40 mg tablets. Although similar to Benicar® and prescribed to treat high blood pressure, Benicar® HCT and Azor® are combination products that combine olmesartan medoxomil with other medications to help patients achieve an optimal blood pressure. Benicar® HCT was approved by the FDA on June 5, 2003 and is olmesartan medoxomil combined with the diuretic hydrochlorothiazide ("HCT"). Azor® was approved by the FDA on September 26, 2007 and is olmesartan medoxomil combined with the calcium channel blocker amlodipine. All of these medications remain on the market today as safe and effective methods for controlling high blood pressure in patients who have been prescribed these medications. These medications have well-established safety profiles with more than 53 million patient years of use worldwide.

On June 25, 2012, a medical journal article was published reporting on "a group of patients with unexplained severe sprulike enteropathy" and "a unique case series to support a novel association between severe spru-like enteropathy and olmesartan [the active ingredient in the Benicar® products]." Rubio-Tapia A. et al., Severe Spru-like Enteropathy Associated with Olmesartan, 87 MAYO CLIN. PRO. 732, 738 (2012). The condition has been reported as rare and was previously unreported in the medical literature in association with ARB medications. The authors of the article reported that the case series "lacks all the information necessary to prove causality but rather reflects an association." *Id.* at 735. This article is purportedly the basis for Plaintiffs' claims. The physician responsible for the paper has confirmed that sprue-like enteropathy is indeed rare. Exhibit A (J. Murray, Transcript of Severe Sprue-Like Enteropathy

[1] Daiichi Sankyo, Inc. also markets another ARB known as Tribenzor®, which is olmesartan medoxomil, amlodipine and HCT. None of the actions pending before the Panel allege use of Tribenzor®.

Associated with Olmesartan (10/15/2012), http://www.youtube.com/watch?v= CmrZBeikR-Y ("rare syndrome that is refactory sprue")(visited 1/5/2015)).

On April 19, 2013, the FDA requested that Daiichi Sankyo, Inc. update the label for Benicar®, Benicar® HCT, Azor® and Tribenzor®. Although a review of the post-marketing safety database did not substantiate the potential association described in the Rubio-Tapia article, Daiichi Sankyo, Inc. complied with the FDA's request and revised the label, which had previously warned of the risk of diarrhea in association with these medications. The following language was added to the label:

> **WARNINGS AND PRECAUTIONS**
> . . . .
> **5.5 Sprue-like Enteropathy**
> **Severe, chronic diarrhea with substantial weight loss has been reported in patients taking olmesartan months or years after drug initiation. Intestinal biopsies of patients often demonstrated villous atrophy. If a patient develops these symptoms during treatment with olmesartan, exclude other etiologies. Consider discontinuation of Benicar in cases where no other etiology is identified.**
>
> ****
>
> **ADVERSE REACTIONS/Post marketing Experience**
> . . . .
> Gastrointestinal. Vomiting, **sprue-like enteropathy [see Warnings and Precautions (5.5)]**

Exhibit B (current label).

B. <u>The 19 Actions Are in Different Phases of Litigation</u>

To date, 19 personal injury actions alleging injuries from use of Benicar®, Benicar® HCT or Azor® have been identified as pending in federal court. Exhibit C (Schedule of Actions, identifying court, Plaintiffs' counsel and product allegedly used). Four actions were the subject of Notices of Related Action since the filing of the MDL Petition. Fourteen actions allege use of Benicar®, 3 allege use of Benicar® HCT and 2 actions allege use of Azor®. *Id.*

The 19 actions are particularly well-suited for informal coordination based on the overlap of plaintiffs' counsel. Spangenberg Shibley & Liber LLP ("Spangenberg firm"), which filed the

MDL petition, is counsel of record in 9 of the 19 actions that were filed in a single federal court within weeks of each other just before the filing of the present motion. Eight of those 9 actions were filed along with Levin, Papantonio, Thomas, Mithell, Rafferty & Proctor, PA ("Levin Papantonio firm"), which is one of the primary firms spearheading the New Jersey state court litigation, as counsel of record, and the remaining action was filed along with the Abbott Law Group ("Abbott firm"), which serves as the Plaintiffs' e-discovery counsel in the New Jersey litigation and is co-counsel in at least two other federal actions.

Another firm actively serving as lead counsel in the almost year-old consolidated state court proceedings in New Jersey is Robins, Kaplan, Miller & Ciresi LLP ("Robins Kaplan firm"). The Robins Kaplan firm is counsel of record in 2 federal actions, one pending in the Central District of Illinois, and another pending in the District of Montana. Rule 16 scheduling conferences were already held in both actions with discovery and pre-trial deadlines set. The Robins Kaplan attorney who has been serving as the point person in the New Jersey litigation, making all appearances and arguing all motions, was co-counsel with the Spangenberg firm and the Levin Papantonio firm in the first filed Ohio federal action, until she filed a Notice of Withdrawal on December 29, 2014, after the filing of the MDL Motion.

One other firm, Rheingold Valet Rheingold McCartney & Giuffra LLP ("Rheingold firm"), which is counsel of record in a Southern District of New York action that was the subject of a Notice of Related Actions, is also counsel of record in 7 New Jersey state court actions.

Counsel at the firms leading the charge in New Jersey are lead counsel or co-counsel in 13 of the 19 federal actions, they are negotiating federal court protective orders and electronic discovery orders based on orders entered in New Jersey, and they have been given access to substantial discovery responses and weekly document productions based on requests that they propounded and served.

Outside of the firms leading the New Jersey litigation with 13 cases among them, there are a total of 6 cases pending in federal court, which have different procedural postures and are at various stages of discovery and pretrial activities. The parties have been working cooperatively in each of these actions, and Defendants should not be required to start over before a different judge. To date, district courts have entered protective orders and case management orders with fact and expert discovery cut-off dates that are approaching in 2015; some courts have set a final pre-trial conference; and another court has set a trial date for August, 2015. Defendants have produced more than 725,000 pages of documents and responded to written discovery demands, all of which will be made available to counsel in each of these cases upon request.

Nine of the actions alleging use of Benicar® were brought by the Spangenberg firm, along with the Levin Papantonio firm (8 actions) and the Abbott Law Group (1 action) and are pending before the Northern District of Ohio, where they can be readily coordinated and managed in that district. *Id*. The first-filed of these Ohio actions is *Brenda Baugh v. Daiichi Sankyo, Inc. et al*., N.D. Ohio, Case No. 4:14-cv-02309, pending before the Hon. Benita Pearson. On January 7, 2015, the Hon. Donald Nugent of the N.D. Ohio granted the unopposed defense motion to transfer the next filed action filed in the N.D. Ohio, *Laney v. Daiichi Sankyo, Inc.*, N. D. Ohio, Case No. 1:14-cv-02515, to Judge Pearson to be coordinated with the *Baugh* action pursuant to Local Rule 3.1(b)(3). Exhibit D. Defendants anticipate that the other N.D. Ohio actions will likewise be transferred pursuant to Local Rule 3.1(b)(3) to Judge Pearson for management. Judge Pearson is also assigned to a third N.D. Ohio action, *Hugley v. Daiichi Sankyo*, N.D. Ohio, Case No. 4:14-cv-02787.

On January 15, 2015, Plaintiffs filed motions to stay in all 9 of the N.D. Ohio actions, arguing that the actions should be stayed pending a decision of this Panel. Defendants opposed the motions and requested that discovery and other pretrial deadlines move forward similar to

actions pending in other district courts throughout the country. Plaintiffs' motions were later granted and resulted in Judge Pearson vacating a Rule 16 conference previously scheduled for February 4, 2015, at which both clients and counsel were required to attend.

Outside of the few select firms that are driving the litigation (Robins Kaplan, Spangenberg, Levin Papantonio, Rheingold, and Abbott) and seeking to delay important discovery of plaintiffs in their cases, there are only 6 other actions pending in federal court. These actions are at a different phase of discovery and litigation. For example, in *Ambler v. Daiichi Sankyo,* C.D. Cal., Case No. 3:14-cv-01475, the court has entered a case management order and discovery has commenced. Defendants have propounded discovery to Plaintiff, and the court has scheduled a final pre-trial conference for February 19, 2016. Defendants have produced more than 725,000 pages of documents. Defendants will make this same document production available to Plaintiffs in other cases subject to the same protective order entered in *Ambler*.

Similarly in *Von Eberstein v. Daiichi Sankyo,* one of two actions pending in the E.D. La., Case No. 2:14-cv-00089, the court entered a scheduling order on July 31, 2014 and set a trial date for August 17, 2015. Depositions of plaintiff and the treating physician have been taken. Defendants have responded to a multitude of interrogatories, document requests and request for admissions.

Other courts, in older federal cases where the Robins Kaplan and Levin Papantonio firms are involved, also have entered case management orders with discovery-cut off and related pretrial deadlines, including deadlines for protective orders and a protocol for production of electronically stored information and trial dates. *Van Dyke et al. v. Daiichi Sankyo, Inc.*, D. Mont., Case No. 1:14-cv-00137 (fact discovery deadline set for January 15, 2016); *Dirksen et al. v. Daiichi Sankyo et al*., C.D. Ill., Case No. 3:14-cv-03318 (fact discovery deadline is February 26, 2015; pretrial conference scheduled for March 17, 2017; trial date set for March 28, 2017). To date, Defendants have successfully coordinated these actions in an effective manner that promotes the interests of fairness and efficiency.

C. New Jersey State Court Proceeding

There are currently 39 actions alleging injuries from Benicar®, Benicar® HCT, Azor® or Tribenzor® that have been consolidated in the Superior Court of New Jersey Law Division, Atlantic County, before the Hon. Nelson Johnson. Defendants have responded to more than 100 document requests and more than 50 interrogatories and have produced more than 725,000 pages of documents. Defendants have coordinated discovery and pretrial matters in New Jersey with the federal court actions to the extent practicable. The protocol for electronically stored information that was submitted in New Jersey was negotiated by lawyers who have federal court cases pending in Illinois, Montana, California, and Ohio. The New Jersey litigation has been quite active, with Judge Johnson hearing motions on the entry of a Protective Order, the document production, Plaintiffs' assertion of the work product privilege, the service of multiple sets of discovery requests and the degree of proof necessary to go forward with a claim.

III. ARGUMENT

A. Plaintiffs Have Not Satisfied Their Burden under 28 U.S.C. § 1407

This Panel is authorized to transfer cases to an MDL proceeding if the moving party demonstrates that the requirements of 28 U.S.C. §1407 are satisfied. Section 1407 states as follows:

> 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 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 the parties and witnesses and will promote the just and efficient conduct of such actions.

The failure of the moving party to satisfy its burden based on the existing inventory of cases is grounds for denial of a motion for transfer and coordination. In ruling on motions for coordination under § 1407, this Panel has used a balancing test that considers issues of commonality between cases and weighs the convenience and efficiencies of proceeding with or without an MDL proceeding. It has been noted that the most important criteria under § 1407 is a

demonstration that the actions will proceed in a just and efficient manner. Charles A. Wright et al., FED. PRAC. AND PROC.: JURIS. AND RELATED MATTERS, § 3863, at 489 (2013).

The analysis of the Panel under § 1407 has traditionally focused on the goals of convenience and judicial economy, taking into consideration the number and type of actions, their complexity, the stage of discovery and pretrial activities in each action, common counsel of record, and other criteria. In applying these factors, this Panel has declined to coordinate a multitude of personal injury actions, with numbers of cases far in excess of the 15 identified in Plaintiffs' Motion and the 4 identified in Notices of Related Action.[2] Legal scholars and parties have noted that the creation of an MDL proceeding may have unintended consequences that has the potential to create inefficiencies, such as inviting lawsuits that have no merit and could distract the parties from the just and efficient conduct of the litigation.[3]

As set forth in more detail below, Plaintiffs have not satisfied their burden to prove the requirements of § 1407. The factors of convenience and economy are best promoted in these 15 personal injury cases involving highly individualized issues where the parties and a small group of lawyers and courts informally coordinate without an MDL proceeding.

1. These Personal Injury Cases Involve Highly Individualized Issues

Each of the 19 personal injury cases will turn on individual issues particular to each plaintiff's claims. *In re: Electrolux Dryer Prods. Liab. Litig*, 978 F. Supp. 2d 1376. Where a common issue is found to exist, it is seldom sufficient, by itself, to justify granting the motion to transfer. *Id.*; Charles A. Wright et al., FED. PRAC. AND PROC.: JURIS. AND RELATED MATTERS, §

[2] *See, e.g., In re Ambulatory Pain Pump Chondrolysis Products Liability Litigation*, 709 F. Supp. 2d 1375 (J.P.M.L. 2010) (declining to establish an MDL proceeding for 102 cases); *see also In re: Electrolux Dryer Products Liability Litigation*, 978 F. Supp. 2d 1376 (J.P.M.L. 1977) (declining to establish an MDL based on 35 actions pending in 21 districts).

[3] *See, e.g.*, Thomas E. Willging, Beyond Mass Torts: Mass Tort Case Management in the Manual for Complex Litigation, 148 U. PA. L. REV. 2225, 2256 (2000); *In re Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006) (declining to adopt but commenting on argument that MDL may invite lawsuits).

3863, at 468 (2013) ("that common question of fact [exist] seldom is sufficient, by itself, to justify granting the motion to transfer.").

Plaintiffs assert that these cases will involve common "discovery issues" such as causation, warnings, marketing, product design and damages. Pl. Mot. at 5-6. To the extent that there may be common discovery issues, this Panel has held that common discovery is not a sufficient basis for consolidation. *See, e.g., In re Mirena*, 2014 WL 4049821, at *2 (denying consolidation of nine cases "[a]lthough the actions share factual questions"); *In re Qualitest Birth Control Prods. Liab. Litig.*, __ F. Supp. 2d __, MDL No. 2552, 2014 WL 4050055, at * 1 (J.P.M.L. Aug. 12, 2014)(denying consolidation where "factual questions arising out of the design, manufacturing and packaging of the Qualitest birth control products.").[4] And in any event, Defendants have already been informally coordinating discovery in this litigation.

The relevant inquiry under § 1407 is whether individual issues in the litigation predominate over common ones. Multiple decisions of this Panel have held that "individual questions of fact concerning the circumstances of each patient's alleged injuries" predominate over convenience and economy in personal injury cases, including individual issues of liability, causation, reliance and damages. *In re Intuitive Surgical, Inc. Da Vinci Robotic Surgical System Prod. Liability Litig.*, 883 F. Supp. 2d 1339 (J.P.M.L. 2012); *In re Abbott Laboratories, Inc. Similac Prod. Liab. Litig.*, 763 F. Supp. 2d 1376, 1377 (J.P.M.L. 2011) ("Although plaintiffs are correct that some factual overlap exists among the present actions, the proponents of centralization have failed to convince us that any shared factual questions in these actions are sufficiently complex and/or numerous to justify Section 1407 transfer at the present time.").[5]

[4] See also *In re Oxycontin Prods. Liab. Litig.*, 395 F. Supp. 2d 1358, 1359 (J.P.M.L. 2005); *In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig.*, 446 F.Supp. 242, 244 (J.P.M.L. 1978).
[5] *See also In re Ambulatory Pain*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010); *In re: American-Manufactured Drywall Products Liability Litigation*, 716 F. Supp. 2d 1367 (J.P.M.L. 2160); *In re:*

A review of the 19 complaints demonstrates that Plaintiffs' claims will turn on different facts, circumstances and alleged injuries. The issues in each case will be highly individualized and case-specific. These plaintiffs allege use of different products, and their medical histories, underlying health conditions and risk profiles are different. The treatment decisions by the prescribing physicians, the label as read by the treating physicians, the cause of the alleged injuries and the extent of the alleged injuries will be unique to each plaintiff. None of these significant issues will be subject to common evidence. *In re: Shoulder Pain Pump-Chondrolysis Products Liability Litigation*, 571 F. Supp. 2d 1367, 1368 (J.P.M.L. 2008) (any "efficiencies that might be gained by centralization [are] overwhelmed by multiple individualized issues (including ones of liability and causation) that these actions appear to present.")

Plaintiffs' assertion that there may be "common discovery" is not a sufficient basis to justify a centralized proceeding. Nor have Plaintiffs satisfied their burden under § 1407 to demonstrate that common issues predominate in these personal injury cases. Accordingly, Plaintiffs' Motion should be denied.

2. Centralization of The Current Inventory of Cases Will Not Promote Convenience, Economy or Efficiency

Under § 1407, convenience and economy are factors that require a careful balancing in ascertaining whether to transfer cases to an MDL proceeding. In weighing these factors, this Panel has considered whether the existing inventory of cases can be managed efficiently and effectively under the current framework without an MDL proceeding, or whether the interests of convenience and economy would be best served with an MDL.

Northeast Contaminated Beef Prods. Liab. Litig., 856 F .Supp. 2d 1354, 1354-55 (J.P.M.L. 2012); *In re Watson Fentyl Patch Prods. Liab. Litig.*, 2012 U.S. Dist. LEXIS 112485 (J.P.M.L. Aug. 7, 2012).

a. Voluntary Coordination of Pre-Trial Activity with the Existing Docket Obviates the Need for Formal Centralization

This Panel has held that "informal cooperation among the involved attorneys and courts is both practicable and preferable" to centralization where there are a manageable number of lawyers and courts.[6]

Most of the Benicar® actions were brought by the same Plaintiffs' counsel who are working in conjunction to pursue this litigation before a handful of judges. *See In re American Manufactured Drywall Prods. Liab. Litig.*, 716 F.Supp.2d 1367, 1368 (J.P.M.L. 2010). One law firm (the Spanenberg firm) is counsel of record in 9 cases, and another (the Robins Kaplan firm) is counsel of record in 2 actions. *In re Cymbalta*, at 2 (citing *In re: Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig.*, 446 F.Supp.2d 242, 244 (J.P.M.L. 1978) (The significant overlap in counsel "suggests that informal coordination with respect to the remaining discovery, as well as other pretrial matters, should be practicable.").

Outside of these firms, there are only 6 cases pending in 5 district courts. Defendants have already coordinated discovery with multiple Plaintiffs' counsel in different cases in both federal and state courts. Courts have entered protective orders, and Defendants have produced more than 725,000 pages of documents. Defendants will make available to Plaintiffs' counsel this same discovery subject to the same confidentiality provisions.

Mechanisms such as cross-noticing depositions, stipulated use of common discovery and cooperation between counsel are sufficient to promote the goals of § 1407. This Panel has previously recognized that informal coordination weighs in favor of denying a motion to transfer.

[6] *See, e.g., In re Intuitive Surgical*, 853 F. Supp. 2d at 1340; *In re Adderall XR (Amphetamine/Dextroamphetamine) Mktg. Sales Practices & Antitrust Litig.*, 968 F. Supp. 2d 1343, 1345 (J.P.M.L. 2013); *In re: Waggin' Train Chicken Jerky Pet Treat Prods. Liab. Litig.*, 893 F.Supp.2d 1357, 1358 (J.P.M.L. 2012) (noting that informal cooperation among counsel was preferable to centralization).

> We observe that suitable alternatives to Section 1407 transfer are available in order to minimize the possibility of duplicative discovery. For example, notices for a particular deposition could be filed in all actions, thereby making the deposition applicable to each action; the parties could seek to agree upon a stipulation that any discovery relevant to more than one action may be used in all those actions; and any party could seek orders from...courts directly the parties to coordinate their pretrial efforts. .

In re Eli Lilly & Co. (Cephalexin Monohydrate Patent Litig.), 446 F. Supp. 2d 242, 244 (J.P.M.L. 1978) (citations omitted); *see also In re Fout & Wuederman Litig.*, 657 F. Supp. 2d 1371 (J.P.M.L. 2009). Defense counsel have experience litigating and managing a similar caseload of actions across jurisdictions and are poised to work cooperatively with Plaintiffs' counsel to focus and advance the litigation in ways that will conserve the resources of the parties and each of the courts where actions are pending. Formal centralization would not meaningfully enhance the convenience or judicial economy in these actions.

b. The Different Phases of Discovery and Litigation Support Denial of Plaintiffs' Motion

Where actions are in different stages of discovery and pretrial proceedings, this Panel has declined to transfer cases to an MDL proceeding because it would interject inefficiencies into a system that is working efficiently and effectively. In the order declining to establish an MDL in *In re: Cymbalta (Duloxetine) Products Liability Litigation* (JPML Dec. 12, 2014), this Panel noted that "the procedural posture of the actions varies significantly" and that while some cases had discovery cut-off dates, "the more recently filed actions are still in their infancy." *In re; Cymbalta* at 1-2 (*citing In re Lloyds Bank plc Int'l Mort. Serv. Loan Litig.*, 997 F. Supp. 2d 1352, 1353 (J.P.M.L. 2014) (denying centralization, in part because the "widely varying procedural postures" of the subject actions.). The Panel concluded that these divergent postures of the cases weighed in favor of denial of Plaintiffs' motion to centralize the actions. *Id.*

Courts in the *Ambler*, *Von Eberstein* and other cases have issued case management orders and have set deadlines for discovery cut-off and related pretrial activities. There is a trial date of

August, 2015 in *Von Eberstein*. The parties have been working diligently to propound and respond to discovery, conduct depositions of plaintiffs and treating physicians, and prepare these cases for trial and should not have to start anew with an MDL proceeding before a different court. As this Panel has recently held, where common discovery has commenced in earlier filed actions centralization may not be warranted, and in fact may create unnecessary inefficiencies. *See In re: Cymbalta* at 1-2.

c. The Inventory of Cases Overwhelmingly Supports Denial of Plaintiffs' Motion

Plaintiffs argue that a centralized proceeding is necessary based on 15 actions and purportedly because they expect that dozens of cases will be filed in the future. Pl. Br. at 1. But this Panel need not, and should not, entertain such speculation as a reason to transfer cases to an MDL. In ruling on disputed motions for coordination, this Panel has consistently looked to the cases currently on file in applying the factors set forth in § 1407.[7]

Whether a dozen or more additional cases will be filed has yet to be seen, and this Panel should not speculate about what might happen in this litigation based on Plaintiffs' counsel's suppositions. There is no history of mass filings, and no party has ever previously moved to create an MDL for Benicar®, Benicar® HCT or Azor®. Plaintiffs' assertion that additional lawsuits will be filed if an MDL is created has been the subject of arguments of parties and legal scholars who have noted that transfer under § 1407 may have unintended consequences that undermine the just and efficient conduct of the litigation.[8]

[7] *See In Re Intuitive Surgical*, 883 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012) (denying motion to transfer, noting, "[w]hile proponents maintain that this litigation may encompass 'hundreds' of cases or 'over a thousand' cases, we are presented with" far fewer.).

[8] *See, e.g.*, Roger D. Blair & Christine A. Piette, Coupons and Settlements in Antitrust Class Actions, 20 Antitrust ABA 32, 36 (2005) (recognizing that MDL coordination an "increase the attractiveness of filing suit," leading to the filing of "more suits."); 148 U. PA. L. Rev. 2225, 2256 (2000).

There is a concern in this litigation, as has been the case elsewhere, that the creation of a multidistrict proceeding pursuant to § 1407 may encourage the filing of numerous actions with little or no merit. An MDL creates the potential to encourage the filing of new copycat cases without diligent efforts to ensure the viability of claims, in attempt to gain leverage based on a large volume of cases. The filing of these copycat actions would be contrary to the purposes of § 1407 and would create additional burdens and expense for the parties. The goals of convenience and economy are promoted where the parties and lawyers will be able to effectively and efficiently reach the merits of a smaller group of cases without the distraction of an MDL proceeding involving copycat claims, particularly where individual issues predominate. This is of particular concern here where the litigation is focused on rare medical condition, newly associated with this prescription medication but could easily explode into mass filings on behalf of anyone who happened to have a spell of diarrhea while taking the product. Notably, to date only 2 of the federal court litigants have produced medical records which confirm the prescription of an olmesartan product and a temporal diagnosis of sprue-like enteropathy.

Where a request for an MDL is designed to facilitate the interests of counsel, the Panel has viewed those motions less favorably. This Panel has stated, "the Panel's primary purpose is not to divine the motives and strategies of the various litigants. . . Nevertheless, where a Section 1407 motion appears intended to further the interests of particular counsel more than those of the statute, we would certainly find less favor with it." *In re: Louisiana-Pacific Corp. Trimboard Siding Marketing, Sales Practices & Prods. Liab, Litig.*, 867 F. Supp. 2d at 1347 (quoting *In re CVS Caremark Corp. Wage and Hour Emp't Practices Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010)). This concern is noteworthy here where the movant law firm here filed 8 complaints one at a time in the N.D. Ohio, which were randomly assigned to 5 different judges in the N.D. Ohio. Within 3 hours of getting a complaint assigned to the Hon. Dan Aaron

Polster, the plaintiffs' candidate MDL judge, they filed a 799 page MDL petition, asking for an MDL to be led by Judge Polster.

Here, convenience and economy do not require an MDL for the current docket and can both be achieved without transfer, while at the same time not encouraging mass filings that have no merit. To the extent that there are overlapping issues of discovery from the Daiichi U.S. Defendants and Forest Defendants in these cases, this discovery can be readily coordinated through, among other things, shared document discovery and cross-noticed depositions. The moving parties have not made any showing that informal coordination is or will be inadequate for this limited number of cases.

Accordingly, Plaintiffs' motion should be denied, and the small group of counsel and parties should be permitted to work informally to achieve convenience and judicial economy without the uncertainties and burdens that may result from an MDL proceeding.

B. <u>The District of New Jersey Is Uniquely Situated In Close Proximity to Documents and Witnesses and Is Best Suited to Manage an MDL Proceeding</u>

To the extent the Panel believes that an MDL proceeding is appropriate here, the MDL should be venued in the District of New Jersey. The selection of a site for an MDL Court is generally guided by multiple factors and balancing of various interests "based on the nuances of a particular litigation." *See* Robert A. Cahn, A LOOK AT THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, 72 F.R.D. 211, 214 (1977). Factors that have been considered include (1) the location of relevant documents and witnesses, (2) the backlog of a court's civil docket and the extent to which it is overtaxed with other MDL cases, (3) a centrally located forum for national litigation, (4) the potential for state-federal coordination, and (5) the preference of the parties.[9]

[9] *See id.* at §§ 6:1-6:23; *In re Inter-Op Hip Prosthesis Prods. Liab. Litig.*, 149 F. Supp. 2d 931, 933-934 (J.P.M.L. 2001); *In re: Express Scripts, Inc., Pharmacy Benefits Mgmt. Litig.*, 368 F. Supp. 2d at 357; *In re Thaxton Group, Inc. Sec. Litig.*, 323 F. Supp. 2d 1374, 1375 (J.P.M.L. 2004); *In re Cuisinart*, 506 F. Supp. 2d 651, 653 (J.P.M.L. 1981).

The District of New Jersey is better suited to meet the goals of "efficiency" and "economy" in an MDL proceeding than the venue recommended by Plaintiffs. There are several judges in the District of New Jersey who are qualified to serve as an MDL judge, including The Hon. Judges Stanley Chesler, Robert Kugler, William Martini, Jerome Simandle or Freda Wolfson.

This Panel has previously held that the District of New Jersey is a convenient location that has sufficient resources to handle an MDL proceeding. *See, e.g., In re: Nickelodian Consumer Privacy Litig.*, 949 F. Supp. 2d 1377 (J.P.M.L. 2013) (finding that the District of New Jersey is "a convenient and accessible forum, relatively close to potential witnesses and evidence located in New Jersey and New York City."). The District of New Jersey also has been considered a strong candidate for transfer when many witnesses and documents relevant to the case are located there. *Id.*; *see also In re: Merck & Co., Inc., Securities, Derivative & ERISA Litig.*, 360 F. Supp. 2d 1375, 1377 (J.P.M.L. 2013) (documents and witnesses likely located at Merck's New Jersey headquarters); *In re: Avandia Marketing, Sales Practices and Products Liability Litigation*, 528 F. Supp. 2d 1339 (J.P.M.L. 2007) (transferring cases to the Eastern District of Pennsylvania because defendants' principal place of business).

The Daiichi U.S. Defendants and Forest Defendants have their principal places of business in the District of New Jersey and that district offers distinct advantages of proximity to witnesses and documents relevant to plaintiffs' claims. *See, e.g., In re: Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011). In contrast, there is no center of gravity for Plaintiffs who have filed cases alleging injuries from olmesartan medications. Those actions are geographically diverse, and there is no single district that is convenient for plaintiffs. *Id.*

The District of New Jersey also is located in a major metropolitan area that can accommodate counsel and courthouses are well equipped to handle an MDL proceeding.[10] Assigning an MDL to the District of New Jersey also will facilitate coordination with the state court proceedings in New Jersey. *See, e.g., In re Internal Revenue Service § 1031 Tax Deferred Exchange Litigation*, 528 F. Supp. 2d 1343, 1344 (J.P.M.L. 2007) (transfer appropriate where defendant is located in venue and state court proceedings would "enhance potential for coordination between state and federal courts regarding this matter."). There are currently 39 actions that have been consolidated and are pending in New Jersey state court. Having both state and federal judges in close proximity in the same state as documents and witnesses will promote the just and efficient conduct of the litigation. There is no other district in the country that has this same benefit. State-federal coordination is an added component that weighs decidedly in favor of the District of New Jersey.

The District of New Jersey also has the resources available and the relative congestion of their dockets that weigh in their favor. *See, e.g., In re GMAC Insurance Management Corp. Overtime Pay Litigation*, 342 F. Supp. 2d 1357 (J.P.M.L. 2004) (the M.D. Fla. had "the resources available to manage this litigation"); *In re Baycol Products Liability Litigation*, 2001 WL 34134820 at *2 (J.P.M.L. 2001) (Minnesota courts are "not currently overtaxed …"). The District of New Jersey has a caseload per judgeship less than the national average at 545 pending actions per judge.[11] The district has several MDL dockets with less than 1,000 pending actions

[10] *See, e.g., In re Educational Testing Service PLT 7-12 Test Scoring Litigation*, 350 F. Supp. 2d 1363, 1365 (J.P.M.L. 2004); *In re Inter-Op Hip Prosthesis Products Liability Litigation*, 149 F. Supp. 2d 931, 933 (J.P.M.L. 2001).

[11] Ex. E, U.S.D.C., Judicial Caseload Profile (D. N.J.) (http://www.uscourts.gov/viewer.aspx?doc=/uscourts/Statistics/FederalCourtManagementStatistics/2014/district-fcms-profiles-june-2014.pdf&page=15).

combined, and is therefore not overburdened with pending MDL litigation.[12] The Hon. Jerome Simandle, Chief Judge of the District of New Jersey, has stated that the District of New Jersey enjoys handling MDLs and "hope[s] to maintain [its] excellence in complex litigation, including patents, class actions, and multi-district litigation generally."[13]

Several judges in the District of New Jersey are well-suited and equipped to handle an MDL docket. Judge Martini is currently presiding over 3 MDL proceedings with a combined caseload of 28. *See* Ex. F. Judge Kugler is not presiding over an MDL proceeding. Judge Chesler is currently presiding over 3 MDL proceedings with a total of 15 pending actions. *Id.* Judge Woflson is currently presiding over the *In re Plavix Prods. Liab. and Mktg. Litig*. (MDL 2418), which currently has only 32 cases. *Id*. Judge Simandle is currently presiding over *In re: Caterpillar, Inc., C13 and C15 Engine Products Liability Litigation* (MDL 2540) with 16 cases. Each of these judges has considered important *Daubert* and dispositive motions and has managed complex litigation.

The location of documents and witnesses, experience of these judges, the caseload in the district, the convenience to major airports and abundance of hotels weighs decidedly in favor of the District of New Jersey. Although there is not currently any action pending in New Jersey, considerations of all of these factors weighs decidedly in favor of New Jersey. *See, e.g., In re: Southwestern Life Ins. Co. Sales Practices Litig.*, 268 F. Supp. 2d 1377, 1378 (J.P.M.L. 2003) (finding that although no action was currently pending in the district, it was appropriate to transfer actions there because "relevant documents are likely located there"). Under similar circumstances, this Panel has assigned cases to districts where defendants are located even

[12] Ex. F, MDL Statistics Report – Distribution of Pending MDL Dockets by District (Jan. 15, 2015) (http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-January-15-2015.pdf).

[13] N.J. State Bar Assoc., Federal Practice and Procedure Newsletter, Vol. 7, No. 1, at 8 (June 2013) (available at http://www.archerlaw.com/files/NJSBA_ Newsletter_Coghlan_2.pdf (Oct. 30, 2014).

though there was no action pending in the particular district. *See, e.g., In re Nutramax Cosamin Mktg. & Sales Practices Litig*., 988 F.Supp. 2d 1371, 1371-72, n. 2 (J.P.M.L. 2013); *In re Darvocet*, 780 F. Supp. 2d at 1381-82. Accordingly, any MDL proceeding should be assigned to Judges Chesler, Kugler, Martini, Simandle or Wolfson.

In the alternative, if an MDL is to be assigned to the Northern District of Ohio, as Plaintiffs suggest, then the MDL should be assigned to the Hon. Benita Pearson, who was assigned to the first-filed *Baugh* action. Two other Benicar® cases are assigned to Judge Pearson, *Hugley v. Daiichi Sankyo, Inc., et al.* and *Laney v. Daiichi Sankyo, Inc., et al.*. The *Laney* action was transferred to Judge Pearson following an unopposed Motion to Transfer dated December 17, 2014 and Order of Reassignment dated January 7, 2015. Four additional motions to transfer to Judge Pearson are pending in *Johnson v. Daiichi Sankyo, Inc.*, Case No. 3:14-02672, *Bonner v. Daiichi Sankyo, Inc.*, Case No. 5:14-02672; *Changet v. Daiichi Sankyo, Inc.*, Case No. 5:14-02782; *McClesky v. Daiichi Sankyo, Inc.*, Case No. 5:14-cv-02784. Judge Pearson presently has one MDL, *In Re: Ford Motor Co. Spark Plug and 3-Valve Engine Products Liability Litigation*, assigned to her involving 5 cases, and she is well qualified to handle an MDL proceeding.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion should be denied, or in the alternative an MDL should be assigned to the District of New Jersey.

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By: /s/ Susan M. Sharko

Susan M. Sharko
DRINKER BIDDLE & REATH LLP
600 Campus Drive
Florham Park, NJ 07932-1047
Tel: (973) 549-7000/Fax: (973) 360-9831
susan.sharko@dbr.com
Attorneys for Defendants Daiichi Sankyo, Inc., and Daiichi Sankyo US Holdings, Inc., Forest Research Institute, Inc., Forest Pharmaceuticals, Inc. and Forest Laboratories, LLC