Oshman & Mirisola, LLP

COUNSELLORS AT LAW

42 BROADWAY-10th FLOOR NEW YORK, NY 10004-1617 TEL: 212/233-2100 FAX: 212/964-8656

MATTHEW OSHMAN
THEODORE OSHMAN
CHARLES J. MIRISOLA, JR. *
THOMAS P. O'MALLEY
DAVID L. KREMEN
LINDSEY R. LEBER

* ADMITTED NY & NJ

May 13, 2010

Civil Practice Division Practice Division Practice Division Property MAY 14 2010 HOWARD VICTOR **

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Honorable Glenn A. Grant, J.A.D. Administrative Director of the Courts Hughes Justice Complex Post Office Box 037 Trenton, N.J. 08625-0037

> Re: Application for Centralized Management of Reglan Litigation

Dear Honorable Judge Grant:

Please accept this letter in support of the Application of the Honorable Eugene J. Cody, Jr., Essex County, P.J.C.V., seeking centralized management of all litigation involving Reglan/Metoclopramide cases which are currently pending in the Superior Court, as well as those which will be filed in the future.

PRELIMINARY STATEMENT

This application pertains to numerous cases pending in the Superior Court, as well as many others yet to be filed, involving the use of the drug metoclopramide (referred to by the common brand name Reglan), a prokinetic drug which increases muscle contractions in the upper digestive tract, thereby increasing the rate the stomach empties its contents into the intestines. While many issues exist regarding the manner in which this drug was marketed to physicians, metoclopramide is intended for the treatment of gastroesophageal reflux disease (GERD) where the use of other medications have failed to bring relief. It has never been approved for long term use, use by children/infants or to promote lactation in mothers who breast feed.

According to the FDA, while metoclopramide has been sold in the United States for over 30 years, there continues to be over 2 million people using the medication, many for long term treatment. In February 2009, the FDA issued a boxed warning on all products containing metoclopramide, the strongest form of medical alert to the public. The warning specifically highlights the risk of using the drug for more than 90 days due to the development of Tardive Dyskinesia. The condition is extremely serious and is incurable, causing involuntary, repetitive movements in facial muscles, limbs, fingers, toes, hips and



Anita Hotchkiss Partner Direct dial 609.986.1350 ahotchkiss@goldbergsegalla.com

VIA LAWYERS SERVICE

Hughes Justice Complex Post Office Box 037

Honorable Glenn A. Grant, J.A.D. Administrative Director of Courts

Trenton, New Jersey 08625-0037

902 Carnegie Center / Suite 100 Princeton, New Jersey 08540 609.986.1300 FAX 609.986.1301 www.goldbergsegalla.com

May 14, 2010

Civil Practice Division

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RECEIVED

Re: Application for Centralized Management of Reglan® Litigation

Dear Judge Grant:

Please accept this letter, submitted on behalf of PLIVA, Inc., The control of the letter and the Codey's Application for Centralized Management of Reglan Litigation, dated March 16, 2010. According to Judge Codey's Application, cases involving Reglan have been filed on a weekly basis in Essex County and the AOC was told by a plaintiffs' attorney that it is estimated that the lawsuits filed by the same law firms representing the plaintiffs in those cases will reach between 75 and 100. The Application also indicates that the main defendant is a New Jersey domiciliary, (referring to Wyeth), and that a significant potential exists for additional cases to be filed in New Jersey.

Background Facts Regarding Reglan/Metoclopramide

Reglan is the brand-name of a pharmaceutical product containing the action in the ac material Reglan was approved by the Federal Food and Drug Administration ("FDA") in December 1980, as shortener (1980) thempy for adults with symptometric decurrenced gustroesophugeal reduction who this to respond to conventional therapy. It also is indicated for the relief of symptoms associated with coute and recurrent diabetic gastric stasis. In March 1985, FDA required that the label be updated to include a warning regarding the risk of tardive dyskinesia. As a result, the labeling for metoclopramide products has for many years included a specific warning related to the development of tardive dyskinesia.

In addition to the name-brand product Reglan, generic versions of metoclopramide have been manufactured and marketed by a number of companies over the years. approximately twelve companies manufacture and distribute the various dosage forms of metoclopramide PLIVA, Inc. manufactured and distributed generic metoclopramide from

Pobruary 1988 through December 23, 2008, at which time it sold its abbreviated new drug

Background Facts Regarding Litigation Involving Reglan/Metoclopramide

Litigation involving metoclopramide and the alleged risk of tardive dyskinesia or other movement disorders dates back two decades. Since the first case, additional cases have been filed, but fawsuits involving metoclopramide never have reached exponential proportions. Furthermore, plaintiffs historically often have named a number of metoclopramide manufacturers as defendants in their complaints. However, the defendants including wyeth and other manufacturers of the branded product. Regian are dismissed to be defendant. As a result, there is no single "main defendant" in the cases.

Farly in 2009, following a change to metoclopramide labeling mandated by FDA plaintiffs in a barrow of metoclopramide cases pending in tederal courts filed a motion under 28.

U.S.C. The product of metoclopramide cases pending in tederal courts filed a motion under 28.

U.S.C. The product of the plaintiffs' motion and a hearing before the JPML, the meton was denied.

In its order, dated June 3, 2009, the JPML concluded that centralization would not "serve the semi-inner of the parties and situeses of further the just and efficient conduct" of the litigation. The JPML's conclusion was based, in part, on the fact that the cases did not involve any single common defendant, and that some entitles were named in only one or two actions. In addition, the JPML noted that the actions were at varying stages in the litigation process, with some actions substantially advanced, having been commenced two to three years earlier. Finally, the JPML took note of the lengthy history of metoclopramide litigation and the fact that a significant amount of the common discovery already had taken place. As a result, the JPML determined that any remaining common questions of fact among the actions were not sufficiently complex and/or numerous to justify centralization in an MDL proceeding. In denying the request for centralization, the JPML neted that alternatives to transfer existed that could minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings.



The situation involving metoclopramide litigation has not changed significantly since the JPML issued its order one year ago. Attheugh additional cases have been filed throughout the country, in a majority of the cases there is no single, common defendant. As has been true throughout the history of metoclopramide litigation, many defendants named in the original complaint are ultimately dismissed because the plaintiff never took the defendants' product. In addition, the majority of the cases have been filed by only a few law firms.

New Jersey Cases Naming PLIVA, Inc. as a Defendant

PLIVA, Inc. is not aware of the number of metoclopramide cases that have been filed in New Jersey courts, but does know it has been served in only seven lawsuits, one of which has been dismissed. Upon information and belief, least the material in September, 2008 (Kohles v. Wyeth, Inc., et al.). The fact discovery deadline is June 1 and the case threatly is set for trial in December of this year. Although the plaintiff's original complaint in that case named Wyeth, Inc. PLIVA, Inc., and Schwarz Pharma, Inc. only PLIVA Inc. remains a defendant because, as is too often the case, plaintiff named the other entities as defendants notwithstanding that plaintiff never took the product manufactured and marketed by those entities.

Four other actions against PLIVA, Inc. were filed and served this year. Those actions all involve citizens of states other than New Jersey and name different combination of defendants. While all the complaints name Wyeth, Inc. and Schwarz Pharma, Inc. as defendants, in addition to PLIVA, Inc., the other named defendants differ from case to case. Finally, PLIVA, Inc. also is aware of four other cases that have been filed naming it as a defendant, but PLIVA, Inc. has not been served in those actions.

Although Wyeth, Inc. and Schwarz Pharma, Inc. are named in almost all lawsuits involving the pharmaceutical product Reglan/metoclopramide, in many cases the companies are subsequently dismissed as the plaintiff never took the product manufactured and marketed by those companies. Recently, plaintiffs have been adding Alaven Pharmaceuticals LLC as a lafendant, but Alaven did to the product of the relation of the formation and belief. Alaven profused the New Brug Application ("NDA") for the fing and to make the product of the product of the fing and to make the product of the product of the fing and the product of th

Centralized Management Is Not Warranted

Litigation involving mescelepramide will not benefit from centralized management. The fact that the cases likely will not involve common defendants alone weighs against centralization, because there will be few, if any, common questions. The issues in the lawsuits pertain to individual defendants, not the litigation as a whole. The defendants are distinct pharmaceutical companies. They did not not consellectively. What one defendant know, did not know, did, or did not do is irrelevant to the other defendants. The absence of common questions is particularly acute in this litigation where each plaintiff might be interested in only one or two defendants.

Furthermore, the criteria set out in Directive #7.09 for designating the lawsuits involving Reglan/metoclopramide as a mass tort are not met because the cases do not possess the following characteristics:

1. The cases do not involve a large numbers of parties.

Centralized management of the New Jersey Reglan/metoclopramide cases is not appropriate given the number of pending lawsuits. Currently there are six active metoclopramide cases naming PLIVA, Inc. The plaintiffs in each case allege causes of action against different combinations of name-brand and generic manufacturer defendants.

Furthermore, the cases do not involve a large number of plaintiffs' firms. The plaintiffs in the actions filed against PLIVA are represented either by the law firm of D'Arcy, Johnson, Day (1 case) or by the law firm of Rheingold, Valet, Rheingold, Shkolnik & McCartney LLP (4 cases).

2. The cases do not involve many claims with common, recurrent issues of law and fact that are associated with a single product.

The questions in these cases do not possess the factual commonality necessary to warrant centralization before a single judge. For instance, the following questions are not susceptible to "common" answers because no two plaintiffs are the same or have the same medical history.

- Whether the plaintiff took metoclopramide;
- Identification of the particular products used, including which defendant manufactured each;
- The dosage or form of metoclopramide taken by each plaintiff, if any;
- The period of use of metoclopramide, if any;
- The frequency of use of metoclopramide, if any;
- Other medications taken by the plaintiff in the past and at the time of the alleged ingestion of metoclopramide;
- The knowledge of plaintiff's prescribing physician as to potential risks and benefits of metoclopramide;
- The risk/benefit analysis performed by plaintiff's prescribing physician;
- The extent to which each plaintiff's prescribing physician read, relied upon, and/or followed the warnings on the label;
- The warnings and instructions provided by each prescribing physician to each plaintiff;
- Whether plaintiff reviewed, read, or received any written information about metoclopramide;

- The knowledge and understanding of each plaintiff as to the risks and benefits of metoclopramide;
- The plaintiff's personal and family medical history;
- Plaintiff's medical conditions at the time of ingestion;
- The medical history provided by each plaintiff to his or her health care provider;
- The extent to which each plaintiff read, relied upon, and/or followed the instructions given;
- The symptoms, if any, manifested by each plaintiff;
- When each plaintiff suspected or reasonably should have suspected the alleged association between symptoms of injury and use of a particular product;
- The entire range of possible causes of injury to each plaintiff;
- The sensitivity of each plaintiff to the product taken;
- The nature and extent of any damages suffered;
- The potential treatments available and recommended for each plaintiff; and
- The likelihood of future damages, and their probable nature and extent.

Every cost will involve the state of the planting the state of the planting. The lack of consistency of the named defendants adds to the individual nature of the cases. In addition, because the causation inquiry will include each plaintiff's medical history and personal risk factors, causation does not provide a common question in these cases.

The variations in law to be applied also weigh against centralization. The plainting in the actions in which PLIVA, Inc. has been served are from five different states, with only one being a New Jersey resident. The other states are Kansas, Tennessee, Onio, and New York. As the plaintiffs were prescribed and allegedly took Reglan/metoclopramide in their home states, the laws of those states may apply to various issues in their cases. See Rowe v. Hoffman-La Roche Inc., 189 N.J. 615 (2007) (applying Michigan law to bar non-New Jersey resident's failure to warn claims against pharmaceutical manufacturer). As the substantive law that will apply to each plaintiff's claims varies, coordination will not advance any of the cases.

3. A high degree of commonality of injury or damages among plaintiffs is not present.

A high degree of commonality of injury or damages among plaintiffs is not present. Although each plaintiff alleges that he or she developed tardive dyskinesia from use of

Reglan/metoclopramide, the damages for each plaintiff will differ depending on various factors and the law applicable in that case. In addition, although each plaintiff has characterized his/her injury as tardive dyskinesia, each plaintiff's individual symptoms and/or injuries may differ. Due to the nature of the various claims and injuries asserted, each action, by necessity, will focus primarily on plaintiff specific issues; a g. product identification, desage injuried, period and frequency of use, and individual medical histories and risk factors for movement disorders.

4. There is no value interdependence between different claims.

Reglan/metoclopramide cases filed in New Jersey do not have common factual or legal issues. Each case will involve predominantly individual issues and the causation and liability issues in each case are not dependent upon the success or failure of similar lawsuits.

5. There is not a degree of remoteness between the court and actual decision-makers in the litigation.

Woodcliff Lake Bergen County, New Jersey: With today's technology, the location of out-of-state national counsel should not factor into the determination regarding centralization.

6. Centralization will cause an unreasonable delay in the progress, increase the expense, and complicate the processing of all actions, and will prejudice the parties.

Centralization of the Reglan/metoclopramide litigation would be prejudicial to the parties. Not only are all but one of the cases that have been served on PLIVA, Inc. by out-of-state plaintiffs, but also each involves different defendants. In one case, PLIVA is the only remaining defendant. Any issues related to other defendants in actions in which PLIVA is not a defendant will not affect the actions against PLIVA and will serve only to delay the progress of those suits in which PLIVA is a served-defendant. In addition, PLIVA has no interest in the fact of the cases to which it is not a party.

Furthermore, because the majority of the plaintiffs who have named and served PLIVA, Inc. are from states other than New Jersey, fact discovery in these cases will occur predominantly in other states i.e., the states in which the plaintiff resides, was prescribed the product, and allegedly ingested the product. The plaintiff's physicians will not be located in New Jersey. The plaintiff's family and friends will not be located in New Jersey. The plaintiff's injuries will not have occurred in New Jersey.

Centralized management would serve only to complicate and unreasonably delay the discovery process, and likely increase expenses for the pending cases.

7. Centralized management would be neither fair nor convenient to the parties, witnesses, and counsel.

Centralized management would be neither fair nor convenient to the parties or witnesses in the pending New Jersey cases against PLIVA, Inc. The majority of witnesses are located out-of-state. Furthermore each case will involve a unique set of facts and circumstances related to the individual plaintiff.

Centralization of the Reglan/metoclopramide lawsuits well may result in increased numbers of out-of-state plaintiffs filing in a jurisdiction with little to no connection to the claims in the lawsuits. The location of a corporate defendant's principal place of business in the state does not equate to significant factual information being located in the state. Furthermore, suits filed by out-of-state plaintiffs place defendants in the untenable position of being unable to obtain live testimony at any trials as the key fact witnesses will be outside the subpoena power of the courts.

8. Any risk of duplicative and inconsistent rulings, orders, or judgments if the cases are not managed in a coordinated fashion is minimal.

The risk of duplicative and inconsistent rulings, orders, or judgments if the cases are not managed in a coordinated fashion is minimal. As the plaintiffs who have filed lawsuits against the plaintiffs who have filed lawsuits against the laws are from different states, any rulings on key issues in any one case likely will not be applicable to the other cases. Furthermore, rulings on key issues in cases in which PLIVA is not a named defendant should not impact or apply to those cases in which PLIVA is a defendant. Gases involving alleged injuries from use of Reglan/metoclopramide have been filed in courts around the country for many years without coordinated proceedings, and inconsistent rulings have been encountered.

9. Coordinated discovery would not be advantageous.

The only discovery that would pertain to more than one case would be discovery from the pertain defendants. However, as the lawsuits do not involve the same of corporate defendants, econdination of discovery would have little to no benefit. Furthermore, as the number of plaintiffs' law firms involved are relatively few, once plaintiffs' counsel has the pertinent discovery from a corporate defendant in one lawsuit, it will have the discovery for the other lawsuits involving that corporate defendant. As a result, centralization is unnecessary to ensure convenient, coordinated, and efficient litigation. Furthermore, the cases can be effectively managed by the presiding judges and cooperative efforts of the parties. In fact, the

parties already have cooperated and econdinated discovery in many Reglan/metoclopramide cases pending across the country.

10. The cases do not require specialized expertise or case processing as provided by the dedicated mass tort judge and staff.

PLIVA, Inc. does not believe that specialized case processing and a dedicated staff is required for the Reglan/metoclopramide lawsuits.

11. Centralization would not result in the efficient utilization of judicial resources or the facilities and personnel of the court.

The pending actions that have been filed in New Jersey predominantly are by out-of-state plaintiffs who chose to file suit in New Jersey rather than the more convenient, cost-effective venue of their home state. As a result, rather than promote the efficient use of New Jersey's judicial time and resources, the lawsuits will tax New Jersey courts even further, requiring them to expend their time and resources to manage lawsuits with little connection to their state.

- 12. PLIVA, Inc. is not aware of any issues regarding insurance, limits on assets, or potential bankruptcy that can be best addressed in coordinated proceedings.
- 13. There are related matters pending in federal court and in other state courts, but they do not require coordination with a single New Jersey judge.

Similar federal and state court litigation is pending in other jurisdictions. In many of those cases, discovery is in advanced stages. In others, discovery has been completed and dispositive motions have been filed. In yet others, the cases are set for trial this year. As a result, coordination by a single New Jersey judge is not necessary.

If the Court Decides Centralization Is Warranted, Bergen County Is Most Appropriate Venue

According to the Court's Directive "issues of fairness, geographical location of parties and attorneys, and the existing civil and mass tort caseload in the vicinage will be considered in determining to which vicinage a particular mass tort will be assigned for centralized management." PLIVA, Inc. is a New Jersey corporation. In the pending New Jersey state court Reglan/metoclopramide actions against PLIVA, the various named co-defendants also are located in northern New Jersey, or are from out-of-state. Should the court determine centralization is appropriate, assignment for coordination in Bergen County best satisfies the criteria in the Court's Directive.

Centralization in Bergen County would undoubtedly be fair because the parties, and counsel are largely from northern New Jersey and/or out-of-state. Also, Bergen County is convenient to New Jersey's only major airport, Newark-Liberty. The Bergen County courthouse is located approximately twenty miles from Newark-Liberty Airport. Bergen County also currently has the lowest centralized case management backlog and case load.

If the court determines that centralization is warranted, following entry of an order transferring the pending Reglan/metoclopramide cases to Bergen County, PLIVA, Inc. respectfully requests that other subsequently filed, related actions be transferred for centralized management without further application.

Conclusion

Defendant PLIVA, Inc. respectfully submits that the Reglan/metoclopramide lawsuits should not be centrally managed. However, if the court determines centralized management is warranted, PLIVA respectfully requests such centralization in Bergen County, and without mass tort designation.

Very trolly yours,

Anita Hotchkiss, Esq.

cc: Paul D. Rheingold, Esq. (via first-class mail)

Andrew D'Arcy, Esq. (via first-class mail)

George E. David, Esq. (via first-class mail)

Jonathan I. Price, Esq. (via first-class mail)

Clell I. Cunningham III, Esq. (via first-class mail)

Kelly A. Waters, Esq. (via first-class mail)

Joseph F. Lagrotteria, Esq. (via first-class mail)

Steven A. Stadtmauer, Esq. (via first-class mail)

Matthew V. Brammer, Esq. (via first-class mail)

May 14, 2010

HARRIS BEACH ₹

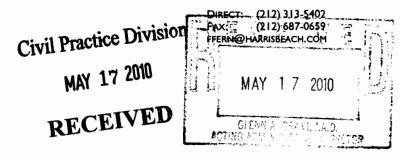
ATTORNEYS AT LAW

ONE GATEWAY CENTER SUITE 2500 NEWARK, NJ 07102 (973) 848-1244

FREDERICK H. FERN

VIA OVERNIGHT MAIL

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



Re: Actavis Elizabeth LLC's Response to Application for Centralized Management of Litigation Involving Reglan® (Without Mass Tort Designation)

Dear Judge Grant:

On behalf of Actavis Elizabeth LLC ("Actavis"), Harris Beach PLLC and Tucker Ellis & West LLP submit the following opposition to the centralization of all pending and future actions in New Jersey relating to claims arising from the purchase and ingestion of Reglan®. The cases on file do not satisfy the essential criteria set forth in the Revised Mass Tort Guidelines as promulgated by Directive #7-09 and thus do not meet the requirements for central case management.

Actavis is named as a defendant in nineteen (12) pending New Jersey cases that allege injury from Regiant ingestion. Whose of the pending actions involve plaintiffs who are New Jorgey residents, and all nineteen are therefore subject to dismissal on *forum non conventens* grounds. The instant Reglan® cases do not satisfy the criteria set by the Court for centralized management. First, the nineteen cases do not involve a large number of parties or claims.

¹ A list of the known New Jersey state court actions involving Actavis is set forth in Exhibit A. To Actavis' knowledge, there were possibly two other metoclopramide cases filed in Essex County, as well as three in Morris County and one each in Ocean and Atlantic Counties, which do not name Actavis as a defendant.

² Actavis expressly reserves its rights with respect to all available affirmative defenses. Moreover, by this application, Actavis does not waive the right to argue *forum non conveniens* or to seek a change of venue in any appropriate individual case filed or yet to be filed. Finally, nothing herein should be construed as

Hon. Glenn A. Grant, J.A.D. May 14, 2010 Page 2

Second, the common issues of fact or law requirement is not met because: (1) tach plaintiff ingested one or more forms of the drug, during different periods, in differing desce, for different medical indications; (2) there is no consistency of named defendants across the cases; (3) the causation inquiry turns on each individual's unique medical history; and (4) plaintiffs' claims are likely governed by at least the laws in eleven different jurisdictions. Third, it has not been established that mass tort coordination would be more convenient and promote the just and efficient conduct of the cases. Discovery and pretrial proceedings can, and previously have been, easily coordinated through cooperation of the parties, protective orders permitting the sharing of discovery across cases and case management orders in individual cases, rendering centralization unnecessary. Finally, the number of pending cases does not rise to the level of a mass-tort.

Should the Court determine that these cases be centralized, despite Actavis' strenuous objections, Rergen County would be the most appropriate venue. Given the geographical location of the pending cases, and the physical location of party witnesses and documents, the interests of fairness indicates that assignment to the Honorable Brian R. Martinotti, J.S.C. is most appropriate.

I. BACKGROUND

Reglan® is a prescription pharmaceutical indicated for treatment of, among other things, certain gastrointestinal disorders. Reglan® is also available in a generic formulation sold under its chemical name, metoclopramide. Metoclopramide is indicated as short-term (4 to 12 weeks) therapy for adults with symptomatic, gastroesophageal reflux who fail to respond to conventional therapy. It is also indicated for the relief of symptoms associated with acute and recurrent diabetic gastroparesis. Metoclopramide is available in a variety of dosages and forms, including oral total total total and orally disintegrating tablets), syrup and injectable formulations. These different forms are indicated for different types of patient settings.

supportive of or a basis for certification of a class action, which would be improper under any set of applicable laws or rules.

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Reglan® was initially approved by the U.S. Food and Drug Administration in 1980.

Over time, Reglan®'s labeling has been revised to reflect new information, as it became available. Although the accompanying package insert for Reglan® includes a warning of the risk of tardive dyskinesia with long-term of high-dose metoclopramide use, there have nonetheless been a smattering of failure to warn cases filed against the brand and generic metoclopramide manufacturers over the past two decades.

Plaintiffs generally allege to have sustained tardive dyskinesia and/or other unspecified personal injuries and economic damages through their purchase and ingestion of Regian@/metoclopramide which was not accompanied by adequate warnings. Plaintiffs seek, inter alia, equitable relief, compensatory and punitive damages under the New Jersey Consumer Fraud, Product Liability and Funitive Damages Acts.

II. REQUIRED CRITERIA FOR CENTRALIZATION ARE NOT SATISFIED

Centralized treatment of only nineteen cases is not warranted where there is to consistent identity of parties and the particular circumstances surrounding each product, plaintiff, and defendant will predominate. Centrally managed proceedings will likely increase expenses, unconsistent will predominate. Centrally managed proceedings will likely increase expenses, unconsistent will predominate. Centrally managed proceedings will likely increase expenses, unconsistent will predominate discovery that would otherwise follow a normal track, and ultimately delay resolution of cases that individual courts could handle more efficiently.

Consideration of the factors set out in Directive #7-09 militates that the pending cases should not be transferred and centralized. The following criteria for centralization, set forth in Directive #7-09, are not substantially satisfied:

A. Whether the cases possess the following characteristics:

1. *[The litigation] involves large numbers of parties.*

Centralized management of the New Jersey Reglan® cases is not appropriate given that there are an insufficient number of suits filed to serve the purposes of centralization. Currently there are nineteen active metoclopramide cases filed in Essex County, New Jersey naming Actavis Elizabeth LLC. Plaintiffs in each of these cases allege causes of action

against differing combinations of brand and generic manufacturer defendants.

Moreover, and of the pending cases against Actavis involve out-of-state plaintiffs with no connection to New Jersey. Actavis anticipates moving to dismiss the non-residents' claims on forum non conveniens grounds. Assuming these motions are granted, there would be no cases involving Actavis pending in New Jersey.

Nor do these cases involve a large number of plaintiffs' firms. All of the complaints naming Actavis were filed by two law firms: Oshman & Mirisola LLP and Rheingold, Valet, Rheingold, Scholnick & McCartney LLP.

2. It involves many claims with common, recurrent issues of law and fact that are associated with a single product.

Centralization is also not appropriate because individual factual and legal issues predominate and outweigh any issues these cases have in common. In each complaint, there is a primary plaintiff, alleging injury or damage due to the alleged purchase and/or ingestion of Reglan®/metoclopramide and sometimes there is a second, spousal plaintiff alleging loss of consortium. These cases will be dominated by individual fact issues, such as dosage ingested, period of frequency of use, effect of other medications simultaneously ingested, the medical literature, state-of-the-art, package inserts, labeling, then in effect individual knowledge and understanding of the risks and benefits of metoclopramide, each plaintiff's personal and family medical history, medical histories provided by individual plaintiffs to his or her healthcare provider, the extent to which each plaintiff read, relied upon, and/or followed the instructions given, individual symptoms manifested, if any, when each plaintiff suspected or reasonably should have suspected the alleged association between symptoms and use of a particular product, specific causation, the nature and extent of any damages suffered, the potential treatments available, and the likelihood of future damages and their probable nature and extent. These questions are not susceptible to "common" answers because no two plaintiffs are the same—not even those who appear to have tardive dyskinesia.

Further, the pending cases require resolution of the threshold issue of product identification to determine whether a brand or generic product was dispensed and ingested. As previously stated, there is no consistent identity of parties; some plaintiffs assert claims against the name brand and one generic, some against the name brand and several generics; and some against generics only. There are unique combinations of fifteen different named defendants in these cases. Given that individual issues

Hon. Glenn A. Grant, J.A.D. May 14, 2010 Page 5

dominate the causation inquiry, causation does not provide a common question in these cases.

Moreover, centralization is not warranted because the pending cases implicate irreconcilable variations in state law that must be adjudicated on a plaintiff-by-plaintiff basis.³ The plaintiffs here are from eleven different states: Alabama, Arizona, Florida, Mississippi, Missouri, New Tork, P. The claims of each plaintiff who was prescribed and ingested Reglan® in their home state, and sustained alleged injury in their home state, likely should be decided under the law of the plaintiff's home state. See Rowe v. Hoffman-La Roche Inc., 189 N.J. 615 (2007) (applying Michigan law to bar non-New Jersey resident's failure to warn claims against pharmaceutical manufacturer). Thus, the substantive law applicable to each plaintiff's claims varies, such that coordinated treatment reaps little gain.

3. There is geographical dispersement of parties.

The current plaintiffs are domiciled throughout the country, and of the pending cases against Actavis, none recide in New Jersey. The fact that the plaintiffs are from eleven different jurisdictions does not satisfy the mass tort criteria of "geographical disbursement." This factor typicany aduresses cases med unougnout the state of New Jersey that would benefit from controlled throughout the state of New Jersey that would benefit disbursed throughout New Jersey (all of the cases against Actavis are filed in Essex County); they are disbursed throughout the United States.

To the extent out-of-state residents seek the benefits of centralized management of pre-trial proceedings, the United States Judicial Panel on Multidistrict Litigation ("J.P.M.L."), has already ruled on that application and denied such transfer. See In re. Reglan Metoclopramide Products Liability Litigation, 622 F.Supp.2d 1380 (J.P.M.L. 2009) (Order Denying Transfer). The J.P.M.L. held that while the actions pending across the United States shared some factual issues, transfer should be denied primarily because there is no single common defendant in any case. Id. at 1381.

³ Under New Jersey's choice of law principles, for each plaintiff, the Court must identify which jurisdictions' law(s) could apply, determine whether there is a conflict between those law(s) and New Jersey law, and, if so, decide which state has the greater governmental interest in resolving the specific issue in dispute. See, e.g., Rowe v. Hoffman-La Roche Inc., 189 N.J. 615 (2007).

4. There is a high degree of commonality of injury or damages among plaintiffs.

There is no high degree of commonality of injury or damages among plaintiffs. Each complaint pleads that plaintiff suffered tardive dyskinesia as well as other unspecified economic and personal interest, and varying coloraries of damages, moluding compensatory damages for present and future physical, emotional, and economic injuries, interest, costs, and attorneys' fees: punitive damages, equitable relief, and in some cases, seeks medical monitoring for potential future physical ailments. As previously stated, given the nature of the various claims and injuries asserted, each action will by necessity focus primarily on plaintiff-specific issues, e.g., product identification, dosage ingested, period and frequency of use, individual medical histories.

5. There is a value interdependence between different claims.

There is no value interdependence between the different claims, because the few Reglan® cases filed in New Jersey lack a high degree of common factual or legal issues. Instead, each of the pending cases, as discussed above, will turn on individual issues. The strengths or weaknesses of the causation or liability aspects of these cases are not dependent upon the success or failure of similar lawsuits.

6. There is a degree of remoteness between the court and actual decision-makers in the litigation.

of the other named defendants are also located in northern New Jersey. Many of the other named defendants are also located in northern New Jersey. Harris Beach PLLC, local counsel for Actavis, as well as local counsel for the co-defendants and plaintiffs are located in northern New Jersey. Medical day advances in technology and communication have made the location of out of state national counsel and several other parties a non-determinative factor. As such, there is little concern of remoteness between the attorneys and the Court and it should not factor into the Court's decision regarding centralization.

7. Whether there is a risk that centralization may unreasonably delay the progress, increase the expense, or complicate the processing of any action, or otherwise prejudice a party.

Unwarranted centralization of the Reglan® litigation would be projected to Actavis. All of the pending New Jersey cases against Actavis were filed by non-residents. It is likely that (1) the physicians who discussed Reglan® with plaintiffs and prescribed it for them are located in plaintiffs'

home states, not New Jersey; (2) plaintiffs were prescribed and ingested Reglan® in their home states; (3) plaintiffs allegedly suffered damages due to their ingestion of Reglan® in their home states; (4) plaintiffs obtained medical care for their alleged injuries in their home states; and (5) witnesses with knowledge of plaintiffs' alleged ingestion and injuries will be located in plaintiffs' home states. Centralized management therefore would complicate the processing, unreasonably delay progress, and increase expenses for the pending cases.

8. Whether centralized management is fair and convenient to the parties, witnesses and counsel.

Centralized management would not be fair and convenient to the parties and witnesses in the pending New Jersey cases against Actavis. As discussed above, the majority of witnesses are going to be located out of state and the cases will be driven by the unique set of facts and circumstances surrounding each individual plaintiff.

Furthermore, centralization in New Jersey will only lead to more forum shopping by out of state plaintiffs and is guaranteed to bring more out of state claims to New Jersey, along with the continuing problems of inability to obtain testimony and evidence from other states for these claims and the burdens of travel and additional litigation expense for parties, witnesses and counsel. New Jersey's mass tort program was not designed to be a mini MDI for plaintiffs across the country.

9. Whether there is a risk of duplicative and inconsistent rulings, orders or judgments if the cases are not managed in a coordinated fashion.

There is minimal risk of duplicative and inconsistent rulings, orders or judgments if the cases are not managed in a coordinated fashion. Rulings on key issues are unlikely to apply generally to all cases given the nineteen plaintiffs are from eleven different jurisdictions. Europermore, there are Region assess pending in federal courts across the country with no coordinated proceedings. In feet, there has never been any directory dispute in any federal court in which Actavis was a defendant. Actavis has little concern regarding the potential for inconsistent rulings on discovery disputes.

10. Whether coordinated discovery would be advantageous.

Centralization is unnecessary to ensure convenient, coordinated, and efficient litigation, because these cases readily can be effectively managed by the presiding judges and anticipated cooperative efforts of the parties.

MAL

Vehicles for coordinated discovery already are in place in the Reglan® cases pending across the country.

11. Whether the cases require specialized expertise and case processing as provided by the dedicated mass tort judge and staff.

Actavis does not believe that specialized case processing and a dedicated staff is required. The pending cases are straightful.

12. Whether centralization would result in the efficient utilization of judicial resources and the facilities and personnel of the court.

As previously noted, none of the pending Reglan® actions in New Jersey involve plaintiffs who are residents of New Jersey. These non-resident plaintiffs chose to file their actions in New Jersey even though they could pursue the same remedies (more conveniently and cost-effectively) in their home states in an effort to create a mini-MDL after the JPML denied a coordinated multidistrict proceeding. The administrative that New Jersey's judicial time and resources will be unnecessarily depleted by these foreign plaintiffs. Accordingly, centralization will not promote the efficient use of New Jersey's judicial time and resources.

13. Whether issues of insurance, limits on assets and potential bankruptcy can be best addressed in coordinated proceedings.

Actavis is not presently aware of any issues of insurance, limits on assets or potential bankruptcy that could affect these proceedings.

14. Whether there are related matters pending in federal court or in other state courts that require coordination with a single New Jersey judge.

As indicated above, there is similar federal and state court litigation pending in other jurisdictions. Discovery in those proceedings are very advanced; in fact several of the cases are scheduled for trial this year. As such, coordination by a single New Jersey judge is not necessary and would only serve to encourage out-of-state plaintiffs to file new cases in New Jersey.

III. SHOULD THE COURT DECIDE CENTRALIZATION IS WARRANTED BERGEN COUNTY IS MOST APPROPRIATE VENUE

business in Elizabeth, New Jersey. In the pending New Jersey state court Reglan® actions against Actavis (all filed in Essex County in northern New Jersey), the various named code form out of state. Should the court determine centralization is appropriate here, assignment for coordination in Bergen County before the Honorable Brian R. Martinotti, J.S.C., would be fair, equitable and most efficient. Centralization in Bergen County would undoubtedly be fair because the parties and counsel are largely from northern New Jersey and/or out-of-state. Also, Bergen County is convenient to New Jersey's only major airport, Newark-Liberty. The Bergen courthouse is located approximately twenty miles from Newark-Liberty Airport.

Judge Martinotti is designated as a "mass tort" judge in Bergen County and is experienced at managing complex products liability and toxic torts litigation. He is familiar with the core issues that arise in pharmaceutical litigation from his management of the Digitek®, NuvaRing®, Yaz® and Zelnorm® litigations. If the court determines that centralization is warranted, following entry of an order transferring the pending Reglan®/metoclopramide cases to Bergen County, Actavis respectfully requests that other subsequently filed related actions be transferred for centralized management without further application.

CONCLUSION

For the reasons set forth above, defendant Actavis Elizabeth LLC respectfully submits that these cases should not be centrally managed. However, if the court determines centralized management is warranted, Actavis Elizabeth LLC respectfully requests such centralization in Bergen County, before Judge Martinotti, and without mass tort designation.

REQUIRED NOTIFICATION

Pursuant to Directive #7-09, all involved parties are hereby notified that this response will be sent by the Administrative Director to all Assignment Judges and Civil Presiding Judges, and will be published by the Administrative Director as a Notice to the Bar in the legal newspapers and in the Mass Tort Information Center on the Judiciary's Internet website, providing information on where and within what time period comments on and objections to the application may be made.

Respectfully submitted,

HARRIS BEACH PLLC

By:

Frederick H. Fern Steven A. Stadtmauer Kelly E. Jones

One Gateway Center Suite 2500 Newark, New Jersey 07102 (973) 848-1244

Of Counsel:

TUCKER ELLIS & WEST LLP

1150 Huntington Building 925 Euclid Avenue Cleveland, Ohio 44115 (216) 696-5000

SAS: KEJ

cc: <u>VIA OVERNIGHT MAIL</u>

Theodore Oshman Oshman & Mirisola, LLP 42 Broadway New York, NY 10004-1617 Hon. Glenn A. Grant, J.A.D. May 14, 2010 Page 11

HARRIS BEACH 월 Attorneys at Law

Hunter J. Shkolnik, Esq. Rheingold, Valet, Rheingold Shkolnik & McCartney, LLP 113 East 37th Street New York, New York 10016

Counsel for Plaintiffs

296070.2

Metoclopramide Cases Filed and Served Upon Defendant Actavis Elizabeth LLC as of 05/14/2010

Case Name	Docket Number	Plaintiff Counsel	Plaintiff Residence
Arruda, Alexander	L-003805-10	Oshman & Mirisola, LLP	New York (Madison)
Broome, Frances	L-003255-10	Rheingold, Valet & Rheingold	Tennessee (Louisville)
Chatfield, Rita	L-003779-10	Oshman & Mirisola, LLP	Texas (Tarrant)
Clein, Lanette	L-002389-10	Oshman & Mirisola, LLP	Alabama (Montgomery)
Davis, Billy Gene	L-003207-10	Oshman & Mirisola, LLP	Missouri (Polk)
Davis, Willie-Nell	L-002967-10	Oshman & Mirisola, LLP	Tennessee (Shelby)
Harris, Patricia	L-003790-10	Oshman & Mirisola, LLP	Pennsylvania (Philadelphia)
Harrison, Panfila	L-003803-10	Oshman & Mirisola, LLP	Texas (Harris)
Hubert, Lucy P.	L-002355-10	Oshman & Mirisola, LLP	Alabama (Madison)
Johnson, Nellie	L-002391-10	Oshman & Mirisola, LLP	Texas (Galveston)
Krystof, Mindy	L-003210-10	Oshman & Mirisola, LLP	Florida (St. Lucie)
Loenig, Ernest	L-002356-10	Oshman & Mirisola, LLP	Florida (Brevard)
Milton, Will	L-002968-10	Oshman & Mirisola, LLP	Tennessee (Knox)
Mouradian, Patricia	L-003208-10	Oshman & Mirisola, LLP	Arizona (Gila)
O'Keefe, Karen	L-001785-10	Rheingold, Valet & Rheingold	Virginia (Hampton)
Peno, Elizabeth	L-002334-10	Oshman & Mirisola, LLP	Vermont (Addison)
Rikard, David	L-002333-10	Oshman & Mirisola, LLP	Mississippi (DeSoto)
Taylor, Dianne	L-003326-10	Rheingold, Valet & Rheingold	Tennessee (Madison)
Willeby, Kimberly	L-002335-10	Oshman & Mirisola, LLP	Tennessee (Davidson)



LAUREN E. HANDLER MEMBER, NJ AND NY BARS CERTIFIED BY THE SUPREME COURT OF New Jersey as a Civil Trial Attorney DIRECT DIAL No.: 973-889-4326 E-MAIL ADDRESS: LEHANDLER@PBNLAW.COM

May 13, 2010

Via Lawyers Service

Honorable Glenn A. Grant, J.A.D. Administrative Director of the Courts Hughes Justice Complex Post Office Box 037 Trenton, New Jersey 08625-0037

GLENN A. GRANT, J.A.D. ACTING ADMINISTRATIVE DIRECTO

Application for Centralized Management of Reglan® Litigation

Dear Judge Grant:

Re:

Pursuant to the March 22, 2010 Notice to the Bar, I write on behalf of Wyeth LLC, Schwarz Pharma, Inc., and Alaven Pharmaceutical LLC (the "Brand Name Defendants"), in opposition to the application for centralized management of the Reglan® Litigation. As outlined in more detail below, the facts do not support centralized management of these cases.

Background

The Medicine and the Parties A.

Reglan®, and its generic equivalent metoclopramide, is a prescription drug used to treat, among other things, gastroesophageal reflux disease and diabetic gastroparesis. in 1979 and brought to market by A.H. Robins Co. In 1989 American Home Products Corporation (later known as Wyeth) became the ablota-sumperand injectable.

> 100 SOUTHGATE PARKWAY, P.O. BOX 1997 MORRISTOWN, NJ 07962-1997 TELEPHONE (973) 538-4006 FAX (973) 538-5146 www.pbnlaw.com



brand name Reglan® tablets from 1989 until December 2001, when it sold the rights associated with that formulation of the drug to Schwarz. At the same time, ESI Lederic ceased manufacturing and selling generic metoclopramide. Schwarz manufactured and sold brand name Reglan® tablets from December 2001 until February 2008. Aleven, who purchased the rights associated with brand name. Reglan® tablets from Schwarz in February 2008, currently manufactures and sells brand name Reglan® tablets. Since the mid-1980's, several companies have manufactured and distributed generic metoclopramide, and almost the entire as lest share belongs to these generic manufacturers.

B. The Plaintiffs

None of these plaintiffs are eitizens of New Jersey, and they have no discernable connection to the state. Each plaintiff asserts claims against some, but not all, of the following defendants: the Brand-Name Defendants: Wyeth; Sohwarz, and Alaven and seven generic manufacturers. Pliva USA, Inc.; Actavis Elizabeth, LLC; Purepae Pharmaceutical Company; Northstar RX, LLC; Duramed Pharmaceuticals, Inc.; Teva Pharmaceuticals USA Inc.; and Watson Laboratories, Inc.: The Plaintiffs allege ingestion of "Reglan and/or metoclopramide" from as long ago as the mid-1980's to as recently

As part of its December 2001 transaction with Schwarz, Wyeth agreed to withdraw its FDA-approved New Drug Application for brand name Reglan® syrup. In a separate transaction, Wanth with the sights associated with brand name Reglan® injectable to an unrelated third party who is not a defendant in these cases, Danter Healthean Corporation. Neither Schwarz are Alayer have ever neid any rights associated with brand name Reglan® syrup of injectable. Neither formulation appears to be at issue in these cases.

² Schwarz and Alaven have never manufactured or sold generic metoclopramide.

³ The Complaints identify the plaintiffs as residents of 13 other states - Alabama, Arizona, Florida, Kansas, Maryland, Mississippi, Missouri, New York, Ohio, Tennessee, Texas, Vermont and Virginia.



as 2009, and claim to have used it for as long as 40 years but also for much shorter periods of time.

Although most of the Complaints describe the injury as tardive dyskinesia, others unege orange dyskinesia akathisia facial twitching or twitching to the extremities.

Plaintiffs are represented by two New York law firms – Rheingold, Valet, Rheingold, Shkolmk & McCartney, LLP, and Oshman & Minisole, which is affillated with Matthews & Associates in Houston, Texas

C. The Litigation

The request for centralized management from the Assignment Judge of Essex County stems from the filing of a handful of Reglan®/metoclopramide cases in that county. Today, only 22 cases have been filed in New Jersey. 3 in Month County and 12 in Essex

The Reglan®/metoclopramide litigation is not new; it is a meture to that her been on soing inco the 1980's. The nearly 20-year history of this litigation in both the state and federal courts has proved that there is no need for coordinated proceedings. During that period, attorneys for plaintiffs have filed a steady flow of cases. They have asserted claims against a spectrum of defendants including the manufacturers of Regran*, manufacturers of generic metoclopramide, distributors, and healthcare providers. The litigation has focused on a variety of issues, such as the adequacy of the metoclopramide label, the risk of tardive dyskinesia, specific causation, the fault of healthcare providers, informed consent, and injuries and damages. All the while, the parties have worked together to coordinate discovery through the use of document productions in multiple cases and the cross-noticing of depositions. There has been little to the depletation of effort, and many cases have been successfully resolved – through motion practice or settlement.

Nearly one year ago, the United States Judicial Panel on Multidistrict Litigation ("JPML") defined plaintiffs' request for federal coordination. In so doing, the Panel remarked that "metoeleprantide Heigation has a lengthy history, and the record indicates that a significant amount of the common discovery has already taken place." Since the JPML denied MDL status, more lawsuits have been filed but the Panel's observations are just as true today.

Monetheless, on January 12, 2010, the Philadelphia Court of Common Pleas designated the 38 metocropramide cases pending there as a mass tort. In the nearly twenty years before the plaintiffs requested this designation only 130 cases had ever been filed in federal and state courts. Since the Philadelphia cases were designated a mass tort, however, the case consus in that Court has grown to over 200 cases and there are now a total of approximately 300 cases nationwide. Although the number of Reglan®/metoclopramide cases has increased outside of Pennsylvania, it has done so at a much slower pace. Indeed, it now appears as though most plaintiffs will bring Reglan®/metoclopramide lawsuits in Pennsylvania.

ARGUMENT

POINT I

The Cases Do Not Warrant Centralized Management

An analysis of several of the criteria set forth by the Court in Directive #11-03 make clear that these cases are inappropriate for centralized management.

A. Does the litigation involve large numbers of parties?

As it currently stands, the metoclopramide cases currently pending in New Jersey involve 22 plaintiffs and ten defendants. These numbers mirror those present at the time the JPML refused to



create a federal MDL for the Reglan®/metoclopramide litigation. This number of eases is simply too small to justify assigning the eases to the Mass Tort court for centralized management.

Further, none of the 22 plaintiffs are New Jersey residents. These plaintiffs apparently were not prescribed metoclopramide in New Jersey, did not ingest metoclopramide in New Jersey, were not diagnosed with their alleged injuries in New Jersey and did not receive medical treatment in New Jersey for their alleged injuries. Because of the lack of nexus these plaintiffs have to this State, the defendants will likely move for an early dismissal of each complaint on *forum non conveniens* grounds. Should these motions be granted, the Courts in each respective plaintiff's rightful place of residence will oversee these cases and there will be no need to manage them here, let alone to do so in a centralized fashion.

B. Does the Litigation Involve Many Claims With Common, Recurrent Issues of Law and Fact That Are Associated With a Single Product, Mass Disaster or Complex Environmental or Toxic Tort?

The answer to this question is no; the cases there ends one factor in common the alleged ingestion of metoclopramide. Not even that fact presents a truly common issue because the plaintiffs.

did not all ingest the same brand of metoclopramide. Those who ingested brand name Reglan® may have done so when it was sold by Wyeth, others when Schwarz or Alaven were responsible for the product. Still others were prescribed up to seven different generic versions of the drug.

There are also other factual and legal distinctions that make centralization improper. As a threshold matter, to resolve forum non convenient motions, the court must analyze the plaintiff's connection to the state of New Jersey and his or her connection to some other state, which will require an individualized inquiry in each case. Among other things, the Court must examine where each



plaintiff resides, where each plaintiff was prescribed and purchased the drug, where treatment was rendered, where a plaintiff's health care providers are located, as well as the substance of each plaintiff's knowledge and the knowledge of their individual health care providers with regard to the risks of the medicine. In this regard, each case is factually distinct, and no efficiency will be created through centralization.

The event that any of these cases proceeds on its merits, each presents a distinct set of facts.

The requires independent analysis. Each plaintiff has a unique medical history. Some plaintiffs may have had pre-existing conditions or taken other medications that caused their injuries, some plaintiffs claim different injuries, and each plaintiff used metoclopramide at different times during which the label contained different warnings. Because the plaintiffs took different drugs manufactured by different defendants, their proofs will depend on individual issues concerning the knowledge and actions of different companies at different times. As such, the defendants' liability in each case will depend on different proofs and different causation analyses.

Finally, if the cases do remain in New Jersey, each case will require an independent choice of law analysis that will result in the application of the laws of thirteen different states to different legal questions, many of which will be of first impression. For example, these cases often involve claims that a Brand Name Defendant may be held liable for injuries caused solely by the ingestion of a competing generic product. Central to the disposition of such claims is a determination on the question of duty -i.e.

The courts have a duty to the ricks of competing and products a legal issue dependent on state law. The courts have already ruled on this issue as



a matter of law under the law of over 20 states, including New Jersey⁴, and have virtually unmorned, held that a Brand Name Manufacturer is not hable for injuries allegedly caused by generic medication. However, no rulings have addressed the issue under the laws of Arizona, Kansas, Mississippi, Missouri, Ohio, Tennessee, Vermont or Virginia – states from which 13 of the plaintiffs who have filed suit in New Jersey hail.

In the absence of common issues of fact or law that can be resolved in a single proceeding, there would be little benefit achieved from centralized management.

C. Is there Geographic Dispersement of Parties?

This is not a situation where centralization will save judicial resources because cases have been filed in many counties throughout the state. The plaintiffs have filed cases in only two counties – three in Morris and nineteen in Essex. Moreover, that the plaintiffs come from 13 states other than New Jersey weighs in favor of dismissal and transfer to the relevant forums, not transfer into the New Jersey mass tort court system.

D. Is There a Value Interdependence Between Different Claims?

Cases involving metoclopramide have been pending in various state and federal courts for nearly 20 years. To the extent the perceived strength or weakness of the causation and the liability aspects of the cases might be dependent upon the success or failure of similar lawsuits in other jurisdictions, there is already a track record. Because of this nearly 20 years of experience, centralization is not necessary to achieve any value interdependence. Moreover, because both factual and medical causation will depend on a number of facts specific to each individual case – the

⁴ See, opinion in Sloan v Wyeth, attached as Exhibit A.



plaintiff's medical history, risk factors and his or her doctor's knowledge about the medicine, label and risks – the outcome in one case will not necessarily affect the resolution of other cases.

E. Is There a Degree of Remoteness Between the Court and Actual Decision-Makers?

The decision-makers and the Court are not remote. All 22 plaintiffs are represented by two law firms, both of which are affiliated with counsel handling metoclopramide cases elsewhere. And while there will be New Jersey and national counsel involved for the defendants as well, this will not prevent case management decisions from being made in an expedited manner. In this day and age, counsel have the ability to – and do – confer efficiently and promptly via phone and email among themselves and with their clients about issues as they arise. The plaintiffs' national counsel have appeared in the PCCP and have a good working relationship with defendants' national counsel. Counsel for all parties have already demonstrated an ability to cooperate on discovery issues and work through them with a minimum of disagreement.

F. Is There a Risk that Centralization May Unreasonably Delay the Progress, Increase the Expense, or Complicate the Processing of Any Action, or Otherwise Prejudice a Party?

Centralized management would certainly delay and complicate these cases and prejudice the parties.

The Court directives do not specify any distinction between cases that are designated as mass torts and those assigned for centralized management without the mass tort designation. Rather, those litigations that have been designated only for centralized management are, for all practical purposes, handled in the same manner as mass torts. They are listed on the New Jersey Judiciary's Mass Tort Information Center, the Court's "Mass Tort" judges oversee them, and those judges, to date, have



utilized the same case management tools they use when a case is called a mass tort (e.g., frequent case management conferences, assignment of liaison counsel, use of plaintiff and defendant fact sheets). If these cases are assigned for centralized management any casual observer of the litigation, as well anyone investigating the litigation on the Court's website, would fall to discern how these cases are any different from those cases that are designated as a mass tort in New Jersey.

As a result, centralization would be extremely projudicial to the Brand Name Defendants. It would convey the impression that a "mass" of users of their product claim to have been injured, a result that may have consequences both in the litigation and to their business. Because the generic method dwarves the brand market, such an impression clearly would be wrong. But the harm will have been done. And because none of the plaintins are New Jersey residents, centralization would no doubt lead to still more forum shopping by non-New Jersey residents. Centralization, with or without the "mass tort" designation, creates the risk that marginar claims will be filed in the hope there will one day be a global resolution of the litigation from which those cases will benefit. This is not mere supposition – it is precisely what secured in Philadelphia where the case census grew from a mere 38 cases to over 200 after the PCCP designated the hitigation as a mass tert.

Centralization would also forever bind those who rightly belong in only a limited number of cases to the larger litigation and severely limit their ability to extricate themselves from cases at an early stage, to it is the practice in the mass tort courts to hold the cases of the minor defendants in abeyance while the litigation proceeds against the perceived "target" defendants. This would not only adversely impact those manufacturers who are only named in a small number of cases. All the defendants would end up spending more, rather than less, time on administrative details such as



negotiations over the form of fact sheets or case management orders, or the procedures for how to stage discovery.

Rather than subjecting these cases to the Mass Tort Court's administrative requirements, it is respectfully suggested that the cases remain where they were filed, where the assigned judges can set a schedule for *forum non conveniens* discovery and motions to dismiss. After that, the parties can target discovery in those cases that remain in New Jersey toward identifying the actual drugs ingested so that those manufacturers whose products plaintiffs did not use can be dismissed. Once the cases include only the proper parties, discovery can proceed as in any other case.

G. Is Centralized Management Fair and Convenient to The Parties, Witnesses and Counsel?

Based on the plaintiffs' states of residence, it is clear that New Jersey is not a convenient forum for them, beyond whatever advantage their lawyers perceived would inure to their benefit by filing suit in this State. Plaintiffs will have to travel to New Jersey for depositions, medical evaluations, and trial.

New Jersey is also an inconvenient forum for the Brand Name Defendants. None are New Jersey residents.⁵ Their documents and employees are not here. Moreover, before they can depose

The application for centralized management expresses concern that significant numbers of cases will eventually be filed in New Jersey because of Wyeth's presence in the State. It states, "Wyeth Pharmaceuticals ... appears to be the primary defendant in these cases," the company is "headquartered in Madison, Morris County, New Jersey," and "The main defendant is a New Jersey Domiciliary." This concern is misplaced and is factually inaccurate for four reasons. First, in 190 of the 22 New Jersey cases are anteged ingestion. The defendant is a New Jersey takes and after Wyeth sold the product line, therefore Wyeth is neither the "primary" nor the "main" defendant at all. Second, even for mose cases in which plaintiffs ingested Regian and did so terore wyeth sold the product lines in 2001 and 2002; it is simply incorrect to see the main defendant is a text Jersey Domiciliary. An or wyeth's operations concerning the product took place in Remarkable places. It is now Wyeth, LLC, whose states of citizenship are Delaware and New York, not New Jersey. Third, because Wyeth sold its Reglan oral tablet product line and discontinued the syrup formulation nine years ago and sold the injectable formulation eight years ago, the complaints of plaintiffs who seek damage from injuries alleged caused by Wyeth's Reglan, are probably timebarred. Finally, Wyeth cannot be deemed the "main defendant" when none of the Complaints definitively alleges use of its product. Instead, each claims only that plaintiff ingested "Reglan and/or metocropramice" (emphasis added). Therefore, it



fact witnesses such as prescribing and treating physicians, defence counsel will be required to obtain commissions from the New Jersey courts and apply to the plaintiffs home state courts for isotance of a subpoena. So long the cases remain in New Jersey defendants will be unable to compel critical appear live at trial.

H. Is There a Risk of Duplicative and Inconsistent Rulings, Orders or Judgments if the Cases Are Not Managed in a Coordinated Fashion?

Any such risk can be resolved by the two counties in which these cases have been filed. A simple the cases and manage them in such a way as to avoid during the cases and manage them in such a way as to avoid during the cases need not be transferred to the mass tort court to accomplish this end. Indeed, that is precisely how the Court handled the Remiende litigation both before and after the application for mass tort designation was rejected. The cases were assigned to Judge Epstein and the parties agreed to utilize a discovery master to assist in resolving any issues they could not work out themselves. Such a model is an appropriate alternative to centralized management within the mass tort construct and has the further advantage of preventing any misperception in the eyes of outsiders that this is a "mass tort."

I. Would Coordinated Discovery be Advantageous?

There is no particular advantage to coordination insofar as discovery addressed to the plaintiffs is concerned. And because metoclopramide cases have existed for many years, many of the defendants

is not clear whether any of the plainting actually used Bashander a generic. If they used generic metoclopramide, then Wyeth (as well as Schwarz and Alaven) was not properly named and should be dismissed from the cases. For each of these reasons, Wyeth's alleged presence here is an insufficient basis to once again turn New Jersey into a locus for a national litigation that will only serve to encourage more filings here of cases with little or no nexus to the citizens of this State.



have already collected and produced documents (or will have done so shortly in the PCCP) so that this discovery can readily be produced in response to discovery requests served here.

J. Can Issues of Insurance, Limits on Assets and Potential Bankruptcy be Best Addressed in Coordinated Proceedings?

These factors are not an issue in these cases.

K. Are There Related Matters Pending in Federal Court or in Other State Courts That Require Coordination with a Single New Jersey Judge?

The PCCP recently designated the cases in Philadelphia as a mass tort. If necessary, coordination with the PCCP proceedings can easily be achieved without centralization or mass tort status in New Jersey.

Bavid Matthews, who represents most of the plaintins in the New Jersey cases is also heavily involved in the PCCP proceedings.

POINT II

If the Court is Inclined to Designate These Cases for Centralized Case Management, Venue is Most Appropriate in Bergen County

According to the Court's Directive "issues of fairness, geographical location of parties and attorneys, and the existing civil and mass tort caseload in the vicinage will be considered in determining to which vicinage a particular mass tort will be assigned for centralized management." Wyeth, Schwarz and Alaven object to centralized management of these cases, but should the Court so designate this litigation, we request that the cases be assigned to Dergen County, for the reasons discussed below.



A. Geographic location of parties and attorneys

Plaintiffs chose to venue their cases in Essex and Morris Counties. Therefore, it is apparent that they deem it more convenient for them to litigate these cases in Northern New Jersey. Because they are all from out of state and would have to travel to New Jersey for depositions, medical examinations and trial, the location of major airports and train stations through which they can travel is relevant. Two of the plaintiffs are from New York, the rest live further from New Jersey. Design County is closer and more easily reached by the New York plaintiffs than is Middlesex or Atlantic Counties, and Middlesex County is more accessible by train than is Atlantic. For the remaining plaintiffs, Bergen County is closest to the New York airports. Although Middlesex County is further from the New York airports than Bergen, it is shorter in terms of both distance and time than is Atlantic County. Both Bergen and Middlesex are about equidistant from Liberty Airport in Newark; Atlantic is further. These facts suggest Bergen as the most appropriate venue, followed by Middlesex County.

Plaintiffs lawyers are in New York City. National counsel for Schwarz and Alaven are also in New York City. This also weighs in favor of choosing Bergen County as the venue as it is only a short drive or train ride from Manhattan. National counsel for Wyeth are in New Orleans and Austin, making travel to New York or Newark and venue in Bergen or Middlesex more convenient than Atlantic.

B. Existing case load

Information about the cases assigned to the mass torts courts are found on the judiciary mass tort website. Six mass torts and one case for centralized management are assigned to Judge Higbee,



the sole mass tort judge in Atlantic County. Seven mass torts are assigned to Middlesex County, two to Judge McCormick and five to Judge Mayer⁶, and the judges have a special master who provides assistance in managing the case load. Judge Martinetti in Bergen County is overseeing four mass tests and two cases for centralized management.

In addition to the number of "litigations" assigned to each county, the actual number of pending cases is relevant. The most up-to-date accounting of the mass tort caseload is contained in the report, New Jersey Judiciary Court Management February 2010. The report lists by county the active inventory as well as the backlog, described as the "number of active pending cases that are not within generally accepted normative case processing time frames." Atlantic County has 1,401 active pending mass torts. Its backlog/100 monthly filings totals 989 cases. Middlesex County has 4,624 active pending cases, with 3,020 backlog/100 monthly filings. Bergen County has only 231 active pending

Conclusion

For the reasons set forth above, the Brand Name Defendants oppose centralized management of the Reglan®/metoclopramide litigation. Should the Court nonetheless assign the cases for centralized

⁶ One of those mass torts, the HRT litigation, is essentially stayed pending an appeal of summary judgment that was granted to the defendants in July 2008.

⁷ See, excerpts from New Jersey Judiciary Court Management February 2010, attached as Exhibit B.



ATTORNEYS AT LAW

management, the convenience of the parties and counsel, as well as the case load of the mass tort court, weigh in favor of the cases being assigned to Bergen County.

Respectfully submitted,

Lauren E. Handler

EXHIBIT

A

FILED

PORZIO, BROMBERG & NEWMAN, P.C.

100 Southgate Parkway Morristown, NJ 07962-1997 (973) 538-4006 Attorneys for Defendant Wyeth, Inc. OCT 0 4 2004

DAVID B. RAND, J.S.C. JUDGE'S CHAMBERS MORRIS COUNTY COURTHOUSE

CIVIL ACTION

DIANNE SLOAN and PAUL WAYNE SLOAN,

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MORRIS COUNTY DOCKET NO. MRS-L-1183-04

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Plaintiffs,

v.

WYETH, INC., et al.,

Defendants.

ORDER Granting

THIS MATTER having been opened to the Court upon application by Porzio, Bromberg & Newman, P.C., attorneys for the Defendant, Wyeth, Inc., and the Court having read and reviewed the moving papers submitted and any opposition thereto and for good cause having been shown;

It is on this 4th day of Octobe, 2004,

ORDERED that the motion of Defendant, Wyeth, Inc., to dismiss the plaintiffs' Complaint as against Wyeth for failure to state a claim, is hereby GRANTED; and it is further

ORDERED, that the plaintiffs' Complaint is hereby dismissed as against Wyeth, Inc. with prejudice.

A copy of the within Order shall be served upon all counsel within

days from

the date of entry.

Hon. Thomas V. Manahan, J.S.C. DAVID B. RAND, J.S.C.

X	The court made the attached findings of fact or reasons for its decision on
	The court set forth its findings of fact or reasons for its decision orally on the record on
This	Motion was:
*	Opposed
	Unopposed

SUPERIOR COURT OF NEW JERSEY

Chambers of David B. Rand Judge



Morris County Courthouse P. O. Box 910 Morristown, NJ 07963-0910 (973) 656-4045

October 13, 2004

Advokat & Rosenberg 22 North Park Place Morristown, New Jersey 07960-7102

Porzio, Bromberg & Newman, P.C. 100 Southgate Parkway Morristown, New Jersey 07962-1997

Re: Sloan v. Wyeth, et. als.

Docket No.: MRS-L-1183-04

Dear Counsel:

Preliminary Matters

Wyeth, Inc. ("Wyeth") is the successor in interest to A.H. Robbins

Co., Inc., and American Home Products Corporation named in counts IV –

VI and IX –XI of the complaint filed by the plaintiffs, Diane and Paul Sloan.

Plaintiffs assert that Wyeth was guilty of common law fraud, made

negligent representations, committed fraud by concealment and violated
the Consumer Fraud Act (N.J.S.A. 56:8-1 et seq.). The defendant Wyeth

moves for Summary Judgment.

The action is factually predicated upon the allegation that Wyeth manufactured and distributed the drug metoclopramide under the brand name "Reglan" until December 27, 2001. The plaintiff, purchased and consumed generic versions of Reglan between June 1999 and April 2002.



These "generic" versions of Reglan were manufactured and distributed by co-defendants Pliva, Sidmak and Harvard Drug Group. Plaintiff alleges that the generic versions of the drug caused her to develop tardive dyskinesia, a neurological syndrome.

The gravamen of plaintiff's complaint against Wyeth is predicated upon the assertion that Wyeth is responsible for the injuries caused by the co-defendants' generic drugs because the plaintiff's physicians, who prescribed the drug, relied on information derived from Wyeth which that defendant promulgated in connection with its brand name product Reglan.

It is not disputed, however, that the brand name drug was never actually used by plaintiff. As noted she actually used "generic" versions of the drug, manufactured and distributed by co-defendants. For reasons, which more particularly are set forth below, Summary Judgment will be granted in favor of Wyeth and those claims asserted against it in the complaint will be dismissed.

Discussion

This action presents a case of first impression in New Jersey, ie., whether a brand name drug manufacturer can be held liable for injuries caused by the generic drug manufactured by another company.

Wyeth cites three decisions as persuasive authority in support of its argument to dismiss plaintiffs' claims. Forster v. American Home Products, 29 F.3d 165 (4th Cir. 1994); Block v. Wyeth, Inc., et al, 2003 WL 203067 (N.D. Texas Jan. 28, 2003): and Beutella v. AH Robbins et al., #980502372

slip opinion at $\underline{6}$ (Utah 5th Judicial District, Washington County, Nov. 7, 2001).

In <u>Forster</u>, the United States Court of Appeals for the Fourth Circuit (applying Maryland law) dismissed an action which involved a similar situation to the instant litigation. In that case, the Court of Appeals considered the decision of the lower Court, which held that a manufacturer of a brand name prescription drug could be liable for an alleged negligent misrepresentation relating to a death caused by another company's generically equivalent drug. The Court of Appeals considered whether the trial court was correct dismissing the plaintiffs' claim for failure to show reasonable reliance by the plaintiffs on the representations made by the brand name drug company. Because the Court in <u>Forster</u> held that the brand name manufacturer could not be held liable for a negligent misrepresentation, it did not reach the second issue on appeal. Id. at 167.

In <u>Forster</u>, Wyeth, as successor to American Home Products, was sued arising from its manufacture of a brand name drug known as Phenergan. The drug was prescribed by a physician in syrup form to the plaintiff's infant twins Brandy and Bradley Forster, who were suffering from colic. The infant twins were given a generic version of the drug several times. One of the infants, Brandy, was found deceased in her crib shortly following the last administration of the drug. An autopsy report attributed the child's death to Sudden Infant Death Syndrome (SIDS), however, a pediatrician related to the University of Maryland attributed the

infant's death to the use of the drug Promethazine, the generic version of Phenergan.

The trial court in <u>Forster</u> granted summary judgment in favor of Wyeth on the product's liability counts based upon the assertion that the product actually sold in the <u>Forster</u> case <u>was not manufactured</u> by the defendant. The drug taken by the infants was a generic version of the brand name drug and was manufactured by others. The District Court stated that if plaintiffs were able to establish that the defendant actually made false presentations concerning the safety of the drug itself, ie. the chemical substance which comprises both the <u>generic and brand name</u> drug, then the drug company "...maybe liable for any harm caused..." to plaintiffs or their children as a result of the ingestion of such drugs. <u>Forster</u>, 29 F.3rd at 67.

The trial court in <u>Forster</u> drew a distinction between the negligent misrepresentation claim and the products liability claims. However, on the particular facts of that action, the trial court granted the defendant's motion for Summary Judgment on grounds that the plaintiffs had failed to establish that the physician relied upon the representations made by the brand name drug company in his decision to prescribe the generic drug to the children. Hence, all claims made by the plaintiffs were dismissed. The plaintiff and defendant appealed and cross-appealed.

Subsequently, the Fourth Circuit acknowledged that there presently existed no recognizable Maryland cause of action based upon negligent misrepresentation against one manufacturer for injuries sustained from

the use of another manufacturer's product. <u>Id.</u> at 168. The Court in Forster further stated:

"We reject the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." <u>Id.</u> at 170.

The Court also noted that Maryland law requires that a plaintiff seeking to recover for injuries by a product must demonstrate that the defendant manufactured the product at issue. See eg., Tidler v. Eli Lily and Co., 851F. 2nd 418 (D.C. Cir. 1988) (applying Maryland law).

Here, the plaintiff seeks to avoid the fatal results dictated by <u>Forster</u>, <u>Block</u> and <u>Beutella</u>, by asserting that there is a distinction to be drawn by the Court, that defendant Wyeth, was a "disseminator" of negligently false and misleading information, rather than a "manufacturer" of a defective product. Plaintiff relies on decisions such as <u>Reynolds v. Lancaster</u>

<u>County Prison</u>, 325 N.J. Super. 298 (App. Div. 1999) to demonstrate the generic view that New Jersey has adopted towards the Restatement (Second) of Torts § 311, which permits third parties to assert claims for negligent misrepresentation involving risk of physical harm to third parties.

Reynolds involved a case action in which plaintiff brought an action against the defendant predicated upon the tort of negligent misrepresentation. There, defendant donated an attack dog to the plaintiff's business without disclosing its vicious nature. Subsequent to the donation, the dog caused serious injuries to the plaintiffs in an alleged

unprovoked and vicious attack. The jury awarded substantial damages to the plaintiffs and the defendants appealed. The Appellate Division upheld the jury verdict on various grounds including the applicability of the Restatement (Second) of Torts § 311.

Hence, it is quite clear that presently in New Jersey, in the appropriate circumstance, the tort predicated upon negligent misrepresentation may be viable. It should be noted, however, in <u>Reynolds</u> there was no issue regarding the connection between the cause of plaintiffs' injuries, ie. a vicious dog, and the source or identity of that injury, ie. the receipt of the animal from the defendants.

The ultimate analysis here requires the Court to determine the effect, if any, of the New Jersey Product Liability Act, N.J.S.A. 2A:50C-1 et seq., ("PLA") upon the ability of the plaintiff to recover in this context.

Stated succinctly, does the PLA immunize Wyeth from plaintiffs' claims when it admittedly was not the manufacturer of the product that caused plaintiff's injuries?

More particularly, Wyeth relies upon N.J.S.A. 2A:52C-2 and asserts that under this part of the PLA any product liability action must, by necessity, involve "...a claim or action brought by a claimant for harm brought by a product, irrespective of the theory of the claim." The complaint alleges "harm caused by a product" as defined by the PLA. Under the PLA, the defendant asserts "harm includes"

- (a) Physical damage to property, other than the product itself;
- (b) personal physical injury or death; (c) pain and suffering,

mental anguish or emotional harm; (d) any loss of consumption of services or other loss deviating from any type of harm described in paragraphs (a) thru (c) of this paragraph. N.J.S.A. 2A:58C-1(b)2.

Hence, Wyeth asserts that for it to be held liable, the cause of action or mechanism of the injury must <u>flow from a product manufactured by</u>

Wyeth or a product under its immediate direction or control.

Plaintiffs counter this argument by asserting that the PLA hardly constitutes their exclusive remedy and maintain that causes of action may also arise by virtue of common law principles of fraud, misrepresentation, etc. Alloway v. General Marine Industries, LP, 149 N.J. 620, 639-40 (1997). Alloway, was not a personal injury action but addressed the appropriate theory of liability a plaintiff must pursue in circumstances of economic or non-personal injury. Nevertheless, the plaintiffs seek to apply generalized dictum that appearing in Alloway to the facts and circumstances.

The Court, however, notes that it has generally been held that the PLA is not merely plaintiffs' proper remedy in New Jersey, it is their exclusive remedy. "the PLA, by its terms," made clear 'three causes of action 'ie; manufacturing defects, failure to warn, [and] design defect' are intended to be inclusive, as the sole basis for recovery on a product claim against the manufacturer or seller to the other terms of the statute." See Dryer, Keefe and Katz, "NJ Products Liability and Torts Law" at 16 (Gann 2000 ed.).

As noted by the defendants in <u>Tirrell v. Navistar, Inter., Inc.</u>, 248 N.J. Super. 390 (App. Div. 1991), <u>cert. denied</u>, 126 N.J. 390 (1991), the Appellate Division held a litigant's negligence and implied warranty claims are subsumed by the PLA because "...the act established a sole method to prosecute a product liability action." <u>Id.</u> at 398, 399. Other cases posit a similar rule. <u>See Ropela v. Morebark Industries</u>, 934 F.2nd 383 (3rd Cir. 1991); <u>Brown X Well Brown v. Philip Morris Inc.</u>, 228 F.Supp. 205 (D.N.J. 2002); <u>Reef v. Convergent Technologies</u>, 957 F.Supp. 573 (D.N.J. 1997).

In this action, plaintiffs seek to bypass the PLA through application of a generic Restatement (Second) of Torts provision (§311). It seeks to expand the liability of brand name manufacturers to damages caused by generic versions of their product. Does a duty even exist upon Wyeth in this action?

Indeed, it is well established that whether a duty exists in a given context is in the first instance for the Court to determine. Carvalho v. Toll Brothers, 143 N.J. 565, 573 (1996) and Wang v. Allstate Insurance, 125 N.J. 2, 15 (1991).

The question of whether a duty exists to exercise reasonable care to avoid harm to another is determined by fairness and policy considerations and may implicates complex factors. See Carvalho, 143 N.J. at 573 and Dunphy v. Gregor, 136 N.J. 99 (1994). Certainly, foreseeability of harm is an important consideration in the determination of the existence of a duty to exercise reasonable care. Carter Lincoln-Mercury Inc. v. Emar Group, Inc., 135 N.J. 182 (1994). As held by the Supreme Court of New Jersey,

once foreseeability of injuries has been established, policy considerations and fairness govern whether the imposition of a duty is warranted. <u>Carter</u>, 135 N.J. at 194-195.

Here, policy considerations must weigh <u>against</u> imposing liability on defendant Wyeth under these circumstances. Certainly, it can hardly be persuasively argued that the PLA was intended to expand the liability of manufacturers, such as defendant, in contexts such as the one presented here. The sole basis for the policy advanced by the plaintiffs at oral argument was that "plaintiffs should have recourse and injured plaintiffs should have the right to recover."

The Court notes that nothing before it allows for any viable argument that either New Jersey or the Federal authorities intended to expand prescription drug manufacturer liability to injuries sustained by consumers of products manufactured by generic drug companies, which use formulations developed by the brand name company. Indeed, there is nothing in the PLA or elsewhere which would suggest such liability will advance the affordably of drugs, one of the main policy foundations for the Hatch-Waxman amendments to the Federal Food Drug and Cosmetic Act.

The Court agrees with Wyeth's assertion that as a practical matter, imposing additional liability upon brand name drug manufacturers would achieve the exact opposite effect sought by the Federal Legislation. Brand name manufacturers would be less likely to develop new products if liability were imposed upon these companies for injuries wrought by products of generic manufacturers.

On the other hand, plaintiffs are hardly without a remedy. Their recourse remains viable against the manufacturers of the generic drug that was in fact prescribed and utilized. Generic manufacturers can hardly claim immunity from liability merely because they relied upon warnings appearing on the defendant's brand name product. (See <u>Forster</u>, 29 F.3d at 169). These entities have the same duty under the PLA as the brand name defendant Wyeth.

For all the foregoing reasons, therefore, Summary Judgment is hereby granted to the defendant Wyeth dismissing all claims against it brought by the plaintiffs.

David B. Rand, J.S.C.

EXHIBIT

B

New Jersey Judiciary

Court Management

February 2010

Stuart Rabner

Chief Justice

Glenn A. Grant

Acting Administrative Director

CRIMOLASI WEAPONS: Indudes weapons cases and withd non-support/interference with custody cases docteted as "FO" Family Division Criminal/Quest-Criminal/Other matters. CRIMQUASI DV CONTEMPT: Includes Domestic Violence Contempt cases CIVIL - MASS TORT: includes Asbestos, Silicon Implant, Blood-clotting Senum, Repetitive Strass Syndrome, Gas Pipe Explosion, Maywood Contamination, Latex, Diet Drug, FRT Phywood, Black, Jack, and Tobacco DOMESTIC V-NEW: Includes domestic violence cases reported as CRIMINAL: Only post-indiciment criminal activity is reported in this CASE TYPE ABBREVIATIONS Criminal Other Matters docketed as "FO." new/not previously adjudicated. delinquency ceses. post-judgment. BACKLOG/ 100 MONTHLY FILINGS; Backlog/(most recent 12 mntha of filings/12) * 100 ADDED: "Added" and "Filing" are used interchangeably to indicate the number ACTIVE PENDING: Cases that have not been disposed of. Does not include 12 months from filing 18 months from filing 24 months from filing 24 months from filing 2 months from filing 4months from filing of incoming cases. Added cases include new, reopened, reactivated, and INVENTORY: Addve pending cases within generally eccepted normative case-processing time frames. The following goals are used: BACKLOG: Number of active pending cases that ere not within generally accepted normative case processing time frames. See "Invertiory." STATISTICAL TERMINOLOGY BACKLOG PERCENTAGE: Backlog/Active Pending *100. CLEARANCE PERCENTAGE: Dispositions/Added *100, RESOLVED: Ceses disposed or terminated. Municipal Appeals Post-Conviction Relief Equity CLEARANCE: Disposed-Added. CMI (Track 1) CMI (Track 2) CMI (Track 3) CMI (Track 4) transferred cases. nective cases. TABLE OF CONTENTS KEY TO TRIAL COURT REPORTS KEY TO MUNICIPAL COURT REPORTS MONTHLY CLEARANCE SUMMARY COUNTY PROFILES CASE MANAGEMENT OVERVIEW PROBATION DEFINITIONS MUNICIPAL COURTS..... Gloucester. Capa May. Somerset. STATE PROFILE. PROBATION

INTRODUCTION

COURT MANAGEMENT provides caseload statistics for New Jersey Superior Trial Courts. Statistics are compiled from monthly statistical reports prepared by division managers in each county and submitted by trial court edministrators.

year-to-date chearance and inventory percentages and current month clearance numbers. The county profile section provides a two-page court year-to-date caseload report for each county. The statewide overview section of the report provides court

Court Management is produced by the Administrative Office of the Courts' Quantitative Research Unit.

QUANTITATIVE RESEARCH UNIT TRENTON, NJ 08625 P.O. BOX 037

docketed as "FO" Family Division Criminal/Quasi-Criminal/Other matters.

CRIMI/QUASI OTHER: Includes other Family Division Criminal/Quasi-

DELINQUENCY-NEW: Includes juvenile definquency cases reported as

DELINQUENCY-PREV. ADJUD: Includes previously adjudicated juvenile

DISSOLUTION-NEW: includes dissolution cases reported as new/pre-judgment

DISSOLUTION-REOPENED: Includes dissolution cases reported as reopened

DOMESTIC V-REOPENED: Includes domestic violence cases reported as reopened/post-judgment.

EQUITY: General Equity

JUV/FAM CRISTS PETITION: Juvenile/Family Crisis Petitions.

NON-DISSOL.-NEW: Includes non-dissolution cases reported as new previously dismissed. NON-DISSOL.-REOPENED: Includes non-dissolution cases reported as reopened/post-disposition.

12 months to permanency hearing

6 months from filing s months from filing months from filing

1 month from filing

Juvenile/Family Crisis Pettion Termination of Parental Rights Criminal/Quasi-Criminal/Other

Child Placement Review

6 months to fact-finding

Abuse/Neglect (out-of-home) Abuse/Neglect (in-home placement)

Domestic Violence

Non-Dissolution

Delinquency

4 months to fact-finding

1 month from filling

6 months from filing 3 months from filing 3 months from filing

Dissolution - Reopened

Dissolution - New

12 months from filing 12 months from filing

Special Civil (small daims & tenancy) Special Civil (ell other)

OTHER FAMILY: Family Division category that includes abuse/neglect, adoptions, child placement review, juvenila/family crisis pellibors, termination of parental rights and criminal/quasi-criminal cases.

P.C. RELIEF: Post-Conviction Relief.

Adoption: Agency=2 months, Stepparent= 4 months, Private Placement = 12 months

Kinship * New Adoption goals pending implementation are:

Percent Change: The percentage increase from last year during the seme period to the current period.

PROBATE: Contested probate.

TERM OF PARENTAL RIGHTS: Termination of Perental Rights

Caseload Profile Atlantic

Atlantic July 2009 - February 2010

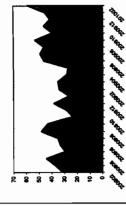
February 2008 - February 2010 Criminal Backlog

Backlog By Month

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CIVII Backlog

General Equity Backlog



989 -29% 147 -3%

1,401 31% 3,973 2%

15%

491 -3% 602 8%

85%

%86

-70

3,230

Civil - Non Mass Tort percent change

35%

65%

910 61% 3,371

47%

-278

521 51% 3,300 9%

Civil - Mass Tort percent change

Special Civil Backlog

NOTE: Mass torts are defined as mass torts and/or centrally managed cases.

8

Bergen February 2008 - February 2010 **Backlog By Month**

Criminal Backlog

Caseload Profile Bergen July 2009 - February 2010

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318 342 24 108% 596 2% -9% 77 152% 355 -17% 27% 77 152% 28% 37,293 35,250 -2,043 95% 5,551 9 124 115 -9 93% 28 18% 16% -9 93% 4% 26,529 25,110 -1,419 95% 4,724 9% 130% -167 95% 278% 3,064 2,897 -167 95% 217 8% -1% -167 95% 217 8% -1% -242 96% 42% 1% -5% -145 95% 145 9% -28 -344 42% 9% -8% -18 95% 145 9% -8% -18 95% 12%	nt change	3,816 2%	4,078	262	107%		87%	715 3%	13%	5,505 -6%	149
149 226 77 152% 28% -17% 27% 77 152% 28% 37,293 35,250 -2,043 95% 5,551 9 124 115 -9 93% 28 18% 16% -1,419 95% 4,724 9% 772 566 -206 73% 238 226% 130% -167 95% 4,724 8% -18 95% 217 8% -1% 6,64 42% 1% -5% -242 96% 42% 368 350 -18 95% 145 9 9% -8% -18 95% 12%	nt change	318 2%	342	25	108%		%68 **	₽ \$	11%	673 3%	194
37,293 35,250 -2,043 95% 5,551 9 124 115 -9 93% 28 18% 16% -1,419 95% 4,724 9% 772 566 -206 73% 238 226% 130% -167 95% 4,724 8% -130% -167 95% 278% 8% -1% 6604 6,562 -242 96% 42% 1% -5% -18 95% 145 9 0% -8% -18 95% 145 9	it change	149 -17%	226 27%	11	152%	352 28%	88%	48 100%	12%	400 34%	148
26.529 25.110 -1,419 96% 4% 4% 4% 4% 4% 4% 4% 4% 4% 4% 4% 4% 4%	Sivil - Total	37,293 9%	35,250 3%	-2,043	%56	5,551 15%	%86	129 61%	2%	5,680	%/5 E
26.529 25,110 -1,419 95% 4,724 8% 8% 226% 130% 226% 130% 2.897 -167 95% 217 8% -1% 6,604 6,562 -242 96% 344 42% 350 -18 95% 12% 12%	nt change	124 18%	115 16%	ф	93%	28 4%	97%	1 -75%	3%	29 -6%	7 %87-
772 566 -206 73% 238 226% 130% -206 73% 278% 3,064 2,897 -167 95% 217 8% -1% 6,604 6,562 -242 96% 344 1% -5% -18 95% 145 9 0% -8% 12%	nt change	26,529 9%	25,110	-1,419	95%	4,724 8%	98%	102 52%	2%	4,826	3 48%
3,064 2,897 -167 95% 217 8% -1% 618 6,604 6,562 -242 96% 344 1% -5% -18 95% 145 9 0% -8% 12%	it change	772 226%	130%	-206	73%	238 278%	%86	4 %001	2%	242 272%	96-
6.604 6.562 -242 98% 344 1% -5% 42% 42% 368 350 -18 95% 145 9	aims it change	3,064 8%	2,897	-167	95%	217 61%	% 76	15 650%	%9	232	4 565%
368 350 -18 95% 145 0% -8% 12%	it change	6,604 1%	6,562	-242	% 96	344	98%	7 40%	2%	351 42%	47%
	ıt change	368 0%	350	-18	85%	145 12%	%66	2 -50%	1%	147	4 45%
43,963 -2,242 95% 13,969 6% 6	Islon - Total	46,205 9%	43,963	-2,242	95%	13,969 6%	93%	1,121	7%	15,090	20

Civil Backlog

1. 1. 2 d d d d d l. 1. 1. d d d d d 8 8 8 8



231 82%

12%

27 2600% 913 1%

88%

20**4** 62%

227%

6

Mass Tort percent change

86%

8,584

Special Civil Backlog

7,671 Non Mass Tort 7,805 7,717 -88 99% percent change 13% 13% 14% on the NoTE: Mass torts are defined as mass torts and/or centrally managed cases. 7,805

10

Caseload Profile Middlesex July 2009 - February 2010

February 2008 - February 2010

Middlesex

Criminal Backlog

Backlog By Month

	_										_				_		==				
Backlog/100	Mthly Filings	285	228	824 50%	291 40%	36	38 -55%	46 %79-	436	-3%	271	295	2,783	20%	6 `	13%	-56%	44%	234%	109	84
	Pending	1,446	2% 2%	46 48%	1,544	201	83 41%	118	14,626 3%	1,696	7,306	844 0%	4,780 8%	5,445	12 100%	4,378	203 497%	126 30%	726	137	20,409
log	percent	%99	44 %	%9 <i>L</i>	56%	%4	8%	7%	28%	7%	20%	21%	20%	2%	%0	2%	2%	2%	%	23%	21%
Backlog	number percent	809 51%	23 5%	35 59%	867 49%	15 -57%	7 -30%	8 %89-	4,131 13%	124 6%	1,456	181	2,370 24%	85 16%	0	75 10%	4 %001	3 50%	3 200%	31	4,262 12%
tory	percent	44 %	%99	24%	44%	%66	85%	93%	72%	93%	80%	79%	20%	%86	100%	%86 %	%86	%86	100%	77%	79%
Inventory	number	637 -6%	8 73	11 22%	677 *8~	186 20%	76 55%	5 \$	10,495 0%	1,572 13%	5,850	663 0%	2,410	5,360 2%	12 100%	4,303	199 522%	123 29%	723 41%	106	16,147 0%
nce	percent	%86	116%	%96	%66	%06	82%	%16	94%	88%	92%	97%	%86	%16	97%	100%	*04	104%	81%	108%	91%
Clearance	number	4	12	7	-33	-37	ল	φ	461	-250	-187	-16	φ	-814	7	φ	009-	98	-289	16	-1,296
	Resolved	2,091	87 50%	23	2,201	325 -5%	142	183	6,699	1,880	3,967	509	343	31,555	58 241%	20,243	392	2,108	8,754	226	38,805
	Added	2,135 5%	75 3%	24 -25%	2,234	362 25%	173 88%	189	7,160	2,130	4,154 -7%	525 29%	351 -72%	32,369 -5%	60 200%	20,252 -5%	992 477%	2,022	9,043 -13%	210 -23%	40,101 -6%
		Criminal percent change	Municipal Appeals percent change	Post-Convict. Relief	Criminal Division - Total percent change	General Equity - Total	Contested Foreclosure percent change	Equity (excluding foreclosure) percent change	Civil - Total percent change	Track 1 percent change	Track 2 percent change	Track 3 percent change	Track 4 percent change	Special Civil - Total percent change	Auto percent change	Contract percent change	Other percent change	Small Claims percent change	Tenancy percent change	Probate percent change	Civil Division - Total

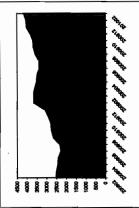
Civil Backlog

8 4 4 % % % % % 5 5 0 0

THE THE CHANGE SEAS SEAS TONE THE THE SEAS SEAS SEAS SEAS TONE

8 8 8 8 8 8 8 8 8 8 8 9 8 9

General Equity Backlog



Special Civil Backlog



3,020 123% 209 0%

10,002 4,624

18% 20% 2,313 24% 1,818 1% 20% 82% 2,311 4% 8,184 1% NOTE: Mass torts are defined as mass torts and/or centrally managed cases. 94% 94% 1 -17 6,433 283 -76% 6,877 Mass Tort percent change Non Mass Tort percent change

torsos. These movements may take the form of facial grimacing, constant protrusions of the jaw, tongue thrusting, chewing, Parkinson's like tremors and Tourette's syndrome.

WHY COORDINATION IS APPROPRIATE

Pursuant to R.4:38A and Directive #07-09, Revised Mass Tort Guidelines, centralized management in the Reglan/Metoclopramide litigation is warranted as:

- 1. It involves a large number of parties;
- 2. There are many claims with common, recurrent issues of law and fact that are associated with a single product;
- 3. There is geographical dispersement of parties;
- 4. There is a high degree of commonality of injury;
- 5. There is a value interdependence between different claims; and
- 6. There is a degree of remoteness between court and actual decision makers in the litigation;

There are approximately 30 cases already filed in the Superior Court involving 5 different plaintiff law firms. In addition to the 24 cases delineated in the annexed Exhibit A, which have been filed by the undersigned, cases have also been filed by the firms of D'Arcy, Johnson & Day, Ralph Pittle, Esq., Rheingold, Valet, Rheingold, Scholnick & McCartney, LLP, Matthews & Associates and Eisenberg, Rothweiler, Winkler, Eisenberg & Jeck, P.C. The counties in which these cases have been filed include Atlantic County, Essex County, Morris County, Ocean County and Somerset County. In addition to these 30 cases, there are approximately 25 – 30 cases which these same firms have yet to filed but which will be filed within the next 90 days. Likewise, based upon my involvement in the consolidated Reglan/Metoclopramide litigation pending in that state, I am aware of at least four to five other law firms who have voiced an intenion on filing approximately 30 – 40 cases of their own in the Superior Court of New Jersey.

While many of the plaintiffs in this litigation reside in the State of New Jersey, there are also residents of New York, Texas, Tennessee, Alabama, Virginia, Missouri, Florida, Pennsylvania, Maryland, Arizona, Vermont, Mississippi, Iowa and Ohio who have filed claims in our Superior Court. Likewise, there are numerous defendants, many who are common to all actions, who are either currently, or prior to the time of being purchased by a third party, domiciled in the State of New Jersey. They include Wyeth, LLC (currently claiming to me a New York business entity); Schwarz Pharma; Actavis Elizabeth, LLC; Pliva USA, Inc. Teva Pharmaceuticals, Barr Pharmaceuticals, Alpharma Pharmaceuticals and Northstar Pharmaceuticals (currently claiming to be a California business entity).

These cases also involve numerous common and recurring issues of law and fact. By example, all cases subject to this application for consolidation, upon information and belief, involve usage by plaintiffs of metoclopramide in excess of 90 days. In addition, all plaintiffs have been found to have developed movement disorders related to Tardive Dyskinesia. Furthermore, there are overlapping factual/liability issues relating to the

knowledge of the defendants prior to the FDA warning, the absence of warnings by brand manufacturers and generic manufacturers to the medical community and their patients of risks associated with long term metoclopramide use, the absence of warnings in the Physicians' Desk Reference for nearly 7 years prior to February 2009, misrepresentations by brand manufacturers as to the statistical frequency of movement disorders in users of metoclopramide, causation and the like.

The cases before the Court contain recurrent legal issues under the state's Product Liability Act which, under the January 8, 2010 decision of the United States Court of Appeals for the Fifth Circuit in a Demahy v Actavis, No. 08-31204, recognized the right of those suffering from tardive dyskinesia caused by long term metoclopramide use to file state-law based claims against manufacturers of metoclopramide, without concern for federal preemption. Likewise, unless set forth otherwise by opponents of this application for consolidation, defendants will raise the same controversial defenses as they have in other jurisdictions where similar cases have previously been filed.

1

Finally, as each of the subject cases are in virtually identical stages of litigation, involve similar injuries, identical claims under the Product liability Act, will likely involve common experts, identical core documents and common discovery of witnesses from around the country, Centralized Case Management would be the most effective method for optimizing judicial economy, litigation expense and ensuring uniform legal rulings.

WHY ATLANTIC CITY IS AN APPROPRIATE MASS TORT VENUE

Clearly, geographical location is a factor to be considered when selecting the most appropriate venue for centralized management and accordingly, plaintiffs request the vicinage of Atlantic County or alternately, Middlesex County, as the locale for the consolidation of these actions. While all of the available venues for centralization — Atlantic, Bergen, and Middlesex counties — are convenient to regional and international airports and are within a reasonable driving distance, only Atlantic County has a filed Reglan/Metoclopramide action which has been assigned to the Honorable Carol E. Higbee, P.J.CV.

Another important factor to consider is the existing civil and mass tort caseload in the vicinage. With the conclusion of the Vioxx and Bextra/Celebrex mass tort consolidations, there are currently 4 mass tort consolidations and one centralized management (Stryker Hip Implants) in Atlantic County. By contrast, there are 7 mass tort consolidations in Middlesex County and 4 in Bergen County (including the burgeoning Yaz/Yasmin litigation), with an additional 2 cases for centralized management (Prudential and Zelnorm). Moreover, based upon my experience as co-lead counsel In Re Depo-Provera Contraceptive Injection Litigation, Superior Court of New Jersey, Law Division, Bergen County, Case No. 276, plaintiffs have certain concerns regarding this vicinage being overwhelmed by another case involving centralized management. While the litigation ultimately concluded favorably for all parties in the litigation, at one point in June of 2008, the Court issued an order dismissing all cases on the grounds of forum non conveniens (which order was eventually stayed). The basis for the decision, as enunciated

by the Court was twofold. First, it was felt an insufficient nexus to the State of New Jersey existed. Second, and of equal significance based upon the Courts decision, was that it was stated that the case was too burdensome on the Court and local community. As the number of cases centralized in Bergen County has only increased since the resolution of the Depo-Provera cases, concern exists as to the issues which were raised by that particular Court in its decision.

Finally, having presided over the settlement of the Vioxx litigation, three Vioxx trials and three Accutane trials in the last few years, the Honorable Carol Higbee has extensive experience in managing, trying and settling complex product liability and mass tort actions. Accordingly, in light of all that set forth above, plaintiffs respectfully request that the Supreme Court designate the Reglan/Metoclopramide litigation for centralized management in the Atlantic County Superior Court.

Respectfully submitted,

Oshman & Mirisola, LLP

By: Theodore Oshman, Esq.

Cc: Hon. Eugene J. Codey, Jr. P.J.CV.

Michelle V. Perone, Esq., Chief Civil Court Programs

FILED REGLAN CASES:

Name	Defendants	Index/
		Docket
		Number
Arruda,	Wyeth;	NJ –Essex
Alexander	Schwarz;	County
I AICAMINGO	Actavis Eliz.;	
J	Actavis MA;	1
	Alparma	
Ashby,	Wyeth;	NJ-Morris
Louise	Schwarz;	County
}	Pliva	
	·	001275-10
Bolton,	Wyeth;	NJ-Morris
Beatrice	Schwarz;	County
}	Pliva	
		001485-10
Chatfield,	Wyeth;	NJ-Essex
Rita	Schwarz;	County
	Actavis;	
1	Purepac;	
(61)	Pliva	\
Clein,	Wyeth;	NJ- Essex
Lanette	Schwarz;	County
	Actavis;	000000 10
	Purepac; Pliva	002389-10
Candannia		NJ-
Condouris, Ruby Edna	Wyeth; Scwarz;	Atlantic
Kuby Eulia	Pliva;	County
	Teva;	County
	Barr	001940-10
		331340-10
Davis, Willie	Wyeth;	NJ- Essex
Nell	Schwarz;	County
	Actavis;	
	Purepac;	002967-10
	Pliva	
Davis, Billy	Wyeth;	NJ-Essex
Gene	Schwarz;	County
	Actavis;	
	Pliva;	003207-10
	Northstar;	4

,	Duramed	Γ
Harris,	Wyeth;	NJ-Essex
Patricia	Schwarz;	County
1 ati icia	Actavis	County
Trominon		NJ- Essex
Harrison,	Wyeth;	
Panfila	Schwarz;	County
	Actavis	
Hubert,	Wyeth;	NJ- Essex
Lucy Phyllis	Schwarz;	County
	Actavis;	
	Purepac	002355-10
Johnson,	Wyeth;	NJ- Essex
Nellie	Schwarz;	County
	Actavis;	
	Purepac	002391-10
Krystof,	Wyeth;	NJ- Essex
Mindy	Schwarz;	County
	Actavis;	
	Purepac	003210-10
Loening,	Wyeth;	NJ- Essex
Ernest	Schwarz;	County
	Actavis;	[
	Purepac;	002356-10
	Pliva_	
Long,	Wyeth;	NJ-Morris
Dennis	Schwarz; Pliva	County
		-
		001121-10
Lynn, Craig	Wyeth;	NJ-Morris
G.	Schwarz;	County
	Pliva	
		001463-10
McLaughlin,	Wyeth;	NJ- Essex
Christine	Schwarz; Pliva	County
		002354-10
Milton, Will	Wyeth;	NJ- Essex
	Schwarz;	County
	Actavis	
		002968-10

Mouradian,	Wyeth;	NJ- Essex
Patricia	Schwarz;	County
	Actavis	
		003208-10
Peno,	Wyeth;	NJ- Essex
Elizabeth	Schwarz;	County
	Actavis	
		002334-10
Rikard,	Wyyoth	NJ- Essex
David	Wyeth;	
David	Schwarz; Actavis;	County
	Pliva	002333-10
	I II va	002333-10
Spurlock,	Wyeth;	NJ-Morris
Wanda	Schwarz;	County
	Pliva	
		001285-10
Turner,	Wyeth;	NJ- Essex
Frances J.	Schwarz;	County
	Actavis;	
	Pliva	
Willeby,	Wyeth;	NJ- Essex
Kimberly	Schwarz;	County
	Actavis	
		002335-10