

## NOTICE TO THE BAR

### **APPLICATION FOR CENTRALIZED MANAGEMENT OF ZELNORM® LITIGATION IN BERGEN COUNTY**

Pursuant to Rule 4:38A and Administrative Directive #10-07, “Mass Torts – Revised Guidelines and Criteria for Designation,” an application has been made to the Supreme Court, through the Administrative Director of the Courts, for centralized management of all Zelnorm® litigation in Bergen County and assignment of that litigation to Judge Jonathan N. Harris. The application specifically requests that the litigation not be designated as a mass tort.

Anyone wishing to comment on or object to this application should provide such comments or objections, with relevant supporting documentation, to the Hon. Philip S. Carchman, P.J.A.D., Acting Administrative Director of the Courts, P.O. Box 037, Trenton, NJ 08625-0037, **by June 2, 2008.**

/s/ Philip S. Carchman

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Philip S. Carchman, P.J.A.D.  
Acting Administrative Director of the Courts

Dated: April 24, 2008



*John Altman*

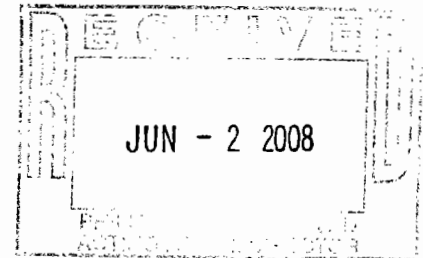
Niki A. Trunk  
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Reply To:  
New Jersey Office

June 2, 2008

**VIA HAND DELIVERY**

Honorable Philip S. Carchman, P.J.A.D.  
Acting Administrative Director of the Courts  
Richard J. Hughes Justice Complex  
PO Box 037  
Trenton, New Jersey 08625-0037



Re: Mass Tort Application – Zelnorm Litigation

Honorable Judge Carchman:

Counsel representing plaintiffs in twelve product liability actions in New Jersey involving Zelnorm prescription medication, which was sold in the United States by East Hanover based Novartis Pharmaceuticals Corporation, request that these cases, and all similar cases filed henceforth, be designated as a mass tort and centralized for purposes of case management. (See Schedule of Cases, attached as Exhibit A.)

In a letter dated April 18, 2008 (attached as Exhibit B), Novartis Pharmaceutical Corporation, a defendant in each of these Zelnorm actions, requests centralized management of these cases. The plaintiffs agree that centralized management is appropriate, and further believe that these cases are ripe for mass tort designation. However, Plaintiffs do not agree with Novartis' rather novel, if not unprecedented, approach of centralizing these cases. Instead, Plaintiffs request that, pursuant to Rule 4:30A and Directive #10-07, the Supreme Court designate Zelnorm litigation a mass tort and order centralized management in an appropriate Court.

**BACKGROUND**

There are currently 12 cases on file in New Jersey wherein plaintiffs assert personal injury claims against Novartis Pharmaceuticals Corporation, and in many cases also against Novartis Corporation, Novartis Pharma Stein AG, and Novartis AG (collectively, "Novartis"). A Schedule of those cases is attached here to as Exhibit A. Plaintiffs allege that they suffered serious cardiovascular injury as a result of use of Zelnorm. It is movants understanding that many more cases will be filed in New Jersey. The best approximation is that there will be between 200-300 cases filed by the end of 2008.



Discovery is in its early stages. Seven depositions have proceeded of witnesses presented under “person most knowledgeable” notices. There has been no necessity of judicial intervention with respect to discovery.

### MASS TORT TREATMENT IS WARRANTED

Pursuant to New Jersey’s Mass Tort Guidelines, coordination of the Zelnorm cases is warranted here. As detailed below, Zelnorm cases involve: (1) a large number of parties; (2) many claims with common, recurrent issues of law and fact associated with one product; (3) geographical disbursement of the parties; (4) a high degree of remoteness between the court and the actual decision-makers; (5) cases before various judges resulting in duplicative and inconsistent rulings; (6) the risk of inefficient and uncoordinated discovery; and (7) possibility of a pending Multi-District Litigation (“MDL”) that would be best coordinated with a single New Jersey judge. Mass tort designation is fair and convenient for the parties, witnesses, and counsel and is the best allocation of the Court’s resources.

#### *1. Large Number of Parties*

The cases filed thus far involve at least twelve plaintiffs who allege either personal injury resulting from ingestion of Zelnorm manufactured or distributed by one or more Novartis entities or who are family members or spouses who are suing for related damages.

#### *2. The Claims Involve Common Recurrent Issues of Law and Fact*

Plaintiffs’ actions against Novartis are classic products liability cases, in which Plaintiffs allege common law and statutory products liability causes of action such as failure to warn, negligence, design defect and breach of warranty. Specifically, Plaintiffs allege that Novartis failed to warn of certain cardiovascular risks associated with Zelnorm, and that such failure resulted in plaintiffs’ injuries, including severe cardiovascular events. While each of the cases raises individualized issues not susceptible to class certification, there exist recurring questions of law and fact concerning specific and general causation and manufacturer and distributor liability. Accordingly, centralized management of these cases will allow for efficient resolution of threshold issues applicable to all cases.

#### *3. Geographical Disbursement of the Parties*

The twelve cases are currently pending in Hudson, Middlesex, Essex and Atlantic counties (see Exhibit A). The plaintiffs reside in at least eight states. Novartis Pharmaceutical Corporation is headquartered in East Hanover, New Jersey. Novartis Corporation is headquartered in East Hanover, New Jersey. Novartis Pharma Stein AG is headquartered in Stein, Switzerland. Novartis AG is headquartered in Basel, Switzerland.

#### *4. High Degree of Remoteness Between the Court and the Actual Decision-Makers*

The New Jersey-based Novartis entities are represented by national coordinating counsel, local counsel and in-house counsel in at least 20 cases nationwide. Additionally, two Swiss Novartis entities are named in at least ten cases. Centralized case management is warranted as it would allow Novartis counsel to make decisions which would have uniform application to all New Jersey cases with consistent implementation and results. Absent centralized management, the high degree of remoteness between each Court and decision makers will impede the efficient resolution of the Zelnorm litigation.

5. *There is a Risk of Inconsistent Rulings In This Litigation*

There are at least twelve cases pending in four counties, in front of at least four different judges, in the Superior Courts of New Jersey. Centralized management of these cases will reduce the risk of inconsistent rulings, benefiting all parties.

6. *Inefficient and Uncoordinated Discovery*

All parties will benefit from centralized management where uniform discovery may be propounded, depositions may be scheduled in an organized and mutually-convenient fashion, with oversight from one judge, who can resolve disputes across all cases.

Furthermore, mass tort treatment and centralized management of these cases will permit any prospective MDL judge to coordinate federal discovery with discovery in these state court cases, a goal set forth in New Jersey's Mass Tort Guidelines and the New Jersey Mass Tort (Non-Asbestos) Resource Book. New Jersey Mass Tort (Non-Asbestos) Resource Book 13 (New Jersey Judiciary, 3d ed. 2007) ("New Jersey mass tort judges have found coordination with the designated MDL judge to be an effective means of avoiding duplication of efforts, coordinating discovery, conserving resources and facilitating global settlements.").

7. *Potential MDL*

In addition to the twelve actions filed by the Plaintiffs in the New Jersey cases, there are currently at least nine other actions filed throughout the country involving plaintiffs alleging similar claims to Plaintiffs' claims here. Like the New Jersey cases, those nine cases against Novartis arise out of the alleged use of Zelnorm manufactured by Novartis.

It is possible, and perhaps even likely, that all federal cases will be transferred to a single federal judge for pretrial coordination. In the interest of judicial efficiency and economy, it therefore makes sense to consolidate the twelve cases pending in New Jersey, as well as those cases yet to be filed, before a single judge. This will allow the federal cases to be efficiently coordinated with the New Jersey state cases in the event the federal cases are consolidated. Even absent federal consolidation, as the defendants state in their application for centralization, informal state-federal coordination would be beneficial.

8. *Centralized Management is Fair and Convenient*



Defendants in the Zelnorm litigation have requested centralized management. Plaintiffs agree that centralized management is fair and convenient to the parties, witnesses, and counsel in that centralized management will allow for efficient and uniform treatment of issues that appear across all Zelnorm cases.

9. *Centralization is Efficient for the Court*

Mass tort designation would result in more efficient use of judicial resources in that, as opposed to consuming the resources of at least five judges in at least four counties, all matters would be pending in front of a single judge responsible for overseeing the litigation.

**PLAINTIFFS REQUEST CENTRALIZED MANAGEMENT IN ATLANTIC COUNTY**

A review of the of the cases currently on file in New Jersey, cross-referenced with a review of available "mass tort" judges indicates that only Atlantic County Superior Court has a Zelnorm case on its docket. Accordingly, Plaintiff would respectfully suggest that Atlantic County Superior Court, Judge Higbee, is the most appropriate Court for this centralization.

In curious contrast to its motion for centralization, Defendants take the position that mass tort designation is not appropriate. As demonstrated above, pursuant to Directive #10-07 and Rule 4:38A mass tort designation is certainly appropriate in this litigation.

If the Court has any questions or is in need of any further information from us, please do not hesitate to contact me.

Respectfully submitted,  
**LOPEZ MCHUGH, LLP**

  
\_\_\_\_\_  
NIKI A. TRUNK

NAT/kat

cc: **Via First Class Mail:**

- Michelle V. Perone, Esquire
- Honorable Peter F. Bariso, J.S.C.
- Honorable Heidi W. Currier, J.S.C.
- Honorable Nicholas J. Stroumtsos, J.S.C.
- Honorable Hector R. Velazquez, J.S.C.
- Diane Lifton, Esquire (via facsimile)
- Tor A. Hoerman, Esquire
- Steven D. Davis, Esquire
- Sapna Patel, Esquire
- All Plaintiffs' Counsel of Record

# Exhibit A

**Schedule of Cases**

	<b>Case</b>	<b>Docket No.</b>	<b>Date Filed</b>	<b>County</b>
1	<i>Jamie L. Wingate v. Novartis Pharmaceuticals Corp., et al.</i>	L-003123-07	6/19/2007	Hudson
2	<i>Dianne Jackson v. Novartis Pharmaceuticals Corp., et al.</i>	L-001619-08	3/31/2008	Hudson
3	<i>Dyanne Chevalier v. Novartis Pharmaceuticals Corp., et al.</i>	L-001714-08	3/31/2008	Hudson
4	<i>Martha E. Dissell v. Novartis Pharmaceuticals Corp., et al.</i>	L-001691-08	3/31/2008	Hudson
5	<i>Carolyn J. Stephens v. Novartis Pharmaceuticals Corp., et al.</i>	L-002043-08	4/22/2008	Hudson
6	<i>James L. Mount v. Novartis Pharmaceuticals Corp., et al.</i>	L-002205-08	4/30/2008	Hudson
7	<i>Estate of Frank J. Ice v. Novartis Pharmaceuticals Corp., et al.</i>	L-002292-08	5/6/2008	Hudson
8	<i>Kathi Sealy v. Novartis Pharmaceuticals Corp., et al.</i>	L-001640-08	3/3/2008	Middlesex
9	<i>Pamela Yohe v. Novartis Pharmaceuticals Corp., et al.</i>	L-002373-08	3/28/2008	Middlesex
10	<i>Brenda Teasdale v. Novartis Pharmaceuticals Corp., et al.</i>	L-001051-08	3/31/2008	Atlantic
11	<i>Sandra Kennedy, Individually and as Personal Representative of Charles Kennedy, deceased v. Novartis Pharmaceuticals Corp., et al.</i>	L-001105-08	2/8/2008	Essex
12	<i>Barbara Serafino v. Novartis Pharmaceuticals Corp., et al.</i>		5/30/2008	Atlantic

# Exhibit B



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April 18, 2008

**VIA FEDERAL EXPRESS**

Hon. Philip S. Carchman, J.A.D.  
Administrative Director of the Courts  
Hughes Justice Complex  
25 W. Market Street  
P.O. Box 037  
Trenton, New Jersey 08625

**Re: Application for Transfer for Centralized Management**

Dear Judge Carchman:

Gibbons P.C. and Faegre & Benson LLP represent Novartis Pharmaceuticals Corporation (NPC) in eight (8) individual cases pending in New Jersey Superior Court alleging injuries from the ingestion of the prescription pharmaceutical Zelnorm®. Plaintiffs seek, *inter alia*, compensatory and punitive damages for failure to warn under the New Jersey Product Liability Act. At present, four (4) cases are pending in Hudson County, two (2) in Middlesex County and one each in Essex and Atlantic Counties. None of the Plaintiffs in these actions reside in New Jersey. Eight different plaintiff's law firms have appeared and only one has appeared on behalf of more than two plaintiffs. To avoid duplicate discovery and inconsistent rulings, NPC believes that these cases would benefit from coordination by a single New Jersey Superior Court judge experienced in handling complex pharmaceutical litigation. Accordingly, NPC writes to request transfer of these eight (8) cases, as well as any subsequently filed cases, to Judge Jonathan N. Harris, Bergen County, for centralized management.

**BACKGROUND**

NPC, a Delaware Corporation with its principal place of business in East Hanover, New Jersey, marketed Zelnorm in the United States from July 2002 to March 30, 2007. Zelnorm was approved by the FDA for two indications: (1) the short term treatment of women with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation (2002); and (2) the treatment of patients less than 65 years of age with chronic idiopathic constipation (2004). NPC suspended marketing of Zelnorm in the United States effective March 30, 2007 at the request of the FDA. Since that time, in addition to the eight cases currently pending in New Jersey Superior Court, five additional cases were filed in Hudson County. NPC removed these five cases and they presently are pending in New Jersey federal court before the Honorable Dickinson

GIBBONS P.C.

Hon. Philip S. Carchman, J.A.D.  
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Page 2

R. Debevoise.<sup>1</sup> Three cases are pending in federal court in Louisiana. There is no multi-district litigation (MDL).

**COORDINATION WILL ELIMINATE DUPLICATIVE DISCOVERY AND  
INCONSISTENT RULINGS AND PROMOTE JUDICIAL ECONOMY**

Written discovery has been served against NPC in the first-filed Zelnorm case, Wingate, consisting of eighty-five (85) individual requests for production and twenty-five (25) individual interrogatories. Plaintiffs also issued multiple Rule 4:14-2, or "corporate representative" deposition notices demanding testimony on corporate structure, marketing, sales training, regulatory and other topics. NPC has begun and is continuing to produce witnesses for deposition in response to these notices. As is common in such litigation, and in light of the number of firms representing the various plaintiffs, NPC anticipates additional voluminous discovery demands will be served by plaintiffs in Wingate, as well as in each of the additional seven actions. NPC also anticipates it will be served with duplicative demands to depose its current and former employees in each of these cases. Coordination of these voluminous requests by a single experienced jurist is necessary to avoid duplicative and burdensome discovery, and to avoid potentially inconsistent rulings among the multiple state court judges presently assigned to these cases. Indeed, coordination also will further judicial economy. Although no MDL exists, informal state-federal coordination with Judge Debevoise also would be beneficial for the same reasons.

In addition, as noted above, all of the plaintiffs in these cases are residents of states other than New Jersey. As all of the operative facts -- prescription and ingestion of Zelnorm and alleged injuries -- appear to have taken place in the plaintiffs' home states. Accordingly, NPC will seek dismissal of each of these cases based on the doctrine of forum non-conveniens.<sup>2</sup> NPC respectfully submits that to avoid inconsistent rulings, these motions should be decided by a single judge.

**A SINGLE JUDGE SHOULD ASSESS WHETHER A STAY IS WARRANTED  
PENDING THE U.S. SUPREME COURT'S PREEMPTION DECISION IN LEVINE**

This summer, the United States Supreme Court will decide if state law failure to warn claims involving FDA-approved pharmaceuticals are preempted by federal law in Wyeth v. Levine. The Supreme Court's upcoming decision in Levine calls into question whether the

<sup>1</sup> The five removed cases bore the following New Jersey Superior Court docket numbers: Sullivan v. NPC, HUD-L-908-08; Martin v. NPC, HUD-L-1645-08; Medlin v. NPC, HUD-L-1646-08; Welch v. NPC, HUD-L-1647-08; and Richard v. NPC, HUD-L-1648-08.

<sup>2</sup> NPC expressly reserves its right as to all available affirmative defenses. Moreover, by this application NPC does not waive its right to seek forum non conveniens dismissals in any of the eight individual cases. Finally, nothing herein should be construed as supportive of or a basis for certification of a class action, which would be improper under any set of applicable laws or rules.

GIBBONS P.C.

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Zelnorm litigation, now in its infancy, will proceed to adjudication on the merits. In light of Levine, NPC may seek to stay each of these cases. NPC respectfully submits that whether a stay is warranted under these circumstances should be addressed by a single judge experienced in complex litigation.

**VENUE IN NORTHERN NEW JERSEY IS APPROPRIATE**

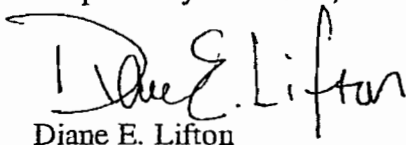
Because the majority of cases are pending in Northern New Jersey, assignment to a vicinage and judge in Northern New Jersey with an amenable docket makes eminent sense. NPC respectfully submits that Judge Jonathan N. Harris, Bergen County, is the logical choice for this assignment. Judge Harris is experienced in the management of complex litigation. He also is familiar with the core issues that arise in pharmaceutical litigation from his current assignments managing pharmaceutical and toxic tort litigations.

Following entry of an order transferring the pending Zelnorm cases to Judge Harris, NPC respectfully requests that any subsequent related actions, if any, be transferred to Judge Harris without further application to Your Honor and the New Jersey Supreme Court.

**CONCLUSION**

For the reasons set forth above -- the need to coordinate discovery, to avoid inconsistent rulings, and to assess the appropriateness of a stay in light of the impending U.S. Supreme Court preemption decision -- NPC respectfully submits that centralized management is warranted. By this application, NPC specifically does NOT seek mass tort designation pursuant to Rule 4:38A and the Mass Tort Guidelines (Directive # 11-03). Indeed, these cases -- for the most apparent reasons that there are only eight (8) and no federal MDL -- do not meet the criteria for such a designation and NPC would object to any such application. NPC further notes that the negative connotation of the term "mass tort" implies, by its title, that the product at issue has been pre-determined to be defective. Accordingly, for this additional reason NPC would object vigorously to any such designation.

Respectfully submitted,



Diane E. Lifton

DEL/cag

GIBBONS P.C.

Hon. Philip S. Carchman, J.A.D.  
April 18, 2008  
Page 4

cc: **VIA FEDERAL EXPRESS**

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Hon. Philip S. Carchman, J.A.D.

April 18, 2008

Page 5

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**GIBBONS**

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APR 22 2008

**CIVIL PRACTICE DIV.**

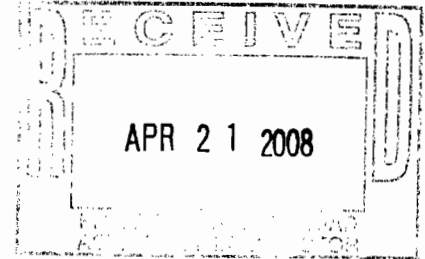
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**CONCLUSION**

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Respectfully submitted,

  
Diane E. Lifton

DEL/cag

# GIBBONS P.C.

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Page 4

cc: **VIA FEDERAL EXPRESS**

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# GIBBONS P.C.

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Page 5

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