

## NOTICE TO THE BAR

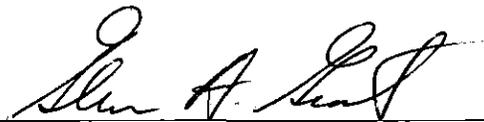
### MULTICOUNTY LITIGATION APPLICATION FOR DESIGNATION OF NEW JERSEY CASES INVOLVING OLMESARTAN MEDOXOMIL MEDICATIONS

The Supreme Court has received an application pursuant to Directive #08-12, "Revised Multicounty Litigation Guidelines," for Multicounty Litigation (MCL) designation of New Jersey state-court litigation involving alleged personal injuries resulting from treatment with medications containing Olmesartan Medoxomil. The litigation is against Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., Daiichi Sankyo Company, Limited, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc.

Anyone wishing to comment on or object to this application should provide such comments or objections in writing, with relevant supporting documentation, by **June 26, 2015** to:

Hon. Glenn A. Grant  
Acting Administrative Director of the Courts  
Attention: MCL Comments – Olmesartan Medoxomil Litigation  
Hughes Justice Complex, P.O. Box 037  
Trenton, New Jersey 08625-0037

A copy of the application submitted to the Court is posted with this Notice on the Judiciary's Internet Website at ([www.njcourts.com](http://www.njcourts.com)) in the Multicounty Litigation Information Center (<http://www.judiciary.state.nj.us/mass-tort/index/htm>).



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Glenn A. Grant, J.A.D.  
Acting Administrative Director of the Courts

Dated: May 26, 2015

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May 18, 2015

**VIA FEDERAL EXPRESS**

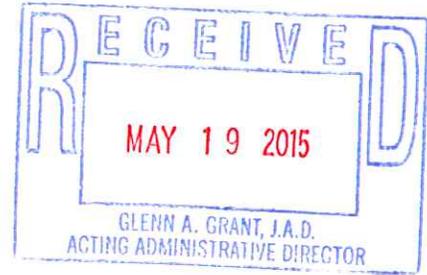
Honorable Glenn A. Grant, J.A.D.  
Acting Administrative Director of the New Jersey Courts  
Administrative Office of the Courts  
Hughes Justice Complex  
25 West Market Street  
Trenton, New Jersey 08625

**Re: Application for Centralized Management of Cases  
Involving Olmesartan Medoxomil Medications.**

Dear Judge Grant:

We represent Defendants Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., Daiichi Sankyo Company, Limited, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. in 58 cases consolidated in Atlantic County and one case recently filed in Hudson County. All 59 cases allege sprue-like enteropathy and related personal injuries as a result of plaintiff's treatment with medications containing Olmesartan Medoxomil. We write to respectfully request Centralized Management before the Hon. Nelson C. Johnson, J.S.C., in Atlantic County of products liability cases involving sprue-like enteropathy as a result of taking Olmesartan-containing products.

The New Jersey state court products liability actions relating to Olmesartan were first filed in February 2014 by Rayna Kessler, Esq., then with the Lopez McHugh firm, now with Robins Kaplan. Defendants moved for a change of venue on April 15, 2014 in connection with the first filed case, as none of the Plaintiffs were from Atlantic County.



Andrew B. Joseph  
Partner responsible for  
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Established 1849

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That motion was denied by the Hon. Julio Mendez, A.J.S.C. on June 25, 2014, after Ms. Kessler located an Atlantic County resident and filed suit on her behalf.

Ms. Kessler simultaneously moved to consolidate all of the then-pending cases for pretrial discovery and management in Atlantic County, which was granted on the same day by Judge Mendez. The cases were originally assigned to the Hon. Carol E. Higbee, P.J.Cv., then to Judge Johnson when Judge Higbee was elevated to the Appellate Division.

Despite having moved for consolidation in 2014, last month Ms. Kessler filed suit on behalf of a New York state resident in Hudson County. Defendants have asked Ms. Kessler to agree to transfer of this case to Atlantic County. She has refused to do so. Defendants have filed a motion to change venue in that case, Langdon v. Daiichi Sankyo, Inc, Docket No. HUD-L-1240-15.

A federal Multi-District Litigation was created on April 3, 2015, and assigned to the Hon. Robert B. Kugler, U.S.D.J. and the Hon. Joel Schneider, U.S.M.J., of the United States District Court for the District of New Jersey, Camden vicinage.

Since being assigned the consolidated Olmesartan cases, Judge Johnson has conducted two Case Management Conferences, has adjudicated various discovery motions, and on May 8, 2015 conducted a "Science Day" presentation. Both Judge Kugler and Magistrate Judge Schneider attended the May 8, 2015 Science Day Presentation. Judge Johnson has ruled that discovery in the cases before him will be coordinated with discovery in the newly-created MDL. In addition, Judge Johnson

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drafted and entered a Protective Order after the sides were unable to reach agreement on the terms of that Order.

Defendants have provided extensive discovery responses in the consolidated litigation before Judge Johnson. The Daiichi defendants and the Forest defendants have each responded to 173 document requests and 78 interrogatories, including subparts, and anticipate serving responses to 156 requests for admissions within the next 45 days. The Daiichi defendants have also responded to case-specific interrogatories in 19 additional cases. After Defendants served written discovery responses, the Mazie Slater firm served in one state court case extensive and overlapping discovery requests on all Defendants. Defendants moved to quash, arguing among other things that in a consolidated proceeding there should be one set of discovery requests. Judge Johnson granted Defendants' motion by Order dated December 18, 2014. Before the motion was decided, Defendants agreed to respond to certain case-specific interrogatories, and have since served answers in 19 cases where individual discovery was served.

To date, Defendants have made 28 productions of documents totaling over 3 million pages, including TIFF productions for electronic mail and data and scanned paper documents, and native productions for certain limited categories of documents. Rolling productions continue on a weekly basis, as they have since September 2014. Defendants' productions include such documents as the Benicar®, Benicar HCT®, Azor® and Tribenzor® Investigational New Drug Applications and New Drug Applications, regulatory submissions and FDA correspondence, marketing and detail training materials,

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adverse event reports, insurance policies, document retention policies, and custodial electronic mail.

Judge Johnson is ably managing these cases as if they were centralized. However, given the volume of cases and the fact that plaintiffs' counsel is now filing cases in other counties, the time has come for centralized case management to be formalized. Centralized management of these cases before Judge Johnson will help conserve judicial resources, avoid the risks of duplicative discovery and avoid the risk of inconsistent rulings.

#### **THE MEDICATION**

At issue in this litigation are four oral prescription medicines – Benicar®, Benicar HCT®, Azor®, and Tribenzor® – indicated for the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure. They belong to the class of drugs known as angiotensin II receptor blockers (ARB). ARBs, which have been on the market for over 20 years, block the action of angiotensin II by binding to AT<sub>1</sub> receptors, which mediate the physiological actions of angiotensin II. All of these medications remain on the market today as safe and effective methods for controlling high blood pressure.

Over 40 million patients worldwide have been treated with olmesartan medoxomil products. The litigation was started after the publication of a case series report on 22 patients with a new and rare gastrointestinal ailment called “sprue-like enteropathy.” The condition is characterized by severe, chronic diarrhea, substantial weight loss and villous

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atrophy, which is erosion of the villi in the lining of the small intestine. See, Rubio-Tapia A. et al., Severe Sprue-like Enteropathy Associated with Olmesartan, 87 MAYO CLIN. PROC. 732 (2012).

Defendant Forest Laboratories, Inc., now known as Forest Laboratories, LLC, co-promoted the medicines between 2002 and 2008. Defendants Forest Laboratories, LLC, Forest Pharmaceuticals, Inc., Forest Research Institute, Inc., and Daiichi Sankyo U.S. Holdings, Inc. have never had responsibility for labeling, designing, or manufacturing the medicines. Daiichi Sankyo Company, Limited is a Japanese parent company.

#### **LEGAL ARGUMENT**

This litigation meets the criteria required under Directive #8-12 for Centralized Case Management. Defendants respectfully request that these cases be consolidated for case management in the Atlantic County Superior Court before Judge Johnson.

#### **I. THESE CASES SATISFY THE CRITERIA FOR CENTRALIZED CASE MANAGEMENT**

##### **A. The litigation involves a large number of parties.**

There are 59 cases pending in New Jersey. The wide majority of plaintiffs are not New Jersey residents. The plaintiffs' firms which have filed the actions so far have stated their intention to file additional claims. The litigation meets the "large number" of parties requirement.

##### **B. The litigation involves many claims with common, recurrent issues of law and fact, all associated with a similar product.**

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Each of the pending cases alleges that treatment with Olmesartan caused gastrointestinal maladies, most notably a newly-discovered and rare condition called sprue-like enteropathy. While each plaintiff will have an individualized medical history, alleged exposure history and unique facts, each of the Complaints contains similar allegations and demands for damages against the Defendants. As such, the recurrent issue of law requirement is met, with the note that the plaintiffs at this time are from 24 different states. The defendants are the same in all the cases.

**C. Geographical dispersment and Remoteness of Counsel require Centralized Management.**

Defendants have offices in New Jersey and Japan. As outlined in the attached case listing at Exhibit A, only five of the 59 plaintiffs are New Jersey residents. This geographical diversity meets the geographic disbursement and remoteness requirement.

**D. Centralized Management will promote fairness and provide convenience to all parties and their Counsel.**

Centralized Management of cases such as those in this litigation that involve a significant number of parties, court filings, court hearings and motion practice is appropriate. It makes no sense in the context of this litigation to have the cases proceed before different Judges in different counties. Centralized Management in a Multi-County litigation venue, with an experienced Judge, will help ensure fairness to the parties, provide a streamlined approach to case management and avoid the possibility of duplicative motion practice and inconsistent discovery rulings between multiple Judges in Atlantic and Hudson Counties.

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Centralized management is particularly appropriate here, as all but one of the cases already were consolidated for discovery in Atlantic County, and Judge Johnson has been managing the consolidated litigation for nearly a year. That all but one of the cases is consolidated before Judge Johnson is solely the result of plaintiffs' motion to consolidate in June 2014. Plaintiffs chose Atlantic County. They cannot argue now that centralization in the venue they chose for consolidation is either unfair or inconvenient.

Centralization of this litigation before Judge Johnson will result in the efficient utilization of judicial resources. Allowing plaintiffs to file lawsuits in counties other than Atlantic County, such as Ms. Kessler's recent filing in Hudson County, will lead to a risk of inconsistent or duplicative rulings, inconsistent orders and inconsistent judgments.

**E. Related Matters Pending**

An MDL has been established, and as noted above Judge Johnson, Judge Kugler and Magistrate Judge Schneider have attended a Science Day scheduled by Judge Johnson. Judge Johnson at the May 8, 2014 Case Management Conference made clear his intent to coordinate discovery with the MDL proceedings. Centralized Management before Judge Johnson, one of New Jersey's experienced Multi-County litigation Judges, together with his staff, will provide the most efficient and fair forum in which to litigate these matters.

**II. ATLANTIC COUNTY IS THE MOST APPROPRIATE VENUE  
FOR THE CENTRALIZED MANAGEMENT OF THESE CASES**

This point bears repeating: Plaintiffs chose Atlantic County when seeking consolidation of these cases. These matters have been pending in Atlantic County for over a year. Judge Johnson has been actively overseeing this docket of cases as it has

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grown. Because of his significant involvement in these matters to date, his knowledge of the litigation and the issues involved therein, and his efficient handling of the cases up to this point, that these matters should be consolidated for management before Judge Johnson in Atlantic County.

Further, based upon review of the current Civil Division caseloads, Atlantic County is the proper venue for this litigation. The Hudson County Superior Court, Civil Division added 34,536 new cases to the docket between July 2014 and March 2015, compared to the Atlantic County Superior Court, Civil Division which added just 16,859 new civil cases in the same time period. See New Jersey Judiciary, Court Management Statistics, July 2014 – March 2015, <http://www.judiciary.state.nj.us/quant/cman1503.pdf>.

### CONCLUSION

All parties are hereby notified that this application will be sent by the Administrative Director to all Assignment Judges and Civil Presiding Judges, will be published by the Administrative Director in the legal newspapers, and will be posted on the Judiciary's Internet website both in the Notices section and in the Mass Tort Information Center. Once the comment period has closed, the Administrative Director will present this application, along with a compilation of any comments and objections received to the Supreme Court for its review and determination.

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For all of the foregoing reasons, Defendants Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. respectfully request each of the matters identified in Exhibit A, and any additional cases filed in New Jersey alleging sprue-like enteropathy as a result of taking prescription medicine containing Olmesartan be consolidated for Centralized Management in Atlantic County.

Respectfully submitted,

DRINKER BIDDLE & REATH LLP  
Attorneys for Defendants

By:   
Susan M. Sharko

-and-

By:   
Daniel B. Carroll

Date: May 18, 2015

cc: Honorable Nelson C. Johnson, J.S.C.  
Honorable Peter F. Bariso, Jr., J.S.C.  
All Plaintiffs' Counsel