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IN RE PELVIC MESH/GYNECARE  
LITIGATION

SUPERIOR COURT OF NEW JERSEY  
APPELLATE DIVISION  
DOCKET NO. A-

Case No. 291  
Master Case No. 6341-10

On Motion for Leave to Appeal  
from an Order of the Superior  
Court of New Jersey

Sat Below:  
Hon. Carol E. Higbee, P.J. Cv.

CIVIL ACTION

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BRIEF OF AMICUS CURIAE NEW JERSEY LAWSUIT REFORM ALLIANCE IN  
SUPPORT OF DEFENDANTS/APPELLANTS' MOTION FOR LEAVE TO APPEAL

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## STATEMENT OF INTEREST

The New Jersey Lawsuit Reform Alliance ("NJLRA") submits this brief as an amicus curiae in support of Defendants/Appellants Ethicon, Inc. and Johnson & Johnson's motion for leave to appeal a May 26, 2011 order precluding Defendants from retaining treating physicians as experts.

NJLRA is an association of New Jersey's leading businesses, including major pharmaceutical manufacturers; individuals; not-for-profit groups; medical societies; and State business associations and professional organizations. It advocates in support of reforms that ensure New Jersey's civil justice system treats all parties fairly and discourages lawsuit abuse. NJLRA strives to ensure that New Jersey courts continue to serve New Jersey residents and New Jersey-centered disputes and do not become a magnet for lawsuits that have little or no connection to this State. NJLRA currently comprises 57 members, a list of which is attached as Addendum A.<sup>1</sup> As amicus, NJLRA would assist this Court by raising awareness of the impact that the trial court's order will have on other Mass Tort and centrally managed

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<sup>1</sup> Defendant/Appellee Johnson & Johnson is a member of NJLRA but has not contributed financially to the preparation of this amicus brief.

litigations, on the state's pharmaceutical industry as a whole, and on the economy more generally.

Interlocutory review is critical in this case because the trial court's ruling seriously impairs pharmaceutical companies' ability to defend themselves on core legal issues in thousands of cases by depriving them of critical expert testimony on those issues, an error that absent interlocutory review may persist for years and result in fatally flawed trials. The implementation of this order will increase the vulnerability of New Jersey's pharmaceutical and medical device companies to suit and the susceptibility of its courts to overwhelming litigation brought by out-of-state plaintiffs. For these reasons, and because the trial court's ruling is so contrary to basic fairness, NJLRA submits this amicus curiae brief respectfully urging the Court to grant interlocutory review in this case.

#### **PROCEDURAL HISTORY AND STATEMENT OF FACTS**

NJLRA adopts and incorporates by reference the Procedural History and Statement of Facts relating to this case as set forth in Defendants/Appellants' Brief of June 15, 2011.

#### **ARGUMENT**

The trial court barred Defendants/Appellants' Ethicon, Inc. and Johnson & Johnson from contacting as a potential expert any physician who has treated any plaintiff in the centrally managed litigation. Because of the critical role that physician expert

testimony plays in pharmaceutical litigation, and because pharmaceutical litigation is so prevalent in New Jersey, this issue has the potential to impact thousands of cases. Absent interlocutory review, the impact may go unchecked for years or even entirely, resulting in unjust outcomes that are unfairly skewed in favor of plaintiffs.

**I. Equal Access to Potential Expert Witnesses Is Critically Important in Pharmaceutical Litigation**

**A. Pharmaceutical Litigation in New Jersey**

New Jersey is the national center of pharmaceutical and medical device litigation. There are currently fourteen pharmaceutical and medical device litigations designated either as Mass Torts or for central management that are pending in New Jersey. In total they represent over 12,000 plaintiffs. Six of these litigations - Accutane, Fosamax, Levaquin, Pelvic Mesh, Reglan, and Stryker Implant - are pending in Atlantic County before Judge Higbee. See Mass Tort Information Center, New Jersey Courts, <http://www.judiciary.state.nj.us/mass-tort/index.htm> (last visited June 28, 2011).

The filing of claims in these litigations shows no signs of abating. The Pelvic Mesh cases, for example, were designated to be centrally managed less than a year ago and already boast nearly 250 plaintiffs. The Accutane Mass Tort, before the same trial court judge, has been pending for six years yet has

tripled in size in the past nine months. See Accutane Case List (June 11, 2011), <http://www.judiciary.state.nj.us/mass-tort/accutane/acccase-2011.pdf>.

This state is an epicenter for these cases because of the presence of so many pharmaceutical companies. Although various factors have eroded New Jersey's pharmaceutical industry, New Jersey has long been recognized as the "medicine chest of the world" and a "premier biotechnology center." Lt. Gov. Kim Guadagno, Sec'y of State, Opening Statement Before the N.J. Assem. Budget Comm. (Apr. 12, 2011), available at [http://www.njleg.state.nj.us/legislativepub/budget\\_2012/Testimony/DOS\\_Guadagno\\_testimony\\_ABU.pdf](http://www.njleg.state.nj.us/legislativepub/budget_2012/Testimony/DOS_Guadagno_testimony_ABU.pdf). In fact, New Jersey is home to fifteen of the world's twenty-five largest pharmaceutical companies. Id. Staggering numbers of lawsuits against pharmaceutical companies in New Jersey have followed from this fact. The American Tort Reform Association has repeatedly identified the New Jersey state court system as a "Judicial Hellhole" and particularly singled out the trial court below in Atlantic County, in which more lawsuits have been filed against pharmaceutical companies than anywhere else nationwide. See American Tort Reform Foundation, Judicial Hellholes 2010/2011 at 14-15 (2010), available at <http://www.judicialhellholes.org/wp-content/uploads/2010/12/JH2010.pdf>.

Even more striking than the sheer number of mass tort claims against pharmaceutical companies, however, is the number of out-of-state plaintiffs in those lawsuits. As of 2008, over 90% of Mass Tort cases involved out-of-state plaintiffs. New Jersey's favorable legal treatment of pharmaceutical lawsuits is, as that proportion clearly demonstrates, a major draw for out-of-state plaintiffs. A 2004 letter from the plaintiffs' law firm Weitz & Luxenberg lays out the advantages for plaintiffs of New Jersey law: "speed of resolution, the standards of admissibility of the scientific evidence, a ruling forbidding ex parte interviews with treating doctors, the potential avoidance of the learned intermediary defense due to NJ law on direct marketing and a very liberal discovery statute of limitations . . . ." Letter from Arthur Luxenberg, Weitz & Luxenberg (Dec. 29, 2004). This situation has persisted despite the Supreme Court's stated guidance that the public policy of New Jersey is "not to encourage tort recoveries by plaintiffs" and legislative initiatives, like the New Jersey Product Liability Act, in which the Legislature "carefully balanced the need to protect individuals against the need to protect [the pharmaceutical industry,] an industry with a significant relationship to our economy and public health." Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 626 (2007). One in four New Jersey employers have now considered relocating their

business outside of New Jersey for lawsuit-related reasons. New Jersey Lawsuit Reform Alliance, Attitudes Toward Litigation Climate In New Jersey 2 (2007), available at [http://www.cianj.org/uploads/hot\\_legislative\\_issues/NJLRA\\_Exec\\_Summary\\_12\\_19\\_07.pdf](http://www.cianj.org/uploads/hot_legislative_issues/NJLRA_Exec_Summary_12_19_07.pdf).

Despite the volume of these cases, there is very limited appellate guidance on the issues they regularly present. That is particularly true with respect to this issue - whether the fact that any Plaintiff in a Mass Tort visited a particular physician, however brief, rules that physician out as an expert for the defendant in every other plaintiff's case. This Court's ruling on the appropriate use of physician experts would therefore have an enormous impact.

**B. The Importance of Expert Testimony in Pharmaceutical and Medical Device Litigation**

Pharmaceutical and medical device litigation is uniquely expert-dependent. Not surprisingly, given the medical issues that are central in such cases, physicians are used as experts in nearly every pharmaceutical or medical device case. Literally every core issue in such cases can - or by law must - be supported by expert physician testimony.

For example, the law requires expert testimony on causation<sup>2</sup> covering both the general causation question of whether a medication is capable of causing the relevant injury and the specific causation question of whether the medication did in fact cause the injury. The law also recognizes the self-evident principle that a party's choice of the *right* expert can impact that party's success in litigation.<sup>3</sup> Yet, under the facts of this case, the leading experts in the field - the most qualified physicians who have the most relevant experience with the products and surgeries at issue - are also the ones most likely barred by the court's ruling. See Db8-11 (discussing the

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<sup>2</sup> See, e.g., Rutigliano v. Valley Bus. Forms, 929 F. Supp. 779, 783 (D.N.J. 1996) (noting that a plaintiff's case "requires expert testimony to satisfy her burden with respect to both general causation and specific causation"); DeLuca v. Merrell Dow Pharm., Inc., 911 F.2d 941, 958 (3d Cir 1990), on remand, 791 F. Supp. 1042 (D.N.J. 1992), aff'd, 6 F.3d 778 (3d Cir 1993); see also Lee v. Baxter Healthcare Corp., 721 F. Supp. 89, 96 (D. Md. 1989), aff'd, 898 F.2d 146 (4th Cir. 1990) (holding that "expert testimony is necessary since the cause of the injury claimed is a technical medical question beyond the common knowledge of laypersons").

<sup>3</sup> See, e.g., Rosenberg v. Tavorath, 352 N.J. Super. 385, 400-01 (App. Div. 2002) (noting that qualifications play a part in the jury's determination of the weight and value of expert testimony); see also Hedvat v. Merwin, 2008 WL 2796446, at \*7 (N.J. Super. Ct. App. Div. July 22, 2008) (per curiam) (affirming a jury's giving greater weight to a better-credentialed medical expert); Russo v. County of Monmouth, 2006 WL 2933880, at \*1-2 (N.J. Super. Ct. App. Div. Oct. 16, 2006) (affirming a judge's finding that a better-credentialed medical expert was more credible than a less-well-credentialed one).

limited pool of potential experts and the growing number of plaintiffs and barred physicians).

In addition to causation issues, physician expert testimony impacts every other core issue in pharmaceutical product-liability litigation. Physicians are often the best experts on the adequacy of a drug's or device's warning, and they are uniquely able to testify about the benefits of a drug or device.<sup>4</sup>

Any ruling limiting a defendant's ability to retain specific physicians as experts runs the risk of fundamentally impairing that defendant's defense. Here, however, the trial court's ruling upsets a fair litigation balance in three particularly broad ways.

First, the rule applies to every plaintiff in the coordinated litigation, regardless of whether they are residents of New Jersey or elsewhere. The rule would be inappropriate in many if not all of the states from which the plaintiffs originate, as many states permit the ex parte interviews of

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<sup>4</sup> See Prince v. Garruto, Galex & Cantor, 346 N.J. Super. 180, 190 n.2 (App. Div. 2001) (noting that "expert testimony must address . . . what a qualified and practicing physician would have understood" and querying whether a "human factors expert is qualified to render an opinion on how physicians would or should react to a labeling precaution"); see also Gobelny v. Baxter Healthcare Corp., No. 05-cv-4645, 2008 WL 2186417, at \*2 (D.N.J. May 23, 2008) ("[The] testimony of a physician would be necessary for the trier of fact to understand whether the warning [on a pharmaceutical product] was adequate.")

treating physicians by defendants without the "extreme cases" exception on which the trial court relied in crafting its order.<sup>5</sup> Da5-6. Because this mass of out-of-state plaintiffs brought suit in New Jersey, however, the trial court imposed an extremely broad preclusive rule that likely would not be justified under the laws of these plaintiffs' home states.

Second, the rule applies to preclude a physician who has treated only a single plaintiff from serving as an expert in the entire coordinated litigation. Thus, the rule means that every individual plaintiff precludes their treating physicians from serving as experts for *all other plaintiffs*. As in this case, such a rule has sweeping effects, precluding Defendants in each individual case from using over 1000 physicians as experts.

Three, the rule applies regardless of the plaintiff's actual relationship to the physician. The specific example Defendants presented below illustrates the problem with this sweep. Based on a single plaintiff visit to one doctor, which Defendants discovered from a careful medical records review after the plaintiff failed to disclose the visit, Defendants

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<sup>5</sup> See, e.g., Reutter v. Weber, 179 P.3d 977, 982-84 (Colo. 2007); Arons v. Jutkowitz, 880 N.E.2d 831 (N.Y. 2007); In re Collins, 286 S.W.3d 911 (Tex. 2009); see also In re Aredia & Zometa Prods. Liab. Litig., No. 3:06-MD-1760, 2008 WL 8576167, at \*2 (M.D. Tenn. Jan. 17, 2008) (noting that at least seventeen states have no bar on ex parte communications with treating physicians).

were forced to cease working with a physician with whom they had worked for two years. See Db5-6 (discussing the retention of Dr. Zycynski). In mass torts dealing with complex alleged drug or device side effects, it is very likely that plaintiffs will consult more than one doctor across multiple medical specialties. To hold that any incidental contact between a patient and a treating physician generates an everlasting fiduciary duty, prohibiting expert testimony against a separate plaintiff, is to wildly overstate the scope of any alleged duty of loyalty - a duty that has no support in New Jersey case law or medical ethics.

**C. The Impact of This Issue In Other Cases**

The trial court judge in this case is presently overseeing six pharmaceutical and medical device Mass Torts and centrally managed litigations, involving thousands of plaintiffs. Because she is a Mass Tort Judge, she is likely to receive further Mass Tort designations.

The trial court has already applied a similar order in another Mass Tort, the Accutane Mass Tort. The Accutane order provides that "Defendants and their attorneys may not communicate with any physician-expert who has or is treating a patient involved in this litigation." Order, In re Accutane Litig., No. 271 (N.J. Super. Ct. Law Div. Mar. 6, 2009). The court orally indicated that the defendants could, through a

burdensome series of motions, ask for this order to be reconsidered on a case-by-case basis.<sup>6</sup> See Mar. 4, 2009 CMC Tr., In re Accutane Litig., at 51:20-52:4. Upon a request for reconsideration in the case of a particular treating physician, the court determined that the defendants may not use that physician as an expert without first notifying the relevant plaintiff of their intent and providing that plaintiff the opportunity to object. Letter to Russell Hewit, In re Accutane Litig., No. 271 (N.J. Super. Ct. Law Div. May 25, 2011).

The Accutane Mass Tort now involves approximately 3500 cases, meaning that the court's ruling can reliably be assumed to exclude thousands or even tens of thousands of physicians as potential experts. Every plaintiff in that Mass Tort was prescribed Accutane by a physician, usually by a dermatologist. And each plaintiff has received treatment for his or her inflammatory bowel disease from at least one gastroenterologist - and often many more than one. Indeed, given the relatively rare nature of inflammatory bowel disease and the small number of research centers focusing on this disease, a great majority of the leading physicians would be

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<sup>6</sup> It appears that the Court is not granting these requests. Moreover, even the burden of having to disclose a potential expert is serious: it risks losing the expert altogether, and it requires the divulgence of work product that would otherwise be protected.

barred from serving as an expert for the defense because they and their centers would likely have treated one of the 3,500 current plaintiffs. The court's order effectively eliminates all of these physicians as potential experts. Thus, the Accutane defendants are deprived of thousands of gastroenterologists as potential experts on general and specific causation. They are similarly deprived of thousands of dermatologists as potential labeling experts, standard of care experts, or experts on the benefits of Accutane.

The Accutane plaintiffs themselves have suggested that there are only 10,000 gastroenterologists in the country and 16,000 dermatologists. Mar. 4, 2009 CMC Tr., In re Accutane Litig., at 42:6-8. Of course, there are many fewer specialists in inflammatory bowel disease or dermatology with the expertise and willingness to testify in these cases. That the defendants are barred from contacting a number of physicians on the same magnitude as the number of relevant specialists *in the entire country* is indicative of the profound impact this order has.

Absent this Court's guidance, the trial court will continue to apply this rule, and other New Jersey trial courts may follow suit. That gives this issue tremendous import.

## **II. Ensuring Fair Access to Potential Experts Is Most Appropriately Reviewed on Interlocutory Appeal**

This Court is given the discretion to permit an interlocutory appeal "in the interest of justice." R. 2:2-4. The exercise of that discretion "turns on whether leave to appeal will 'prevent the court and the parties from embarking on an improper or unnecessary course of litigation.'" Grow Co. v. Chokshi, 403 N.J. Super. 443, 461 (App. Div. 2008) (quoting Brundage v. Estate of Carambio, 195 N.J. 575, 599 (2008)). Moreover, this Court more regularly grants permission to appeal when the order will "resolve a fundamental procedural issue." Brundage, 195 N.J. at 599. Interlocutory appeal is therefore particularly appropriate when the delay from waiting until final judgment may render years worth of litigation improper based on a fundamental procedural error. This case presents such a situation.

Absent interlocutory review, Defendants' only meaningful recourse to appellate review of this issue will be if they lose a trial. And trials in these cases may be years away. For example, an earlier Mass Tort before the same Judge - the Accutane Mass Tort - had been designated for three years before the first trial. The appellate review of that verdict took another two years. This Mass Tort is less than a year old, suggesting that it may be years before a case is appealed

following a plaintiff verdict. Defendants' entire defense across these cases may be permanently impaired by not being able to secure the experts of their choosing during this time period. And if this Court were then to find in Defendants' favor, years of effort and expense by both the litigants and the courts would be nullified.

On appeal, moreover, Defendants may not ever be able to raise successfully the issue of this order because of the difficulty of demonstrating prejudice. As Defendants will hopefully secure some expert to testify on their behalf, the very real and serious injury done to them by the order may not be demonstrable; that demonstration would require comparing the hypothetical performance of and assistance rendered by Defendants' expert of choice to the actual trial outcomes, an impossible task. The interest of justice require that this Court not place the trial court's improper order beyond review.

#### **CONCLUSION**

For all the foregoing reasons, and for the reasons set forth in Defendants'/Appellants' papers, the motion for leave to file an interlocutory appeal of the trial court's order precluding Defendants from retaining treating physicians as experts should be granted, and the court's order should be reversed.

**ADDENDUM A**

Members of the New Jersey Lawsuit Reform Alliance include:

The American College of Emergency Physicians, NJ Chapter  
The American Insurance Association  
Bayer Healthcare  
Becton, Dickinson and Company  
BIO NJ  
Bristol-MYERS Squibb  
The Chemistry Council of New Jersey  
CNA Insurance  
The Commerce and Industry Association of New Jersey  
Deloitte LLP  
DuPont  
Eisai  
Eli Lilly  
Ernst & Young  
The Gateway Regional Chamber of Commerce  
General Electric, Inc.  
Georgia Pacific, Inc.  
GlaxoSmithKline  
The Healthcare Association of New Jersey  
The Healthcare Institute of NJ  
Johnson & Johnson  
KPMG  
McCarter & English LLP  
The Medical Society of NJ  
Merck & Company  
MetLife  
National Federation of Independent Business  
NJ Academy of Family Physicians  
NJ Alliance for Action  
NJ Association of Osteopathic Physicians  
NJ Bankers Association  
NJ Business and Industry Association  
NJ Coalition of Automotive Retailers  
NJ Dental Association  
NJ Food Council  
NJ Fuel Merchants Association  
NJ Gasoline/C-Store/Automotive Association  
NJ Hospital Association  
NJ Licensed Beverage Association  
NJ Manufacturers Insurance Company  
NJ Obstetrical and Gynecological Society

NJ Petroleum Council  
NJ Restaurant Association  
NJ Society of Certified Public Accountants  
NJ Society of Oral and Maxillofacial Surgeons  
NJ State Chamber of Commerce  
NJ State Nurses Association  
NJ Technology Council  
Novo-Nordisk  
Pfizer Inc.  
PhRMA  
PricewaterhouseCoopers LLP  
Roche  
Somerset County Business Partnership  
Suburban Propane  
Sunovian Pharmaceuticals, Inc.  
WalMart, Inc.