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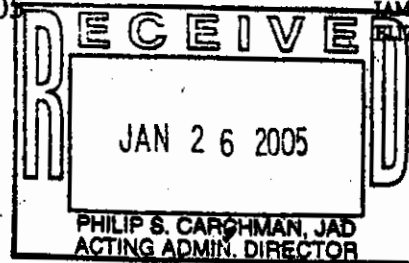
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January 25, 2005



**BY FEDERAL EXPRESS**

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

***Re: Request for Designation of a Case as a Mass Tort***

Dear Judge Carchman:

Pursuant to Rule 4:38A and the Mass Tort Guidelines (Directive #11-03), the undersigned hereby applies to designate all litigation, pending and subsequently filed, alleging damage arising from the ingestion of the acne drug Accutane as a mass tort to receive centralized case management. The Accutane litigation meets all of the criteria set forth in the Mass Tort Guidelines and will be most fairly and efficiently resolved through mass tort centralization.

The Accutane litigation involves a large number of parties. There are currently approximately 68 Accutane cases filed in New Jersey. Approximately 62 are pending before the Honorable Higbee in Atlantic County; another six are pending before the Honorable Schott in Essex County. In addition, plaintiffs anticipate that a substantial number of additional cases will be filed, as news of the Accutane litigation becomes more widespread.

All Accutane litigation involves similar claims stemming from injuries sustained as a result of ingesting Accutane. The claims share common issues of law and fact, including whether Accutane causes the injuries alleged by plaintiffs, whether defendant adequately warned of the risks of ingesting Accutane, and whether defendant violated the New Jersey Products Liability Act in its marketing and sale of Accutane.

There is geographic dispersment of the parties involved in this litigation. While Hoffman-La Roche, Inc., the manufacturer of Accutane, is located in New Jersey, users around the country were injured by taking Accutane. Thus the plaintiffs in these cases are located in geographically disperse areas, and will benefit from consolidated case management. It should be noted that, indicative of the common issues pervading all Accutane cases, all Accutane cases that were pending in Federal Court have been consolidated before the Honorable James S. Moody, Jr.

in the United States District Court for the Middle District of Florida pursuant to an order of the Judicial Panel of Multidistrict Litigation.

The injuries involve systemic and neurological/psychiatric conditions that are all recognized as side-effects reported with the use of Accutane. The injuries claimed by the plaintiffs in these cases are highly similar, and are accordingly able to be addressed in consolidated proceedings.

The strengths and weaknesses of these cases will likely only be determined by the trial of some initial Accutane cases, whether in this jurisdiction or in others. Once similar cases either succeed or fail, both sides will be able to more accurately determine the value of these cases. The possibility of a global settlement following the establishment of those values is greatly increased by the consolidation of these cases as a mass tort.

There are a number of decision-makers in this litigation. While plaintiffs cannot speak to the complete decision-making process of defendant, it is reasonable to conclude that numerous levels of local, national, and house counsel will be involved in guiding defendant's decisions during the Accutane litigation.

Centralization will facilitate the efficient management of the Accutane cases. There will be no unreasonable delay because these cases are still in their early stages. Approximately 62 cases are currently before Judge Higbee, who is already familiar with this litigation. If all of the remaining and subsequently-filed Accutane cases are consolidated before Judge Higbee, those cases will benefit from assignment to a judge who already knows the background of the case and where discovery and case management procedures are already in place.

Consolidation also eliminates the risk of duplicative arguments and inconsistent rulings being made in different New Jersey courts. The assigned court will be the only court hearing arguments on scientific and evidentiary issues, and will consequently be the only court in the state to rule on those issues. This also places less of a burden on New Jersey's courts, since each motion will only need to be heard and decided once, instead of numerous times by different judges. Similarly, consolidation has the added benefit of streamlining the discovery process by allowing defendant to produce its relevant documents and witnesses once, as opposed to numerous times in the separate cases.

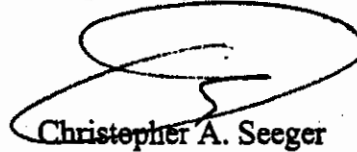
Plaintiffs represented by the undersigned counsel respectfully request that the Accutane mass tort be consolidated in Atlantic County before Judge Higbee. As was noted previously, over 62 cases are currently before Judge Higbee. Judge Higbee is therefore already familiar with this litigation and is in the best position to efficiently manage a mass tort involving Accutane. The assignment of Judge Higbee will best effectuate the principles of fairness and efficiency that underlie the Mass Tort Guidelines.

For the foregoing reasons, plaintiffs, through their undersigned counsel, hereby respectfully request that all litigation, pending and subsequently filed, alleging damage arising

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from the ingestion of the acne drug Accutane, be consolidated as a mass tort to receive centralized case management.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "Christopher A. Seeger", enclosed within a large, hand-drawn oval scribble.

cc: Diane E. Lifton, Esq. (via facsimile)  
Michelle V. Perone, Esq. (via facsimile)  
All counsel (via legal newspapers and the Judiciary's website)

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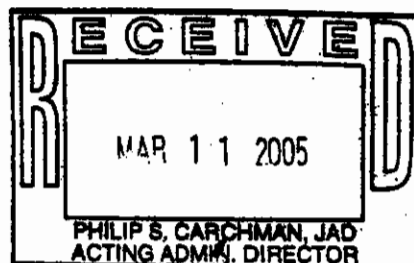
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March 10, 2005



## VIA FEDERAL EXPRESS

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

Re: Opposition to Mass Tort Designation of Cases Involving Accutane

Dear Judge Carchman:

### I. INTRODUCTION

Gibbons Del Deo Dolan Griffinger & Vecchione, P.C. represents Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Roche" or "Defendants") in New Jersey product liability cases alleging injury from the ingestion of the prescription drug Accutane. Roche respectfully submits this letter brief in opposition to the January 25, 2005 application by the Accutane Litigation Group<sup>1</sup> for mass tort designation of New Jersey cases involving Accutane. The application should be denied because, *inter alia*, (1) centralization will delay trial-ready cases that are ripe for resolution; (2) discovery in this litigation is advanced, and the cases are presently

<sup>1</sup> In addition to the Seeger Weiss firm as New Jersey counsel, according to correspondence received from the law firm of Michael Hook, The Accutane Litigation Group consists of Krupnick Campbell; Paul Smith and Associates; Beggs & Lane; Hook, Bolton, Kirkland & McGhee; Levin, Papantonio; Thomas, Mitchell, Echsner & Proctor; Campbell, Waller & Poer; and the McNulty firm.

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assigned by type of injury to just two judges<sup>2</sup>, rendering further centralization and "mass tort" designation unnecessary; and (3) Accutane cases filed in New Jersey, which involve two general categories of alleged adverse drug events ("ADEs") (psychiatric<sup>3</sup> and gastrointestinal conditions (virtually all inflammatory bowel disease (IBD)<sup>4</sup> cases)) as well as other miscellaneous ADEs, involve distinct legal and factual issues and, thus, are not amenable to mass tort treatment.

## II. ACCUTANE

In 1982, the Food and Drug Administration ("FDA") approved Accutane (isotretinoin), a prescription drug, for the treatment of severe recalcitrant nodular acne ("SRNA"), a disfiguring disease that, left untreated, can result in permanent scarring. Accutane is the only drug that has the potential to clear SRNA permanently after a single course of treatment, and has been prescribed to more than 6 million patients in the United States.

Unlike the majority of pharmaceuticals that become subject to mass tort treatment after being taken off the market, Accutane remains on the market with the full support of the FDA. See, e.g., *The Power of Accutane, The Benefits and Risks of a Breakthrough Acne Drug*, FDA CONSUMER MAGAZINE, March-April 2001 ("Considered the biggest breakthrough in acne drug

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<sup>2</sup> As set forth in more detail, *infra*, The Honorable Francine A. Schott manages the psychiatric cases in Essex County. The Honorable Carol E. Higbee manages the IBD and other cases in Atlantic County.

<sup>3</sup> The ADEs alleged in the "psychiatric" cases include, *inter alia*, depression, psychosis, suicide ideation, attempted suicide and suicide.

<sup>4</sup> The ADEs alleged in the IBD cases include, *inter alia*, irritable bowel syndrome, Crohn's disease and colitis.

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treatment over the last 20 years, Accutane is the only drug that has the potential to clear severe acne permanently after one course of treatment.”) (available at:

[http://www.fda.gov/fdac/features/2001/201\\_acne.html](http://www.fda.gov/fdac/features/2001/201_acne.html)).

### III. HISTORY OF ACCUTANE LITIGATION IN NEW JERSEY AND AROUND THE COUNTRY

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Each of the plaintiffs in New Jersey claim that they suffered adverse events from ingesting Accutane. These lawsuits assert products liability claims against Roche that raise three legal questions: (1) general causation: whether Accutane can cause the injuries of which plaintiffs complain; (2) specific causation: whether Accutane actually caused the injuries the plaintiffs experienced; and (3) adequacy of the warning: whether, in light of the information available, Roche’s warnings to physicians for each ADE were adequate.<sup>5</sup>

The Accutane cases already are consolidated by type of case, with the virtually trial ready psychiatric cases pending before The Honorable Francine A. Schott in Essex County, and the IBD cases pending before The Honorable Carol E. Higbee in Atlantic County. The facts relevant to the legal questions at issue in these cases vary completely depending upon the condition alleged and on each plaintiff’s medical history. In addition, only a single plaintiff in the IBD cases before Judge Higbee and a single plaintiff in the psychiatric cases before Judge Schott resides in New Jersey. The remaining plaintiffs are out-of-state residents. Thus, applicable state

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<sup>5</sup> Under the “learned intermediary” doctrine, a pharmaceutical manufacturer satisfies its duty to warn by adequately warning the prescribing physician. See *Niemiera by Niemiera v. Schneider*, 114 N.J. 550, 559, 555 A.2d 1112, 1117 (1989).

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laws may vary significantly. Moreover, there will be distinct issues regarding not only labeling, but scientific causation issues, depending on the adverse events alleged by each plaintiff.

A. The Small Handful of Psychiatric Cases, Pending Only in Essex County, are Mature and Ready For Trial

All of the Accutane cases pending in the state of New Jersey involving alleged psychiatric effects -- and there are only a few -- are pending before Judge Schott.<sup>6</sup> Discovery has been handled in these cases by Judge Schott, and Judges Mary C. Jacobson and Edith K. Payne before her, in a coordinated fashion and is now largely complete. Thus, but for expert discovery and related motion practice, and in some instances depositions of case specific witnesses, these cases are trial ready or nearly so.

The earliest Accutane case presently pursued by The Accutane Litigation Group, *Palazzolo et al. v. Hoffmann-La Roche Inc. et al.*, ESX-L-5498-99, which involves claims that Accutane caused depression, attempted suicide, suicide ideation and suicide, was filed in Essex County in 1999, following revisions to the Accutane psychiatric warnings in February 1998. Until recently, *Palazzolo*, which was consolidated with four other cases, involved numerous plaintiffs, including plaintiffs who had ingested Accutane, their parents, and one grandparent. At a hearing on January 18, 2005, after nearly six years of discovery, Judge Schott advised counsel that *Palazzolo*, reduced by voluntary dismissals and summary judgment to just three (3)

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<sup>6</sup> Roche was served yesterday, March 9, 2005, in two new cases brought by an Illinois plaintiff and a Texas plaintiff in Atlantic County. Although the complaints in these cases offer very little detail about the plaintiffs' exact use of the product, injuries alleged, etc., it appears that they allege psychiatric injury. If so, Roche will seek to transfer these cases to Judge Schott in Essex County where the psychiatric cases are being managed.

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plaintiffs, Virginia Palazzolo, Eleanor Wright<sup>7</sup> and Amanda Callais, would be set for trial in May or June 2005. The court instructed counsel to bring their calendars to the next case management conference to schedule expert disclosures, motions and a May or June trial date. (See Excerpts of the Transcript of January 18, 2005 Proceedings at p. 52, Ex. A.) (“... in all likelihood in terms of trial dates we’re probably looking at either end of May, beginning of June ...”). One week later, the Accutane Litigation Group filed the instant application seeking to take *Palazzolo* and the only other psychiatric cases pending in the State of New Jersey (*Casey Balsham v. Hoffmann-La Roche Inc. et al.*, ESX-L-5808-01, *Donna Cheek v. Hoffmann-La Roche Inc. et al.*, ESX-L-7983-01, *Nicholas E. Pampell v. Hoffmann-La Roche Inc. et al.*, ESX-L-5144-02, *Susan Turney and Martin Turney et al. v. Hoffmann-La Roche Inc. et al.*, ESX-L-5143-02), away from Judge Schott, and, presumably, any chance of an appropriately prompt trial date.

Notably, in addition to the expected trial settings, recent rulings by Judge Schott have effectively led to the voluntary dismissal of two other Essex County psychiatric cases, *Douglas Hoefs v. Hoffmann-La Roche Inc. et al.*, ESX-L-8357-01 (voluntary dismissal following ruling on Defendants’ motion to compel Plaintiff to appear in New Jersey for deposition) and *Jessica Boers v. Hoffmann-La Roche Inc. et al.*, ESX-L-5498-99 (voluntary dismissal following ruling on Plaintiff’s parents’ motion for protective order regarding their mental health histories). The previously presiding Judge, The Honorable Mary C. Jacobson, granted summary judgment in *Robert Rowe v. Hoffmann-La Roche Inc. et al.*, ESX-L-2971-01 (finding, *inter alia*, that

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<sup>7</sup>Virginia Palazzolo is the mother, and Eleanor Wright the grandmother, of Christopher Tremain, who is alleged to have ingested Accutane and to have committed suicide.



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applicable Michigan law precluded Plaintiff's product liability claims for psychiatric injuries)<sup>8</sup>.  
Thus, only five psychiatric cases remain in New Jersey.

Ultimately, Defendants expect to prevail in the psychiatric cases. In fact, Plaintiffs have never been able to show, in any case that has been brought, that Accutane causes psychiatric effects: Roche prevailed in the only psychiatric case to reach a jury, *see Gray v. Hoffman-La Roche, Inc.*, 82 Fed. Appx. 639 (10th Cir. 2003) (unpublished); and, in another case, the plaintiffs' lead expert on whether Accutane can cause psychiatric effects was disqualified because he could not identify any "epidemiological or clinical studies" which establish a causal link and instead relied only on "isolated, anecdotal case reports, many of which were from a nineteenth century Arctic explorer's journal," *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672, 679-80 (W.D. Tex. 2002). Additionally, no causal link has ever been established in the medical/psychiatric literature between Accutane and psychiatric conditions, as the FDA has repeatedly recognized.

Indeed, still other psychiatric cases around the country have been resolved without judgment against Roche: one case, as noted, by verdict for Roche; three cases by summary judgment for Roche; twelve cases by dismissal (seven with prejudice); and five cases by settlements of less than \$50,000.

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<sup>8</sup> Judge Schott also dismissed with prejudice *Boes v. Hoffmann-La Roche Inc. et al.*, ESX-L-9069-03 (finding, *inter alia*, that Michigan law applied to bar the Michigan plaintiffs' claims in their entirety). Judge Jacobson dismissed with prejudice *Banner v. Hoffmann-La Roche Inc. et al.*, ESX-L-547-03 (finding, *inter alia*, Accutane warnings regarding birth defects to be adequate as a matter of law). The *Boes*, *Rowe* and *Banner* dismissals presently are on appeal.

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B. Inflammatory Bowel Disease Lawsuits

All of the Accutane cases involving IBD claims are pending in Atlantic County before Judge Higbee. In late 2003, The Accutane Litigation Group filed their first case in New Jersey to allege gastrointestinal effects (IBD) in Atlantic County, *McCarrell v. Hoffmann-La Roche Inc. et al.*, ATL-L-1951-03. Within a short period of time thereafter, Plaintiffs' counsel filed *Beard, Reynolds, Fields and Savary*<sup>9</sup> and, following consolidation of these cases by Judge Higbee, discovery has proceeded promptly. Plaintiffs' depositions in these cases will be taken in March, 2005, and discovery is to be completed by December 7, 2005. None of these Plaintiffs reside in New Jersey.

In October 2004, The Accutane Litigation Group began filing additional IBD cases in Atlantic County. Only one of the plaintiffs in these cases resides in New Jersey. The Accutane Litigation Group has continued to file new cases in Atlantic County on a rolling basis, notwithstanding the fact that a federal multi-district litigation was established on November 1, 2004. All of these cases have been assigned to Judge Higbee for case management. In the past few months alone, Judge Higbee has actively case managed these files, among other things, entering orders adopting a Plaintiffs' Fact Sheet agreed upon by the parties, setting a schedule for Plaintiffs' service of responses, and setting a schedule for Defendants to update their prior production of certain categories of Accutane IBD documents and information. (See Case

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<sup>9</sup> *Beard v. Hoffmann-La Roche Inc. et al.*, ATL-L-2645-03, *Reynolds v. Hoffmann-La Roche Inc. et al.*, ATL-L-2644-03, *Fields v. Hoffmann-La Roche Inc. et al.*, ESX-L- 10325-03, *Savary v. Hoffmann-La Roche Inc. et al.*, ATL-L-341-03.

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Management Orders ("CMOs") 1, 2 and 3 and Fact Sheet Order, attached as Exs. B, C, D, and E.) As illustrated by the Court's CMOs, little in terms of new discovery from Defendants remains, and it will be completed by April 1, 2005.

In the first instance, the statute of limitations may have run on many of these cases. Moreover, Defendants expect to prevail both with respect to liability (the adequacy of the IBD warnings) and causation. In *Mikell v. Hoffman-La Roche, Inc.*, 649 So. 2d 75, 80 (La. Ct. App. 1994), an IBD case filed well before the current collection of cases brought by The Accutane Litigation Group, the Court granted summary judgment in Roche's favor, finding the Accutane IBD warning to be adequate as a matter of law. In addition, no plaintiff has established that Accutane causes IBD, nor does the medical literature contain any known means by which Accutane causes IBD.

C. Other Conditions

Roche also has been sued by plaintiffs claiming that Accutane caused birth defects. Roche's extensive warnings of the risks of taking Accutane while pregnant have repeatedly been held to be adequate as a matter of law. As set forth above, Judges Jacobson and Schott in Essex County dismissed *Banner* and *Boes*, respectively. Thus, no such cases remain pending in Essex County. One new pregnancy case has been filed in Atlantic County, *Clark v. Hoffmann-La Roche Inc. et al.*, No. ATL-L-67-05, as well as one alleging birth defects as a result of the father's alleged ingestion of Accutane over twenty years ago. *Crosland v. Hoffmann-La Roche, Inc. et al.*, No. ATL-L-3998-04. Both *Clark* and *Crosland* have been assigned to Judge Higbee.

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Roche expects they will be dismissed before discovery, but, regardless, the factual and legal issues differ significantly from the other cases.

The Accutane Litigation Group also has filed in Atlantic County cases alleging kidney, vision, bone disease, lupus and musculoskeletal claims. Each of these cases has been assigned to Judge Higbee, and each involves distinct issues of whether Accutane is capable of causing such conditions, whether Accutane caused these Plaintiffs' conditions, and whether the package insert contained adequate warnings regarding these specific conditions.

D. The MDL Proceeding is Limited in Scope

On May 27, 2004, The Accutane Litigation Group filed a motion on behalf of several Plaintiffs for Transfer, Coordination and Consolidation of Accutane cases pursuant to 28 U.S.C. § 1407. Defendants opposed the motion on numerous grounds. Nevertheless, on November 1, 2004, the Judicial Panel on Multi-District Litigation (MDL) granted the motion and created MDL 1626, with cases to be transferred to The Honorable James M. Moody in the Middle District of Florida. As of November 1, 2004, the MDL consisted of only two psychiatric cases and five gastrointestinal cases. Since November 1, 2004, very few additional cases have been filed in or transferred to the MDL, and, in fact, a number of the Plaintiffs in the MDL have just dismissed their claims voluntarily. Notwithstanding the creation of an MDL, the Accutane Litigation Group has continued to file new gastrointestinal cases in Atlantic County. At a recent court conference in *McCarrell*, Judge Higbee advised that she had been contacted by Judge Moody and, notwithstanding the absence of an official mass tort designation, advised counsel of

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her intent to coordinate the New Jersey cases pending before her with the MDL proceedings.

(See Excerpts of Transcript of February 9, 2005 Proceedings at p. 88, Ex. F.) Moreover, although Defendants view there to be few, if any, open issues regarding their discovery responses in either the MDL psychiatric cases or in the Essex County psychiatric cases, Defendants will continue to coordinate discovery in these two sets of cases.

IV. MASS TORT DESIGNATION OF ACCUTANE CASES IS NOT WARRANTED BECAUSE ACCUTANE IS A MATURE, LIMITED LITIGATION INVOLVING MULTIPLE, DISTINCT LEGAL ISSUES

A. Centralization Will Delay Trial Ready Cases That Are Ripe for Resolution

It is no coincidence that The Accutane Litigation Group made its application for mass tort designation of all Accutane cases one week after Judge Schott announced that one or more of the psychiatric cases pending before her cases would be assigned May or June, 2005 trial dates.

(January 18, 2005 Tr., Ex. A, at 52.) Judge Schott has scheduled a case management conference for March 21, 2005 at 9:00 a.m., at which time expert disclosure and trial dates will be set.

Plaintiffs contend they have evidence of liability and an expert on causation (Feb. 18, 2005 Tr., Ex. G, at pp. 56-57); thus, no impediments to trial exist.

Simply stated, the age and extensive history of the Essex County psychiatric cases render most of them nearly trial ready. By contrast, most of the IBD cases are recent filings. Transfer and consolidation of psychiatric cases with the IBD cases in Atlantic will substantially delay their resolution, perhaps delaying trial dates for a year or more. There is no conceivable benefit

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for delaying resolution of these cases, none of which depend upon discovery or rulings in the IBD cases. Moreover, neither a verdict for a Plaintiff in a psychiatric case, an unlikely scenario in any event, nor a summary judgment decision in a psychiatric case will inform or impact resolution of the IBD cases. Accordingly, this factor does not favor mass tort designation.

Similarly, discovery in the first five IBD cases will be completed within a matter of months. It could take many months for the newly filed cases, still in their infancy with no discovery produced by plaintiffs, to progress. There is no reason to delay prompt motion practice and trial settings in *McCarrell*, *Beard*, *Reynolds*, *Fields* and *Savary*, an inevitable result if all Accutane cases are designated as a mass tort.

B. Discovery from Defendants in the New Jersey Accutane Cases is Advanced, and Case Management is in Place, Rendering Further Centralization and Mass Tort Designation Unnecessary.

Discovery in the psychiatric cases is essentially completed. Although much case-specific discovery remains in the IBD cases, discovery from Defendants is advanced. Moreover, the parties and courts already are in agreement that neither document discovery nor corporate depositions shall be duplicated. Indeed, existing protective orders in *Palazzolo* and elsewhere expressly permit use of discovery from Roche by Plaintiffs' counsel signatories in other cases. (See *Palazzolo* Protective Order, Ex. H.) Accordingly, the principal goals of coordinated proceedings will not be furthered by an official "mass tort" designation.

As set forth above, the psychiatric cases have been pending in Essex County for six years and are nearly trial ready. Although the Accutane Litigation Group has made amorphous,

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unsupported claims that there might be open areas of discovery, that claim has essentially been rejected (February 18, 2005 *Palazzolo Tr.*, Ex. G, at p.64, directing Plaintiffs to refrain from filing motions to compel.) Any such claim must be taken for what it is - - a further attempt to delay trial.

By contrast, in the IBD cases, the first five IBD cases, *McCarrell, Beard, Reynolds, Fields* and *Savary*<sup>10</sup>, are only just entering into the deposition phase, with plaintiffs, physicians and non-parties either scheduled or to be scheduled in the coming months. No discovery has been received from the many remaining Atlantic County plaintiffs, with fact sheets to be served on a rolling basis in the coming months until all are completed. (See Ex. E, Fact Sheet Order.) Thereafter, statute of limitations dismissals are expected. Finally, to the extent necessary, Judge Higbee already is coordinating with the MDL.

In light of the advanced, trial ready status of the psychiatric cases, the impending discovery deadlines in the first filed IBD cases, the contrasting level of discovery in the IBD cases, and the amount of coordination and cooperation already taking place before just two judges, mass tort designation, and further consolidation, is unnecessary.

C. The Psychiatric, Gastrointestinal and Other Cases Involve Distinct Legal and Factual Issues

Each of the Plaintiffs in these pending New Jersey cases allege very specific injuries as a result of their ingestion of Accutane. Because their principal claims are that Roche failed to

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<sup>10</sup> Savary's deposition has been delayed because Plaintiffs' counsel has reported that Savary was in a car accident.

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adequately warn of the risk of each of their specific injuries, each type of case will, necessarily, involve unique legal issues. In the IBD cases, the Court may assess whether, as a matter of law, the Accutane package insert, which has contained information regarding gastrointestinal symptoms for more than two decades, provided adequate information to Plaintiffs' physicians. By contrast, in the psychiatric cases, the central issue is whether the Accutane package insert, which contained information regarding depression for over 20 years, adequately warned the prescribing physicians regarding potential psychiatric adverse effects. Similarly disparate issues will arise in connection with pregnancy, kidney, vision, bone disease, lupus and musculoskeletal claims, all of which are pending in Atlantic County, and involve completely different parts of the Accutane package insert. Thus, there is no commonality with respect to the liability claims among these various conditions.

Moreover, each case necessarily will involve disparate questions of whether Accutane is capable of causing the alleged injury (general causation) as well as individual determinations of specific medical causation. There is no commonality of issues either with respect to the science relating to general causation for each alleged effect, or with whether, in a particular individual, alternate explanations may exist for the plaintiffs' claimed conditions (specific causation). Indeed, many of these plaintiffs will have lengthy medical histories requiring individual treatment. Thus, success or failure in a given case will have little or no influence on the result in other cases. As distinct issues exist at all levels, this factor plainly does not favor mass tort designation.



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Nor is there concern regarding inconsistency on substantive rulings. Courts in New Jersey and around the country have agreed that the IBD, pregnancy and other Accutane warnings are adequate as a matter of law. The current assignment of these cases to only two judges makes inconsistent rulings highly unlikely. There is no reason to expect otherwise absent an official "mass tort" designation.

D. The Remaining Factors Do Not Favor Mass Tort Designation

The remaining factors set forth in Directive #11-03, issued pursuant to R. 4:38A, also do not favor a "mass tort" designation. First, the majority of the IBD cases likely are time-barred. The Accutane Litigation Group's reliance on their expected number of filings of additional cases in Atlantic County therefore is a red herring. Defendants expect that, as with the initial five IBD Plaintiffs in Atlantic County, and with cases around the country, the overwhelming majority of these cases will be time barred, and, ultimately, dismissed. For example, *McCarrell* and *Beard* ingested Accutane, and experienced their first IBD symptoms prior to 1997, well more than two years before they filed suit in Atlantic County. Thus, the claimed number of potential filings does not support a mass tort designation.

Second, a mass tort designation will enhance neither coordination among Plaintiffs' counsel, nor coordination between Plaintiffs' and Defendants' counsel. These cases are unique in the degree to which they are driven by a unified set of plaintiffs' attorneys: All of the New Jersey cases involve The Accutane Litigation Group as counsel, consulting counsel or affiliated counsel, the same plaintiffs' attorneys that are counsel in the MDL cases. Through entry of

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protective orders in New Jersey and around the country, CMOs in various jurisdictions, and cooperation of counsel, The Accutane Litigation Group has deposed some twenty-three (23) current and former Roche employees, as well as shared documents and data, in virtually all Accutane cases. Thus, there is no need for a mass tort designation to address a dispersed group of counsel.

Third, as set forth above, coordination with the MDL is already in place. Thus, there is no need for an official designation to foster such cooperation.

Finally, providing mass tort designation will create a *de facto* national class action, as literally all of these plaintiffs reside outside of New Jersey. Rather than achieve the goal of coordination, which already is in place, such a designation will continue to foster filing of non-meritorious, time-barred suits by non-New Jersey residents.

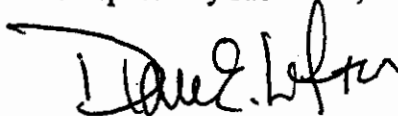
E. In the Alternative, Psychiatric Cases Should Be Excluded from Mass Coordination with the IBD Cases.

Simply stated, the psychiatric cases pending in Essex County are advanced and are ready for trial. Combining them with the IBD cases and sending them to Atlantic County literally would erase six years of progress. The psychiatric cases already are pending before an

Hon. Philip S. Carchman, J.A.D.  
March 10, 2005  
Page 16

experienced civil trial judge. These cases should remain in Essex County, and proceed to trial.

Respectfully submitted,



Michael R. Griffinger  
Diane E. Lifton

DEL/cag  
Enclosures

cc: The Honorable Francine Schott (via overnight delivery)  
The Honorable Carol E. Higbee (via overnight delivery)  
Michelle V. Perone, Esq. (via overnight delivery)

For the Plaintiffs:

Christopher A. Seeger, Esq. (via overnight delivery)  
Michael D. Hook, Esq.  
Paul L. Smith, Esq.  
David P. Affinito, Esq.  
Michael L. Rosenberg, Esq.  
Michael J. Ryan, Esq.  
Timothy O'Brien, Esq.

Co-Counsel for Defendants:

Kristine V. Ryan, Esq.  
Allison B. Neidoff, Esq.  
Bonnie L. Gallivan, Esq.  
Michael X. Imbroscio, Esq.  
Colleen H. Hennessey, Esq.

Exhibit A

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION, CIVIL PART  
ESSEX COUNTY  
A.D.# \_\_\_\_\_

1	PALAZZOLO,	)	
2		)	
	Plaintiff,	)	
3		)	
	Vs.	)	DOCKET NO. ESX-L-5498-99
4	HOFFMAN-LA ROCHE, INC.,	)	
5		)	
	Defendant.	)	
6	<hr/>		
7	TAYLOR,	)	
8		)	
	Plaintiff,	)	
9		)	
	Vs.	)	DOCKET NO. ESX-L-5645-03
10	HOFFMAN-LA ROCHE, INC.,	)	
11		)	
	Defendant.	)	
12	<hr/>		
13	WEBER,	)	
14		)	
	Plaintiff,	)	
15		)	
	Vs.	)	DOCKET NO. ESX-L-1965-03
16	HOFFMAN-LA ROCHE, INC.,	)	
		)	
	Defendant.	)	

17  
18 Place: Hall of Records  
19 465 Dr. Martin Luther King Blvd.  
20 Newark, New Jersey 07102

21  
22 Date: January 18, 2005  
23 Volume 2 of 2

24  
25 Transcriber, Gail M. Tornetta  
G&L TRANSCRIPTION OF NJ  
40 Evans Place  
Pompton Plains, New Jersey 07444

Sound Recorded  
Recording Operator,

1           THE COURT: Let's do this, we'll make it for  
2 Friday, February 18<sup>th</sup> at 1:30, okay? That is a motion  
3 day, but I'm usually finished with my motions about  
4 1:30, so. And as I said, counsel, that day what the  
5 Court is gonna look to do is find out from both sides  
6 what remains to be done in terms of discovery. I'll  
7 set schedules for that and may not make everybody  
8 happy, but there's gonna be dates, deadlines set.  
9 We'll set dates for dispositive motions if any and  
10 we'll also pick the trial date. So you should probably  
11 come in with your calendars, all right, so you know  
12 where your conflicts are in terms of dates and in all  
13 likelihood in terms of trial dates we're probably  
14 looking at either end of May, beginning of June, in  
15 that area, okay?

16           MR. AFFINITO: I guess -- for a trail date --  
17 Your Honor.

18           THE COURT: Um-hum. Counsel, this is from  
19 1999 and whatever four or five years we've had delay  
20 because of the motions that I couldn't get to. The  
21 case is from 1999, okay, I can't imagine six years  
22 later how much could be left to be done. I mean I know  
23 it may not be perfect, but no litigation is perfect,  
24 so. And -- and I'm not saying I set that date in  
25 stone, I'll hear from everybody, but this way I've

Exhibit B

GIBBONS, DEL DEO, DOLAN  
GRIFFINGER & VECCHIONE  
A Professional Corporation  
One Riverfront Plaza  
Newark, New Jersey 07102  
(973) 596-4500  
Attorneys for Defendants  
Hoffmann-La Roche Inc. and  
Roche Laboratories Inc.

ANDREW McCARRELL,

Plaintiff,

vs.

HOFFMANN LA ROCHE, INC. and ROCHE  
LABORATORIES INC.

Defendants.

**FILED**

JAN 26 2004

CAROL E. HIGBEE, J.S.C.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION:  
ATLANTIC COUNTY

DOCKET NO.: ATL-L-1951-03

CIVIL ACTION

CASE MANAGEMENT ORDER  
NO. 1

THIS MATTER, having been opened at the Court's request, and the Court, having conducted a telephone conference on November 14, 2003, and Christopher A. Seeger, Esq. of Seeger Weiss LLP having participated on behalf of Plaintiff, and Diane E. Lifton, Esq. and Kristine V. Ryan, Esq. of Gibbons, Del Deo, Dolan, Griffinger & Vecchione having participated on behalf of the Defendants,

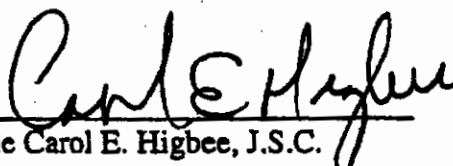
IT IS on this 26<sup>th</sup> day of January, 2004, ORDERED:

I. DISCOVERY SCHEDULE

1. All discovery in this matter shall be completed on or before December 29, 2004;
2. The parties shall serve responses to written discovery requests on or before January 15, 2004, and all discovery requests shall be responded to in accordance with the New Jersey Rules of Court;
3. Depositions of the parties and all non-expert witnesses shall be completed on or before July 1, 2004;
4. Counsel for the parties shall appear for a status conference on March January 1, 2004 at 3:30 o'clock am/pm.

II. PRESERVATION OF DOCUMENTS AND DATA.

1. Defendants have gathered, preserved and are producing documents in other pending litigation that relate to Accutane® and gastrointestinal adverse events. These documents are documents which would be within the scope of documents responsive to document requests in this matter. Defendants shall continue to preserve these documents until the parties agree upon, or until further order of the Court regarding, the appropriate time frame and scope for discovery in this matter.
  
2. Plaintiffs shall preserve all potentially relevant hard copy documents, and shall preserve all computer hard drives, emails and internet service provider information, until the parties agree upon, or until further order of the Court regarding, the appropriate time frame and scope for discovery in this matter.

  
\_\_\_\_\_  
Honorable Carol E. Higbee, J.S.C.

**FILED**

FEB 19 2004

*Exhibit c*

**CAROL E. HIGBEE, J.S.C.**

By the Court:

ANDREW MCCARRELL, : SUPERIOR COURT OF NEW JERSEY  
Plaintiff, : LAW DIVISION  
vs. : ATLANTIC COUNTY  
HOFFMANN LA ROCHE, INC. and : DOCKET NO. ATL-L-1951-03  
ROCHE LABORATORIES, INC., : Civil Action  
Defendants. :

REBECCA REE WILKINS REYNOLDS, : SUPERIOR COURT OF NEW JERSEY  
Plaintiff, : LAW DIVISION  
vs. : ATLANTIC COUNTY  
HOFFMANN LA ROCHE, INC. and : DOCKET NO. ATL-L-2644-03  
ROCHE LABORATORIES, INC., : Civil Action  
Defendants. :

EMILY J. BEARD, : SUPERIOR COURT OF NEW JERSEY  
Plaintiff, : LAW DIVISION  
vs. : ATLANTIC COUNTY  
HOFFMANN LA ROCHE, INC. and : DOCKET NO. ATL-L-2645-03  
ROCHE LABORATORIES, INC., : Civil Action  
Defendants. :

TROY SAVARY, : SUPERIOR COURT OF NEW JERSEY  
Plaintiff, : LAW DIVISION  
vs. : ATLANTIC COUNTY  
HOFFMANN LA ROCHE, INC. and : DOCKET NO. ATL-L-341-04  
ROCHE LABORATORIES, INC., : Civil Action  
Defendants. :



THIS MATTER being opened on the court's own motion following a management conference with counsel on February 19, 2004, and for good cause shown;

IT IS on this 19<sup>th</sup> day of Feb, 2004, ORDERED as follows:

1. The above entitled matters are hereby consolidated under Docket No. ATL-L-1951-03 for discovery purposes only.
2. If at any time in the course of discovery it appears to any party that the matter should be severed, the appropriate application can be made to the Court.
3. All request for written discovery shall be propounded by April 5, 2004 and responses to those requests shall be provided by May 20, 2004.
4. The management conference scheduled on March 1, 2004 by case management order in McCarrell v. Hoffman-LaRoche, Inc., Docket No. ATL-L-1951-03, is hereby adjourned.
5. The next case management conference is scheduled for **May 27, 2004 at 9:00 a.m.** by telephone. Plaintiff's counsel shall initiate the conference call.
6. Preservation of documents which is set forth in the January 26, 2004 management order entered in the McCarrell v. Hoffmann-LaRoche, Inc. matter shall continue in effect for all cases. If the parties desire a more comprehensive order, application may be made to the Court.
7. The new discovery end date for all these consolidated cases will be February 13, 2005.
8. Best Practices does apply to these matters.
9. The parties are free to contact the Court at any time in order to schedule telephone conferences to discuss any issues that are of concern to the parties.

  
CAROL E. HIGBEE, J.S.C.

EXHIBIT D

**FILED**

FEB 01 2005

**CAROL E. HIGBEE, J.S.C.**

ANDREW McCARRELL

Plaintiff,

v.

HOFFMANN-LA ROCHE INC. and  
ROCHE LABORATORIES INC.

Defendants.

EMILY J. BEARD,

Plaintiff,

v.

HOFFMANN-LA ROCHE INC. and  
ROCHE LABORATORIES INC.

Defendants.

REBECCA REE WILKINS REYNOLDS,

Plaintiff,

v.

HOFFMANN-LA ROCHE INC. and  
ROCHE LABORATORIES INC.

Defendants.

TROY SAVARY

Plaintiff,

v.

HOFFMANN-LA ROCHE INC., and ROCHE  
LABORATORIES INC.

Defendants.

JAMIE NICHOLE FIELDS and ELIZABETH  
EILEEN FIELDS,

Plaintiffs,

v.

HOFFMANN-LA ROCHE INC. and  
ROCHE LABORATORIES INC.

Defendants.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION  
ATLANTIC COUNTY  
DOCKET NO. ATL-L-1951-03

CASE MANAGEMENT ORDER NO. 3

DOCKET NO. ATL-L-2645-03

DOCKET NO. ATL-L-2644-03

DOCKET NO.: ATL-L-341-04

DOCKET NO. ATL-L-10325-03

**THIS COURT**, having conducted a Case Management Conference on December 20, 2004, and David Buchanan, Esq., Michael Rosenberg, Esq., Michael Ryan, Esq., Paul Smith, Esq., and Michael Hook, Esq. having appeared on behalf of Plaintiffs, and Diane E. Lifton, Esq. and Bonnie Gallivan, Esq. having appeared on behalf of defendants Hoffmann-La Roche Inc. and Roche Laboratories Inc. (the "US Defendants"), and having reviewed the submissions offered by the parties in advance of the conference, and having listened to the arguments of counsel made during the conference,

IT IS on this 1<sup>st</sup> day of Feb, 2005.

**ORDERED** that this Case Management Order ("CMO") 3 shall amend prior CMOs to the extent inconsistent therewith, and it is further

**ORDERED** as follows:

**I DISCOVERY FROM PLAINTIFFS**

A. The parties shall confer regarding any outstanding case specific discovery due from Plaintiffs in connection with the captioned actions in advance of the next case management conference ("CMC").

B. The parties shall confer regarding the list of topics in connection with Plaintiffs' search for and production of electronic information from their personal computers and internet service providers in advance of the next CMC. The parties' agreed upon list shall be used in connection with the production by Plaintiffs in the captioned actions as well as in the Atlantic County Accutane actions listed on Schedule A to this Order.

**II DISCOVERY CUT OFF FOR PRODUCTION**

A. Defendants have produced documents in *McClain v. Hoffmann-LaRoche, Inc.* to counsel for certain of the plaintiffs herein. Defendant has agreed to allow those documents to be used in the above-captioned actions. Defendants have designated certain of such documents confidential pursuant to the protective orders in those related proceedings. Until such time as a protective order is entered in these actions, the parties agree to use the documents herein subject to the restrictions of such order(s).

B. Plaintiffs will advise of any plaintiff in the captioned actions or in the Atlantic County Accutane actions listed on Schedule A to this Order, who was prescribed Accutane after the December 2003 *McClain* production date for purposes of a possible supplemental document production by Defendants.

C. By April 1, 2005, Defendants shall produce responsive documents, including but not limited to, core corporate type files, scientific studies and analyses, exchanges with the FDA, adverse events and label changes relevant to the adverse events claimed in these actions, as well as the Accutane IND/NDA generated through the end of 2004. Thereafter, both parties shall supplement their production of records in a timely manner.

### III. ADVENT (Adverse Event Database)

Before the next management meeting, the parties shall submit to the Court the information requested by the Court.

### IV. REDACTION

A. Subject to paragraph IV.B herein, Defendants shall produce previously redacted documents that are being made available for use herein pursuant to paragraph II.A in an unredacted form. This production shall be started on or before February 15, 2005.

B. Documents produced under paragraph IV.A., *supra*, can be redacted for trade secrets, and shall be redacted for confidential patient/reporter identifying information. If Defendants seek to keep redacted any information other than trade secrets or confidential patient/reporter identifying information Defendants shall provide the Court with a list of any categories they seek to continue to maintain as redacted on or before February 15, 2005. The Defendants shall clearly identify the presence of any redaction and shall note the basis for the claimed redaction on the document.

### V. SWISS DOCUMENTS

Documents located overseas that are to be produced in January, 2005 in the Accutane multi-district litigation (MDL) are available to Plaintiffs in the captioned actions as well as in the Atlantic County Accutane actions listed on Schedule A to this Order. As with any documents, such documents will be subject to the New Jersey Rules of Court as to admissibility at trial.

### VI. PRODUCTION FORMAT

The format for production of future documents as well as documents previously produced in hard copy will be decided on February 9, 2005 at the oral argument for the motion for a protective order concerning ADVENT database.

### VII. NEW DISCOVERY END DATE/NEXT CONFERENCE

A. The date for completion of discovery in the captioned actions has been adjourned to December 1, 2005.

B. The next Case Management Conference shall take place on March 10,  
2005 at 1:30 p.m.


  
\_\_\_\_\_  
Honorable Carol E. Higbee, J.S.C.

EXHIBIT E

SUPERIOR COURT OF NEW JERSEY  
ATLANTIC COUNTY: LAW DIVISION

**FILED**  
JAN 31 2005  
CAROL E. HIGBEE, J.S.C.

**ALL CIVIL ACTIONS LISTED AT SCHEDULE A**

**CASE MANAGEMENT ORDER REGARDING PLAINTIFF'S FACT SHEET**

This matter having been brought before the Court for a case management conference on December 20, 2004 and all counsel having been present,

It is on this 31 day of Jan, 2005 ORDERED as follows:

**I. PLAINTIFF'S FACT SHEET**

Each plaintiff in cases listed on Schedule A shall complete, and comply with, the Plaintiff's Fact Sheet attached to this CMO.

The Plaintiff's Fact sheet shall be deemed served on all plaintiffs in cases in which Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("the US Defendants") have filed their Answers and/or responsive pleadings (hereinafter "Initial Plaintiffs"). All other plaintiffs whose cases are subsequently filed (hereinafter "New Plaintiffs") shall be deemed served with the Plaintiff's Fact Sheet at the time that the US Defendants filed their Answers or other responsive pleading.

**II. DUE DATES ON ANSWERS TO PLAINTIFF'S FACT SHEET**

The Initial Plaintiffs shall provide answers to the Plaintiff's Fact Sheet, together with executed verification and records release authorizations and any responsive documents and/or things, as follows:

The first fifteen plaintiffs listed on Schedule A, within 45 days of entry of this Order;

The next fifteen plaintiffs listed on Schedule A, within 90 days of entry of this Order; and

The next fifteen plaintiffs listed on Schedule A, within 135 days of entry of this Order.

Each subsequent group of fifteen plaintiffs shall provide answers in 45 day intervals.

All new plaintiffs not listed on Schedule A shall provide answers to the Plaintiff's Fact Sheet, together with the executed verification and records release authorizations and any responsive documents and/or things, within 45 days of filing by the US Defendants of their Answers or other responsive pleadings.

All Plaintiffs shall make reasonable efforts to execute and return all subsequent authorizations within ten (10) days of receipt from Defendants.

**III. SUPPLEMENTAL INTERROGATORIES AND DOCUMENT DEMANDS**

The US Defendants may serve supplement interrogatories and requests for documents ("supplemental requests") that seek to clarify or expand on the responses to the Plaintiff's Fact Sheet. Plaintiffs shall advise within 20 days of service of the supplemental requests if they object or decline to respond as beyond this Order. Otherwise, Plaintiffs shall respond to the supplemental requests within 30 days of service. If Plaintiffs fail to respond to the supplemental requests or the responses to the supplemental requests are inadequate, the US Defendants may seek appropriate relief from the Court.

  
Honorable Carol E. Higbee, J.S.C.

## SCHEDULE A

SCHEDULE A			
Kelly Andrews	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffman La-Roche, LTD.; and Roche Holding, LTD.	ATL-L-3319-04
Jody Bantz	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffman La-Roche, LTD.; and Roche Holding, LTD.	ATL-L-3283-04
Emily J. Beard	v.	Hoffmann-La Roche Inc. and Roche Laboratories Inc.	ATL-L-2645-03
Douglas Bedell	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3364-04
Christopher Bonacarti	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3252-04
Anita Brown	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3379-04
Daniel Bruett	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3380-04
Robert Caruso	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3363-04
Chanda Cirfaks	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3392-04
Dustin Conhally	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3253-04
Amy Cook	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3254-04
Paul M. Durham	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3573-04
Joseph Fago	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3362-04
Jemie Nichole Fields and Elizabeth Eileen Fields	v.	Hoffmann-La Roche Inc. and Roche Laboratories Inc.	ESX-L-10325-03
Patrick Fisherty	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3255-04



## SCHEDULE A

SCHEDULE A			
Glilian Gaghan	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3361-04
James Groff	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3320-04
Kenneth Hinz	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3256-04
Thomas House	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3589-04
Randy Howell	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3391-04
George W. Hyde	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3042-04
Chakedra Johnson	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3574-04
Tasha Kennedy	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3393-04
Gavin Kilduff	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3287-04
Bridget Marshall	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3360-04
Jason Maxwell	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-2866-04
Cheryl B. Mayhew	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3365-04
Jonathan Mayhorn	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3321-04
Andrew McCarrell	v.	Hoffmann-La Roche Inc. and Roche Laboratories Inc.	ATL-L-1951-03
Douglas McCaskell	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3322-04
David M. McClain	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3381-04

## SCHEDULE A

PLAINTIFF		DEFENDANT	
Chelsea Ann Praus	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3258-04
Rebecca Ree Wilkins Reynolds	v.	Hoffmann-La Roche Inc. and Roche Laboratories Inc.	ATL-L-2644-04
Lindsey Sackett	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3284-04
Troy Savary	v.	Hoffmann-La Roche Inc. and Roche Laboratories Inc.	ATL-L-341-04
Christine Jo Singer	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3382-04
Melissa Smith	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3285-04
Trevor Taber	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3324-04
Chetan P. Tanna	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3366-04
Melissa Turcolto	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3575-04
Carey Wagner	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3259-04
Daryl Weathersbee	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3280-04
Nancy Werkmeister	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3394-04
Sarah Wiebers	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3201-04
Anita F. Willard	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3368-04
Christopher Williams	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3383-04
Karen Winkles	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3287-04

**SCHEDULE A**

Plaintiff	Defendant	Docket No.
Christopher Wishert	v. Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3286-04
Timothy Ziegler	v. Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3367-04

SUPERIOR COURT OF NEW JERSEY  
ATLANTIC COUNTY/CIVIL DIVISION  
DOCKET NO. ATL-L-1951-03

-----X  
ANDREW MCCARRELL,

PLAINTIFF,

VS.

HOFFMAN-LA ROCHE INC. AND  
ROCHE LABORATORIES, INC.,

DEFENDANTS.  
-----X

STENOGRAPHIC TRANSCRIPT  
OF:

- MOTION FOR -  
PROTECTIVE ORDER

PLACE: ATLANTIC COUNTY COURTHOUSE  
1201 BACHARACH BLVD  
HAYS LANDING, NJ 08530

DATE: FEBRUARY 9, 2006

B E F O R E:

THE HONORABLE CAROL E. HIGBEE, J.S.C.

TRANSCRIPT ORDERED BY:

DAVID BUCHANAN, ESQUIRE AND DIANE LIFTON, ESQUIRE

A P P E A R A N C E S:  
DAVID BUCHANAN, ESQUIRE  
SEGER, WEISS, LLP

MICHAEL RYAN, ESQUIRE  
KRUPNICK, CAMPBELL  
ATTORNEYS FOR THE PLAINTIFFS

DIANE E. LIFTON, ESQUIRE  
GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE

BONNIE GALLIVAN, ESQUIRE  
ICE, HILLER  
ATTORNEYS FOR THE DEFENDANTS

REGINA A. TELL, CSR-CRR  
OFFICIAL COURT REPORTER  
1201 BACHARACH BOULEVARD  
ATLANTIC CITY, NJ 08401

Colloquy

P R O C E E D I N G S

- 1
- 2 THE COURT: You can be seated.
- 3 MS. LIFTON: Good morning, your Honor.
- 4 THE COURT: Counsel.
- 5 MS. GALLIVAN: Hello, Judge Higbee.
- 6 THE COURT: Let us know if you can't hear,
- 7 but hopefully with the phone system we have you'll be
- 8 able to hear.
- 9 MS. GALLIVAN: Okay. Thank you.
- 10 THE COURT: This is McCarrell versus Hoffman
- 11 LaRoche Docket number 1951-03. Counsel, enter your
- 12 appearances for the record.
- 13 MR. BUCHANAN: David Buchanan with Mike Ryan
- 14 for plaintiffs, your Honor. Also with us is a
- 15 consultant, Keith Altman.
- 16 MS. LIFTON: Good morning, your Honor. Diane
- 17 Lifton from Gibbons on behalf of defendants Hoffman
- 18 LaRoche and Roche Laboratories.
- 19 THE COURT: And counsel on the phone?
- 20 MS. GALLIVAN: Bonnie Gallivan for Hoffman
- 21 LaRoche.
- 22 THE COURT: Okay. This is a motion for
- 23 protective order for Hoffman LaRoche. The issue
- 24 basically is the ADVENT database and the production of
- 25 that database, and the questions basically for the

## Colloquy

1 MR. BUCHANAN: No objection.  
 2 THE COURT: All right. Then we'll submit an  
 3 order. One of you submit an order.  
 4 MR. BUCHANAN: We'll produce an order.  
 5 THE COURT: We'll try again.  
 6 MS. LIFTON: Keep it short, Mr. Buchanan.  
 7 That's my only request.  
 8 MR. BUCHANAN: Okay. I think the orders are  
 9 always straightforward.  
 10 THE COURT: Entire ADVENT database is  
 11 producible. It should be produced by April 1st in the  
 12 searchable format that was used in the psychiatric  
 13 cases. It should be three or four sentences.  
 14 MS. LIFTON: And, your Honor, I apologize,  
 15 the only reason I say that is because we spend a lot of  
 16 time going back and forth on what the language of the  
 17 order should be.  
 18 THE COURT: I don't think the language of the  
 19 order needs to include like general statements to  
 20 counsel or things like that. I know everybody likes if  
 21 it was favorable to one side and they want to -- you  
 22 have got it. You can order the transcript. You can  
 23 remind me of it, but let's move ahead with this. We'll  
 24 sign the order as quickly as possible and then we'll --  
 25 April 1st you'll have the documents to them and we'll

## Colloquy

1 move on to the next issue. The MDL has been in  
 2 effect -- it just started.  
 3 MR. RYAN: Yes, Judge. It's been in effect  
 4 since November 1st. The first status conference was  
 5 January 28th, and we have a hearing in front of the  
 6 Magistrate on Friday afternoon.  
 7 MS. LIFTON: And my understanding, Judge, is  
 8 that at least at present it consists of mature cases,  
 9 but I understand from reading the record at the last  
 10 conference that that may or may not change.  
 11 MR. RYAN: You'll be happy to know there will  
 12 be new cases for them to also work on.  
 13 THE COURT: This is Judge Moody?  
 14 MS. LIFTON: Yes.  
 15 THE COURT: He phoned me. He told me that he  
 16 was the MDL judge. He told me that he was going to be  
 17 handling these cases. It was basically a -- literally  
 18 a two- or three-minute conversation, and he indicated  
 19 that as much as possible we could try to work together  
 20 and coordinate things, so I don't know how that is  
 21 going to affect the magistrate down there decision or  
 22 not affect his decision. That's totally up to them,  
 23 but -- and I told him that I would attempt to do that  
 24 with him, too, obviously. Any way we could do anything  
 25 that would be beneficial to both sides so we're not

Exhibit G

1 SUPERIOR COURT OF NEW JERSEY  
2 ESSEX COUNTY  
3 LAW DIVISION, CIVIL PART  
4 DOCKET NO.: L-5498-99  
5 A.D. NO.

6 PALAZZOLO, )  
7 )  
8 Plaintiff, )  
9 )  
10 vs. )  
11 )  
12 HOFFMANN-LAROCHE INC., )  
13 )  
14 Defendant. )

TRANSCRIPT  
OF  
CASE MANAGEMENT  
CONFERENCE

Place: Essex County Court House  
50 West Market Street  
Newark, New Jersey 07102

Date: February 18, 2005

11 BEFORE:

12 HONORABLE FRANCINE A. SCHOTT, J.S.C.

13 TRANSCRIPT ORDERED BY:

14 LAUREN M. SKLENAR, ESQ., (Gibbons, Del Deo, Dolan,  
15 Griffinger & Vecchione)

16 APPEARANCES:

17 DAVID P. AFFINITO, ESQ., (Dell'Italia Affinito  
18 and Santola)  
19 Attorney for the Plaintiff

20 MICHAEL RYAN, ESQ. (Pro Hac Vice)

21 DIANE E. LIFTON, ESQ., (Gibbons, Del Deo, Dolan  
22 Griffinger & Vecchione)  
23 Attorney for the Defendants, Hoffman LaRoche Inc.  
24 and LaRoche Laboratories Inc.

25 Transcriber Cynthia Dyson-Colon  
KING TRANSCRIPTION SERVICES  
FRANK H. ULRICH  
65 Willowbrook Boulevard  
Wayne, NJ 07470  
Audio Recorded

1 important.

2 THE COURT: All right.

3 MR. RYAN: Part of what I suspect and I hear  
4 the defendant saying that they're at the end of their  
5 discovery. It's important to understand that I have  
6 asked the defendant's already prepared to certify at  
7 least on the areas we've agreed to. And like I said  
8 earlier that's about one hundred issues. There are  
9 approximately 60 areas of which we never reached an  
10 agreement. And Your Honor may say well why weren't  
11 those filed. Why weren't those addressed? Because  
12 those issues have been addressed in a more global  
13 fashion sometimes in the course.

14 There are cases that have been set on trial  
15 dockets that consider all of that that is outstanding  
16 discovery as well as documents that they are obligated  
17 to produce that are physically overseas. And Your  
18 Honor knows with some discussion about that before.  
19 This list the defendant's are saying they're not  
20 prepared to produce until June the documents that are  
21 physically located overseas. I just don't want to be  
22 in a position --

23 THE COURT: Let me ask you a practical  
24 question. In the course of the six years of discovery  
25 that has been done, have the plaintiff's discovered any

1 documents that would indicated that Hoffmann LaRoche  
2 was aware of the potential psychological side affects  
3 of Accutane?

4 MR. RYAN: Yes.

5 THE COURT: Okay. Once you have that and I  
6 assume you have an expert that makes a causative  
7 connection, right?

8 MR. RYAN: Based on what we have right now  
9 and without the documents from the scientists overseas,  
10 correct.

11 THE COURT: Okay. Well what could possibly  
12 come from overseas that would help your case any  
13 further?

14 MR. RYAN: Exactly. The science of the drug.  
15 Courts that have looked at this both Judge Jacobson,  
16 Judge Payne and the Federal court in -- look at this  
17 issue. Have all said we are entitled to discover the  
18 science. And we made a record in all those situations.

19 THE COURT: No, no. I know that.

20 MR. RYAN: The the scientist overseas. And  
21 this is not an insubstantial issue. They made a drug  
22 committee decision overseas. One of the critical  
23 documents that established that their own scientist  
24 thought that kids should be monitored for depression  
25 which never made it to the label. And which they



1           THE COURT: Well, I think at this juncture  
2 certainly the setting of the case management conference  
3 was not an invitation to file motions that have not yet  
4 been filed. I think at this juncture we'll proceed  
5 knowing that the management conference is coming. And  
6 to the extent that there are any outstanding area again  
7 hopefully they can be resolved in a phone call. And if  
8 they can't, we'll make a laundry list of them. At the  
9 conference those that I can address at the conference  
10 and resolve I will. Those that I can not, well, we'll  
11 deal with whether or not motions are appropriate or if  
12 it's time to go ahead and just set a trial date. But  
13 we'll deal with all of that at that time. So don't  
14 file any more motions.

15           Just be sure and have that conversation  
16 between yourselves and exchange between yourselves  
17 prior to that management conference. And submit to me,  
18 make it the Thursday before the conference an outline  
19 of what areas remain what you agree remains in dispute  
20 from what you might dispute remains in dispute. All  
21 right. And we'll deal with it all that day.

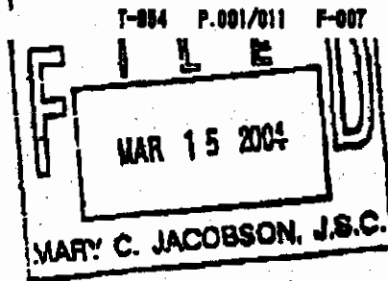
22           MISS LIFTON: Your Honor, thank you and have  
23 a nice weekend Judge.

24           MR. RYAN: Thank you Your Honor for your  
25 time.

22-Mar-2004 11:08am From

Exhibit H

**GIBBONS, DEL DEO, DOLAN,  
GRIFFINGER & VECCHIONE**  
A Professional Corporation  
One Riverfront Plaza  
Newark, NJ 07102-5496  
(973) 596-4500  
Attorneys for Defendants  
Hoffmann-La Roche Inc. and  
Roche Laboratories Inc.



**VIRGINIA PALAZZOLO, ET AL.,**

Plaintiff,

v.

**HOFFMANN-LA ROCHE INC., ET AL.,**

Defendants.

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: ESSEX COUNTY**

**DOCKET NO.: ESX-L-5498-99**

**CONSENT PROTECTIVE ORDER  
REGARDING DISCLOSURE OF  
CONFIDENTIAL DOCUMENTS**

**ROBERT ROWE,**

Plaintiff,

v.

**HOFFMANN-LA ROCHE INC., ET AL.,**

Defendants.

**DOCKET NO.: ESX-L-2971-01**

**CASEY BALSAM,**

Plaintiff,

v.

**HOFFMANN-LA ROCHE INC., ET AL.,**

Defendants.

**DOCKET NO.: ESX-L-5808-01**

**DONNA CHEEK,**

Plaintiff,

v.

**HOFFMANN-LA ROCHE INC., ET AL.,**

Defendants.

**DOCKET NO.: ESX-L-7983-01**

**DOUGLAS HOEPS, ET AL.,**

Plaintiffs,

v.

**HOFFMANN-LA ROCHE INC., ET AL.,**

Defendants.

**DOCKET NO.: ESX-L-8357-01**

22-Mar-2004 11:18am From

T-854 P.002/011 F-007

---

**MATTHEW M. TURNEY, ET AL.,**

**Plaintiffs,**

**v.**

**HOFFMANN-LA ROCHE INC., ET AL.,**

**Defendants**

---

**DOCKET NO.: ESX-L-5143-02**

22-Mar-2004 11:16am From

T-054 P.009/011 F-007

---

NICHOLAS B. PAMPELL,

Plaintiff,

v.

HOFFMANN-LA ROCHE INC., ET AL.,

Defendants

---

DOCKET NO.: ESX-L-5144-02

22-Mar-2004 11:16am From-

T-854 P.004/011 F-007

**THIS MATTER** is before the Court on the parties' request for entry of a Protective Order Regarding Discovery ("Order").

This is a pharmaceutical products liability action. Claims for faulty design, marketing, testing, warning and manufacturing have been asserted and are likely to generate significant amounts of pretrial discovery material. Given the sensitive nature of much of the discovery likely to be produced, a protective order is needed to expedite the flow of discovery material, preserve the integrity of truly confidential information, trade secrets, and commercial and proprietary information, promote the prompt resolution of disputes over confidentiality, and facilitate the preservation of material worthy of protection. The Order strikes an appropriate balance between the parties' interests in prosecuting and defending this case, the judicial interest in the efficiency and integrity of the discovery process, and the public interest in access to information.

Accordingly, it is **ORDERED** and **ADJUDGED** as follows:

1. A party ("Producing Party") may designate as "Confidential" any documents and material ("Material") it produces in this litigation to a receiving party ("Receiving Party") if such Producing Party or counsel for such Producing Party in good faith believes that such Material contains a trade secret or other confidential or proprietary research, development, or commercial information. In addition, this shall include, without limitation, information which, if disclosed, would invade physician-patient privileges and privacy interests or rights of persons not party to this action.
2. Absent a further order of this Court, Material produced in this case shall not be used for any purpose other than the prosecution or defense of this captioned action, and shall not be shown, disseminated, or disclosed in any manner to anyone not authorized under this Order. Counsel for the Receiving Party ("Receiving Party Counsel"), however, may use the documents consistent with the restrictions in paragraphs 3 and 4 of this Order.
3. This Order shall apply to all counsel, co-counsel who appear in the case, experts, persons noticed for depositions, actual or potential witnesses, and their respective counsel in this litigation, and associates, assistants, or employees. In addition, Receiving Party Counsel may

22-Mar-2004 11:10am From

T-954 P.006/011 F-807

disclose the documents produced under this protective order to other counsel representing Accutane® plaintiffs (hereinafter "Other Counsel") in matters in which Receiving Party Counsel are co-counsel if, and only if, Other Counsel enter into this protective order or one identical to it.

4. Receiving Party Counsel shall ensure that each of the attorneys and/or individuals associated with them by employment or otherwise in the handling of this case have read and are familiar with the terms of this Order. Receiving Party Counsel and each of the attorneys and/or individuals associated with them by employment or otherwise in the handling of this case shall be deemed to be bound by the terms of this Order and subject to the jurisdiction of the Court for appropriate proceedings in the event of any violation of alleged violation of this Order. Before showing or divulging the contents of any of the Confidential Material produced in this case to any person identified in paragraph 3, other than counsel of record and employees of the law firm for counsel of record, Receiving Party Counsel shall first obtain a signed statement from that person reciting that the person is familiar with the terms of this Order and has agreed to abide by those terms. The requirement of obtaining such a signed statement may be satisfied by affixing the name, affiliation and business address, as well as obtaining the signature of such person, on a copy of this Order. A copy of each such signed statement shall be retained by Receiving Party Counsel for five (5) years after the conclusion of this case, including any appeal. A copy of the signed statement of any testifying expert, treating physician, or other witness to whom Confidential Material has been provided under this Order, shall be provided to Producing Party Counsel upon either the date of said witness's deposition or the date of disclosure of such person as a testifying witness, whichever date is earlier. At the conclusion of this case, Receiving Party Counsel shall retrieve all Confidential Material from testifying experts, consulting experts, and any other person or entity to whom Confidential Material has been disclosed pursuant to this Order and otherwise comply with paragraph 14 hereof.

5. Confidential Materials shall not be disclosed by Receiving Party Counsel or otherwise made public except in compliance with the terms of this Order. If any person or entity, other than those described in paragraph 3 or paragraph 4, seeks to obtain or compel the production of any Producing Party's Confidential Material from a Receiving Party or any other

22-Mar-2004 11:10am From

person to whom Confidential Material has been disclosed pursuant to this Order (collectively "Receiving Party"), by requests for documents, subpoena or other compulsory process, the Receiving Party from which the Confidential Material is requested and/or demanded shall immediately notify the Producing Party in writing of the demand in order to permit the assertion of all applicable rights and privileges with respect to the Confidential Material, shall advise the person or entity seeking production of Confidential Materials of the existence of this Order, and shall cooperate fully to assert all applicable rights and privileges in any proceeding relating to any such request for documents, subpoena or other compulsory process. This provision, however, is not intended to restrict, abridge or impose any obligation upon Defendants in the exercise of their reporting responsibilities in conformance with the provisions of the Food, Drug & Cosmetics Act and/or its enabling regulations.

6. In addition, to protect against unauthorized disclosure of confidential personal information or invasion of the physician-patient privilege and/or individual privacy interests or rights, Defendants may redact from Material names, addresses, and other identifying information pertaining to: research subjects or patients; reporters of adverse events or persons or entities identified in such reports; and other individuals or entities whose names and other identifying information are protected from disclosure by the FDA or Defendants by the regulations of the Food, Drug & Cosmetics Act, including, but not limited to, 21 C.F.R. 20.63, 21 C.F.R. 20.111, 21 C.F.R. 20.112, 21 C.F.R. 50.25, 21 C.F.R. 314.80 and 21 C.F.R. 803.9, or by the regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

7. If a Receiving Party, or any person or entity to whom Confidential Material has been disclosed pursuant to this Order, believes in good faith that Confidential Material produced in this case should be used for any purpose outside of this litigation, the party or witness shall first obtain the consent of the Producing Party for such disclosure. If consent is not forthcoming, the party shall make a good faith effort to resolve such dispute with counsel for the Producing Party, explaining the reason(s) that the Material should be used outside of this litigation. If the dispute cannot be resolved, either the party or the witness may apply to the Court for a determination concerning the propriety of using the Material outside of this litigation.

22-Mar-2004 11:11am From-

T-054 P.007/011 F-007

8. If a Receiving Party disputes the designation of Material as "Confidential," the Receiving Party Counsel shall inform counsel for the Producing Party in writing of the objection. Counsel for the Producing Party shall, within ten (10) business days after receipt of the objection, set forth in writing the basis for the designation. If the dispute cannot be resolved, the Producing Party shall apply to the Court for a Protective Order. All documents designated "Confidential" shall remain so designated until they are re-designated by Producing Party Counsel or the issue is resolved by the Court.

9. A party may designate a portion of a deposition transcript and/or videotape which refers to Material produced in this case as Confidential by, within ten (10) business days after the deposition transcript is delivered to the party, providing to all counsel written notice identifying those portions of the deposition transcript that counsel in good faith believes to contain Confidential Material. All deposition transcripts and videotapes shall be treated as Confidential until the expiration of the ten business day period. All parties shall label their copies of depositions accordingly.

10. Nothing in this Order shall be interpreted to prohibit or prevent the Producing Party from using or discussing its own Confidential Material in any way it sees fit to so use or discuss them. Any such use or discussion of Confidential Material by the Producing Party shall not be deemed a waiver of the terms of this Order.

11. Nothing in this Order shall be interpreted to require disclosure of Material that the Producing Party contends is protected from disclosure by the attorney-client privilege or the attorney work-product doctrine.

12. The inadvertent or unintentional production of Material containing, or otherwise disclosing, confidential, privileged, private, proprietary or trade secret information without being designated Confidential at the time of production or disclosure shall not be deemed a waiver in whole or in part of the claim of confidentiality or privilege, either as to the specific information disclosed or as to any other information relating thereto on the same or related subject matter. The issue of waiver, to the extent contested by the parties, shall be determined by this Court.



22-Mar-2004 11:11am From

T-854 P.008/011 F-807

Any error in designation shall be corrected as soon as reasonably possible after the Producing Party becomes aware of the error.

13. The designation of Material as Confidential, pursuant to this Order, shall not be construed as a concession by any Party that such information is relevant or material to any issue or is otherwise discoverable or admissible as evidence.

14. Within forty-five days (45) of the conclusion of all proceedings by settlement, adjudication, or otherwise, all Material furnished pursuant to the terms of this Order, any copies thereof, and any materials recording and/or otherwise containing said information or documentation, and which are not in the custody of the Court, shall be returned to the Producing Party, along with a certification by affidavit that all copies of these materials have been so returned. The parties may keep one copy of the records and documents produced in their closed files under confidential seal for the exclusive purpose of maintaining an accurate record of the work done on this case for liability insurance/malpractice concerns.

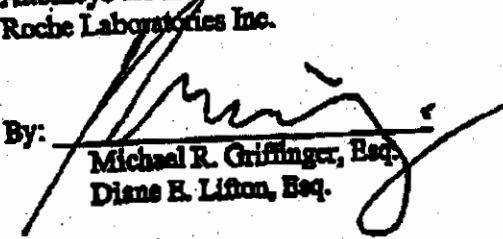
15. The disclosure of Confidential Material produced in this case or Confidential information contained therein to any person not qualified to receive such information pursuant to this Order and subject to its terms, or without following the terms and conditions of this Order, may subject the person making such disclosure to a finding of contempt and the imposition of sanctions, fees, costs, or other penalties, as determined by the Court. Each person to whom disclosure Confidential Material or information is made pursuant to this Order shall subject himself to the jurisdiction of this Court for the purposes of contempt proceedings in the event of any violation of this Order.

22-Mar-2004 11:12am From

T-884 P.009/011 F-007

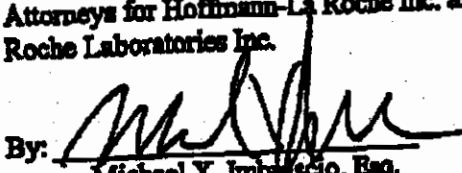
We hereby consent to the form and entry of this Order:

**GIBBONS, DEL DEO, DOLAN,  
GRIFFINGER & VECCHIONE, P.C.**  
Attorneys for Hoffmann-La Roche Inc. and  
Roche Laboratories Inc.

By:   
Michael R. Griffinger, Esq.  
Diane H. Lifton, Esq.

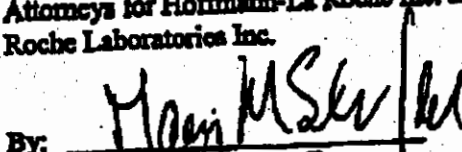
Dated:

**COVINGTON & BURLING**  
Attorneys for Hoffmann-La Roche Inc. and  
Roche Laboratories Inc.

By:   
Michael X. Imboscio, Esq.  
Admitted Pro Hac Vice

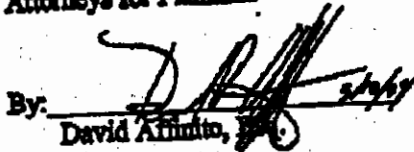
Dated:

**PEABODY & ARNOLD**  
Attorneys for Hoffmann-La Roche Inc. and  
Roche Laboratories Inc.

By:   
Mary M. Sullivan, Esq.  
Colleen M. Hennessey, Esq.  
Admitted Pro Hac Vice

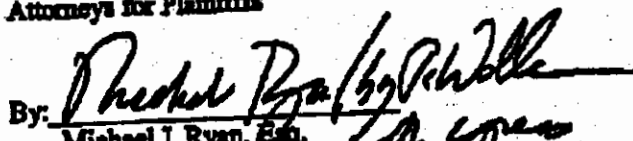
Dated:

**DELL'ITALIA, AFFINITO, SANTOLA**  
Attorneys for Plaintiffs

By:   
David Affinito, Esq.

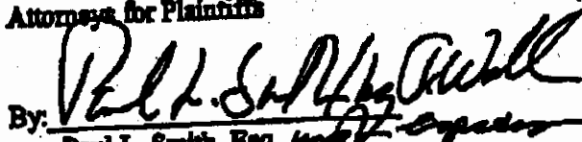
Dated:

**KRUPNICK CAMPBELL MALONE BUSER  
SLAMA HANCOCK McNELLIS LIBERMAN &  
McKEE**  
Attorneys for Plaintiffs

By:   
Michael J. Ryan, Esq.  
Admitted Pro Hac Vice  
*with eyes person*


Dated:

**PAUL L. SMITH & ASSOCIATES**  
Attorneys for Plaintiffs

By:   
Paul L. Smith, Esq. *with eyes person*  
Admitted Pro Hac Vice

Dated:

**CAMPBELL, WALLER & POER, LLC**  
Attorneys for Plaintiffs

By:   
Jonathan H. Waller, Esq.  
Admitted Pro Hac Vice

Dated:

22-Mar-2004 11:12am From

Gibbons 973-596-4500 3/11/2004 10:08

T-994 P.010/011 F-997

11-Mar-2004 07:30am From

T-TR P.010/010 F-994

**LAW OFFICES OF PETER J. McNULTY**  
Attorneys for Plaintiffs

By: \_\_\_\_\_  
Peter J. McNulty, Esq.  
Admitted Pro Hac Vice

Dated:

**HOOK, BOLTON, MITCHELL, KIRKLAND & MCCHEE, P.A.**  
Associated Counsel for Plaintiffs

By: Michael D. Hook  
Michael D. Hook, Esq.

Dated: 3-10-04

SO ORDERED:

Mary C. Jacobson, J.S.C.  
Hon. Mary C. Jacobson, J.S.C.

Dated: 3-15-04

22-Mar-2004 11:12am From

T-884 P.011/011 F-807  
T-724 P.018/018 F-804

11-Mar-2004 07:38am From

LAW OFFICES OF PETER J. McNULTY  
Attorneys for Plaintiff

By: *Peter J. McNulty*  
Peter J. McNulty, Esq.  
Admitted Pro Hac Vice

Date:

HOOK, BOLTON, MITCHELL, KIRKLAND &  
MCGHEE, P.A.  
Associated Counsel for Plaintiff

By: Michael D. Hook, Esq.

Date:

SO ORDERED:

*Mary C. Jacobson* JSC  
Hon. Mary C. Jacobson, J.S.C.

Date: 3-15-04

Jane

CHRISTOPHER A. SEEGER\*\*  
STEPHEN A. WEISS\*  
DAVID R. BUCHANAN\*\*  
SETH A. KATZ\*  
DIOGENES P. KEKATOS\*

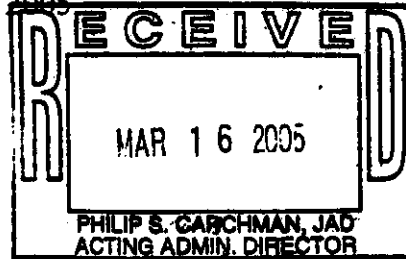
MICHAEL L. ROSENBERG\*\*  
MARC S. ALBERT\*\*

ADMITTED IN  
\*NJ, \*NY, \*CT  
\*MA, \*PA  
\*COUNSEL

SEEGER WEISS LLP  
ATTORNEYS AT LAW  
550 BROAD STREET  
NEWARK, NEW JERSEY 07102-4573  
(973) 639-9100  
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AMY P. ALBERT\*\*  
ERIC T. CHAFFIN\*\*  
PATRICIA D. CODEY\*  
DONALD A. ECKLUND\*\*  
MICHAEL S. FARKAS\*\*  
JEFFREY S. GRAND\*  
ROOPAL P. LUHANA\*\*  
LAURENCE V. NASSIF\*\*  
JAMES A. O'BRIEN III\*\*  
ELIZABETH A. WALL\*\*

March 15, 2005



**BY FEDERAL EXPRESS**

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

**Re: Request for Designation of a Case as a Mass Tort**

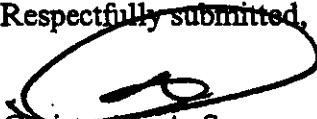
Dear Judge Carchman:

Further to our January 25, 2005 request for the Accutane litigation to be designated as a mass tort, we wanted to provide an update as to the number of cases currently pending in New Jersey. As you will recall, at the time of our request, there were approximately 68 total Accutane cases filed in New Jersey, with 62 cases pending before the Honorable Carol Higbee in Atlantic County and six cases pending before the Honorable Francine Schott in Essex County.

Presently, there are approximately 95 cases pending in New Jersey. All but six of those cases are pending in Atlantic County. In addition, we expect a substantial number of additional cases to be filed in the near future. It is important to note that two of the cases that were filed in Atlantic County subsequent to our January 25, 2005 request involve claims of psychiatric injuries.

For the reasons discussed in our January 25, 2005 request, along with the information contained above, plaintiffs, through their undersigned counsel, hereby respectfully request that all litigation, pending and subsequently filed, alleging damage arising from the ingestion of the acne drug Accutane, be consolidated as a mass tort to receive centralized case management.

Respectfully submitted,

  
Christopher A. Seeger

cc: The Honorable Carol E. Higbee (via overnight delivery)  
The Honorable Francine Schott (via overnight delivery)  
Michelle V. Perone, Esq. (via facsimile)

**RECEIVED**

MAR 22 2005

**GIVE PRACTICE**

David R. Buchanan , Esq.  
Michael L. Rosenberg, Esq.  
Michael Ryan, Esq. (via facsimile)  
Michael Hook, Esq. (via facsimile)  
Paul Smith, Esq. (via facsimile)  
Tim O'Brien, Esq. (via facsimile)

Michael R. Griffinger (via facsimile)  
Diane E. Lifton, Esq. (via facsimile)  
Bonnie Gallivan, Esq. (via facsimile)  
Kristine V. Ryan, Esq. (via facsimile)  
Allison B. Neidoff, Esq. (via facsimile)  
Michael X. Imbroscio, Esq. (via facsimile)  
Colleen H. Hennessey (via facsimile)

# GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE

A PROFESSIONAL CORPORATION

ATTORNEYS AT LAW

ONE RIVERFRONT PLAZA

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DIRECT FACSIMILE

(973) 639-6216

[difton@gibbonslaw.com](mailto:difton@gibbonslaw.com)

DIANE E. LIFTON

Director

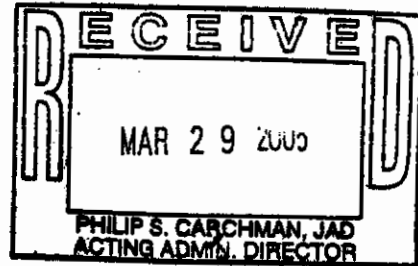
(973) 596-4805

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MAR 29 2005

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March 28, 2005



## VIA FEDERAL EXPRESS

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

### **Re: Opposition to Mass Tort Designation of Cases Involving Accutane**

Dear Judge Carchman:

Please allow this letter to supplement the March 10, 2005 letter brief submitted by Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Roche") in opposition to the January 25, 2005 application by the Accutane Litigation Group<sup>1</sup> for mass tort designation of New Jersey cases involving Accutane. Following service of the Roche submission, the Seeger Weiss law firm submitted a letter, dated March 15, 2005, purporting to update the Court as to the number of cases currently pending in New Jersey. The letter advised the court of the additional 27 cases filed in Atlantic County and specifically highlighted two additional cases recently filed in Atlantic County that involve claims of psychiatric injury. The referenced cases are Lake v.

<sup>1</sup> In addition to the Seeger Weiss firm as New Jersey counsel, according to correspondence received from the law firm of Michael Hook, The Accutane Litigation Group consists of Krupnick Campbell; Paul Smith and Associates; Beggs & Lane; Hook, Bolton, Kirkland & McGhee; Levin, Papantonio; Thomas, Mitchell, Echsner & Proctor; Campbell, Waller & Poer; and the McNulty firm.

#825303 v1  
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Hoffmann-La Roche Inc., Docket No. ATL-L-1276-05 and Fernuik v. Hoffmann-La Roche Inc.,  
Docket No. ATL-L-1753-05.

Roche submits that the filing of the additional matters in Atlantic County provides no basis to approve the Mass Tort Designation Application, particularly since, as stated in Roche's original opposition, the majority of those cases likely are time-barred and their viability questionable. Moreover, for the reason set forth in our original opposition papers, the matters alleging psychiatric adverse events are more appropriately venued in Essex County. Accordingly, concomitant with the filing of this letter, Defendants are moving to transfer the venue of the recently-filed Lake and Fernuik cases to Essex County.

As stated more fully in the transfer of venue moving papers, copies of which are enclosed herewith, Defendants in those cases seek a change of venue in the interests of justice and judicial economy. Five other cases that allege claims involving the ingestion of Accutane® and alleged psychiatric adverse effects are pending before the Honorable Francine A. Schott in Essex County. These actions involve the same complex issues of liability and medical causation, and discovery on the issues involves multiple experts and fact witnesses specific to the claimed psychiatric effects, as well as a significant amount of documents. Because the cases are complex and allege similar causes of action and allege similar injuries as matters pending in Essex County, it makes plain and practical sense that, like the others, the Lake and Fernuik actions should be managed by Judge Schott in Essex County.

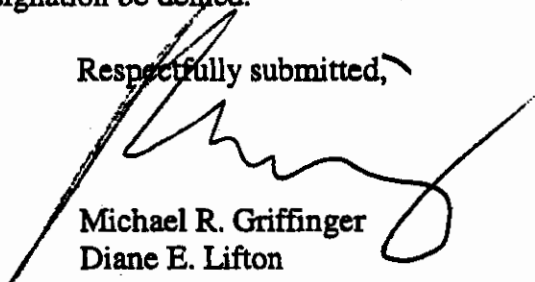


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In addition, Roche recently filed a motion for summary judgment in Turney v. Hoffmann-La Roche Inc., Docket No. ESX-L-5143-02, one of the psychiatric matters pending in Essex County. As indicated by the filing of that motion, and by the pre-trial schedule recently issued by Judge Schott in Palazzolo v. Hoffmann-La Roche Inc., ESX-L-5498-99, the matters pending in Essex County are ready for disposition and, therefore, should not be transferred to Atlantic County pursuant to a Mass Tort designation. Such a transfer will only delay a resolution of these matters on the merits.

For these and the other reasons outlined in the March 10, 2005 letter, Roche respectfully requests that the application for Mass Tort Designation be denied.

Respectfully submitted,



Michael R. Griffinger  
Diane E. Lifton

DEL/cag  
Enclosures

cc: The Honorable Francine Schott (via overnight delivery)  
The Honorable Carol E. Higbee (via overnight delivery)  
Michelle V. Perone, Esq. (via overnight delivery)

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Exhibit A

BRANDI MARIE LAKE,

Plaintiff,

v.

HOFFMAN-LA ROCHE, INC., ROCHE  
LABORATORIES, INC., F. HOFFMAN-  
LA ROCHE, LTD., and ROCHE  
HOLDING, LTD.,

Defendants.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-001276-05

Civil Action

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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'  
MOTION TO CHANGE VENUE**

---

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GRIFFINGER & VECCHIONE**  
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Nicholas E. Pampell v. Hoffmann-La Roche Inc. et al.,  
Docket No. ESX-L-5144-02 ..... 3

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## **PRELIMINARY STATEMENT**

Defendants Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Defendants") submit this memorandum of law in support of their motion pursuant to Rule 4:3-3 of the New Jersey Rules of Court seeking an order changing the venue of this pharmaceutical product liability action involving the prescription drug Accutane® and allegations of psychiatric injury from the Superior Court of New Jersey, Atlantic County, to the Superior Court of New Jersey, Essex County. Defendants seek this change in the interests of justice and judicial economy. Five other cases that allege claims involving the ingestion of Accutane® and alleged psychiatric adverse effects are pending before the Honorable Francine A. Schott in Essex County. These actions involve similar complex issues of liability and medical causation, and discovery on these issues involves multiple experts and fact witnesses specific to the claimed psychiatric effects, as well as a significant amount of documents. Because the cases are complex, allege similar causes of action, and allege similar injuries, it makes plain and practical sense that, like the others, this action should be managed by Judge Schott in Essex County. Moreover, Defendants' principal place of business is in Essex County, as are their witnesses and documents, while Plaintiff does not even reside in the State of New Jersey. Therefore, Defendants submit that in this matter, as between Essex County and Atlantic County, the proper venue is Essex County.

## RELEVANT STATEMENT OF FACTS

In this pharmaceutical drug product liability action, Plaintiff Brandi Marie Lake ("Plaintiff"), a resident of the state of Illinois, filed a complaint against Defendants for injuries she alleges stem from her ingestion of Accutane® (isotretinoin), a prescription drug indicated for treatment of severe recalcitrant nodular acne. Specifically, the Complaint alleges that, as a result of taking Accutane®, Plaintiff suffers from "severe injury manifesting itself in psychological injury including but not limited to depression, thoughts of suicide, suicidal ideation, emotional instability, uncontrollable impulse, delirium, frenzy, rage, aggressive behavior, acting without conscious volition and other psychological and/or emotional injury." See Complaint, annexed to the Certification of Shira Rosenman ("Rosenman Cert.") at Exhibit A, ¶ 21.

### Essex County Actions

Beginning six years ago, seven other actions were commenced against Defendants in Essex County, each of which allege psychiatric claims similar to those in the instant matter. Each of these cases alleged that, as a result of their ingestion of Accutane®, plaintiffs suffered from psychiatric injuries including depression, attempted suicide, suicide ideation and suicide. Each involve similar complex issues of liability and causation, including whether the Accutane® package insert, which contained information regarding depression for over twenty years, adequately warned the prescribing physicians of potential psychiatric adverse events and whether there is a causal link between the ingestion of Accutane® and psychiatric injuries. These actions are: Virginia Palazzolo et al. v. Hoffmann-La Roche Inc., Docket No. ESX-L-5498-99<sup>1</sup>; Robert Rowe v. Hoffmann-La Roche Inc., Docket No. ESX-L-2971-01<sup>2</sup>; Casey Balsham v. Hoffmann-La Roche Inc., Docket No. ESX-L-5808-01; Donna Cheek v. Hoffmann-La Roche Inc. et al., Docket No. ESX-L-7983-01; Douglas Hoefs v. Hoffmann-La Roche Inc. et al., Docket No. ESX-

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<sup>1</sup> Plaintiffs Jessica Boers, Arie Boers, and Jane Boers voluntarily dismissed their claims against Defendants following a ruling on Arie and Jane Boers' motion for a protective order regarding the discoverability of their mental health histories for purposes of addressing alternate causation.

<sup>2</sup> The Court granted summary judgment in Defendants' favor in Rowe, finding that Michigan law precluded plaintiff's product liability claims for psychiatric injuries.

L-8357-01<sup>3</sup>; Matthew M. Turney et al. v. Hoffmann-La Roche Inc. et al., Docket No. ESX-L-5143-02; and Nicholas E. Pampell v. Hoffmann-La Roche Inc. et al., Docket No. ESX-L-5144-02. See Complaints attached to Rosenman Cert. at Exhibit B. The five remaining actions are pending before the Honorable Francine A. Schott in Essex County.

But for expert discovery and related motion practice, and in some instances depositions of case specific witnesses, these five cases are trial-ready or nearly so. Indeed, Plaintiffs have indicated that they already have evidence of liability and an expert on the issue of causation, thereby demonstrating their readiness to proceed to trial. Thus, at the most recent Case Management Conference on March 21, 2005, Judge Schott set these cases on the path to trial, and ordered, inter alia, that (i) Plaintiffs are to designate experts by July 11, 2005 and provide expert reports by August 22, 2005; (ii) Defendants are to designate experts by July 18, 2005 and provide expert reports by September 19, 2005; (iii) expert depositions by both parties shall be completed by October 31, 2005; and (iv) the trial will proceed in January 2006.

#### Atlantic County Actions

Until this action and Ronald Andrew Fernuik v. Hoffman-La Roche, Inc. et al., Docket No. ATL-L-001753-05, were filed, there were no cases before this Court in Atlantic County alleging that Accutane® caused psychiatric injuries. To date, actions involving alleged gastrointestinal adverse events as a result of the ingestion of Accutane® have been filed in or transferred to Atlantic County, and are pending before this Court. The first of these actions was only recently filed, in late 2003. Most of the actions alleging gastrointestinal adverse events are in their infancy, having only just begun the discovery process.

#### Plaintiffs' Application for Mass Tort Designation

Despite the clear centralization of each of the psychiatric and gastrointestinal actions filed in Essex County and Atlantic County, respectively, the plaintiffs in all of these actions recently

<sup>3</sup> Plaintiff Douglas Hoefs voluntarily dismissed his claims against Defendants following a ruling on Defendants' motion to compel the plaintiff to appear in New Jersey for a deposition.



sought mass tort designation of all of the Accutane® cases, regardless of injury, only one week after Judge Schott stated that the psychiatric cases would be set for trial forthwith.

On March 10, 2005, Defendants opposed the application, arguing that (i) the cases are already centralized by injury before this Court and Judge Schott and (ii) the legal issues attendant to each injury are so distinct as to render them unfit for mass tort designation. Defendants also argued that because the psychiatric and gastrointestinal actions are at such different stages in discovery, mass tort designation would only serve to unnecessarily delay the psychiatric actions.

This action is a pharmaceutical product liability actions that involves complex issues of liability and medical causation and shares similar claims and injuries with the five other psychiatric actions pending in Essex County. In the interests of justice and judicial economy, if this matter remains in New Jersey,<sup>4</sup> Defendants submit that the appropriate venue for this action is Essex County.

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<sup>4</sup> Defendants reserve the right to challenge the appropriateness of a New Jersey forum for this action.

## ARGUMENT

### IN THE INTERESTS OF JUSTICE AND JUDICIAL ECONOMY, THE PROPER NEW JERSEY VENUE FOR THIS ACTION IS ESSEX COUNTY

The Rules Governing the Courts of the State of New Jersey require venue to be laid by the plaintiff in accordance with the provisions of Rule 4:3-2. However, “[v]enue requirements are not jurisdictional...they are rules of practice designed to place litigation at a location convenient to parties and witnesses...Accordingly, an action may be changed from one venue to another where the convenience of parties and witnesses is not served by strict application of venue rules.” State of N.J., Dep’t of Envtl. Prot. v. Middlesex County Bd. of Chosen Freeholders, 206 N.J. Super. 414, 420 (Super. Ct. Ch. Div. 1985) (citing R. 4-3:3(a)(3)); Diodato v. Camden County Park Comm’n, 136 N.J. Super. 324, 327-328 (App. Div. 1975); Doyley v. Schroeter, 191 N.J. Super. 120, 123, 126-28 (Super. Ct. Law Div. 1983); Engel v. Gosper, 71 N.J. Super. 573 (Super. Ct. Law Div. 1962)). Thus, notwithstanding a plaintiff’s discretion to select the place of venue in the first instance, the Rules expressly permit change of venue “for the convenience of parties and witnesses in the interest of justice.” R. 4:3-3(a).

As noted above, five other cases alleging psychiatric injuries are pending before Judge Schott in Essex County. Like this case, the five Essex County cases are pharmaceutical product liability actions alleging that plaintiffs’ ingestion of Accutane® caused psychiatric adverse events. Like this case, the five Essex County cases each involve the same complex issues of liability and medical causation, including whether the product warnings regarding potential psychiatric injuries are adequate and whether Accutane® is capable causing psychiatric injuries. Like this case, the five Essex County cases assert causes of action for failure to warn, negligence, misrepresentation, and violations of the New Jersey Product Liability Act. Given the obvious similarities between the Essex County cases and the instant matter, it makes economic and practical sense for this case to be managed by Judge Schott in Essex County.

Change of venue will undoubtedly serve the interests of judicial economy. Having all cases alleging psychiatric injuries located in Essex County before one judge will conserve judicial resources by having only one judge become familiar with and adjudicate the complex scientific and medical issues germane to the alleged psychiatric adverse events.

For the last six years, the aforementioned psychiatric cases have been efficiently and effectively managed in Essex County. Since the filing of the first Essex County action alleging that Accutane® caused plaintiffs to suffer from psychiatric injuries, massive amounts of discovery, including document production and depositions, have taken place in the Essex County psychiatric cases. Additionally, many orders have been entered in the psychiatric actions, all of which create the law of these cases. The prior presiding judge in the Accutane® psychiatric cases pending in Essex County, the Honorable Mary C. Jacobson, alone entered nine consecutive Case Management Orders that, inter alia, defined the scope of discovery. In the last year, Judge Schott has decided key discovery issues unique to the psychiatric actions, such as permitting Defendants to obtain plaintiffs' parents' records relating to their mental health histories pertinent to the issue of whether Accutane®, or other factors such as genetics, caused each plaintiff's psychiatric problems. A number of the psychiatric cases pending before her are now proceeding to expert discovery. Judge Schott's hands-on approach to managing the psychiatric cases to the advanced stage at which they are today ensures that she will be intimately familiar with the complex issues regarding whether the product warnings are adequate and whether Accutane® is capable causing psychiatric injuries. Therefore, Judge Schott is uniquely qualified to manage the instant action.

This Court, in connection with the pending gastrointestinal cases, will address whether, as a matter of law, the Accutane® package insert, which has contained information regarding gastrointestinal symptoms for more than twenty years, provided adequate information to the prescribing physicians. Meanwhile, Judge Schott has been and continues to be immersed in the legal, factual and scientific details of the actions alleging psychiatric injuries. In the cases

pending before Judge Schott, the issue will be whether the package insert adequately warned the prescribing physicians of potential psychiatric adverse events and whether there is a causal link between the ingestion of Accutane® and psychiatric injuries - issues that are factually and scientifically distinct from those in the gastrointestinal action.

In addition to addressing these issues in the trial set cases, currently pending before Judge Schott is a motion for summary judgment in Turney et al. v. Hoffmann-La Roche Inc. et al., which motion seeks a determination that the package insert was adequate as a matter of law. Clearly, changing the venue of the instant action from Atlantic County to Essex County, where the issues in this case are advanced and being actively adjudicated, will serve the interests of judicial economy.

Finally, Plaintiff cannot assert prejudice by a change in venue. Plaintiff is a resident of the State of Illinois and, therefore, it is of no consequence to her in which county in New Jersey this matter will proceed.<sup>5</sup> Meanwhile, Defendants' principal place of business is in Nutley, New Jersey, which city is in Essex County.

Therefore, in the interests of judicial economy and justice, Defendants respectfully request that venue be changed to Essex County.

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<sup>5</sup> Although a plaintiff has discretion to chose his or her forum, courts disapprove of inappropriate forum shopping or, in this case, venue-shopping, particularly where, as here, it appears the foreign Plaintiff's ties to the forum are tenuous.

**CONCLUSION**

For the foregoing reasons, Defendants respectfully request that, pursuant to Rule 4:3-3, the Court change the venue in this matter from the Law Division, Atlantic County to the Law Division, Essex County.

Respectfully submitted,

**GIBBONS, DEL DEO, DOLAN,  
GRIFFINGER & VECCHIONE**  
A Professional Corporation  
Attorneys for Defendants  
Hoffmann-La Roche Inc. and  
Roche Laboratories Inc.

By: \_\_\_\_\_



Diane E. Lifton

Dated: March 28, 2005

Exhibit B

RONALD ANDREW FERNUK,

Plaintiff,

v.

HOFFMAN-LA ROCHE, INC., ROCHE  
LABORATORIES, INC., F. HOFFMAN-  
LA ROCHE, LTD., and ROCHE  
HOLDING, LTD.,

Defendants.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-001753-05

Civil Action

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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'  
MOTION TO CHANGE VENUE**

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GRIFFINGER & VECCHIONE**  
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Roche Laboratories Inc.

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## PRELIMINARY STATEMENT

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### Essex County Actions

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<sup>1</sup> Plaintiff also includes "gastrointestinal problems" as an alleged injury in his Complaint. *Id.* However, unlike his alleged psychiatric injuries, Plaintiff fails to articulate with any specificity what those "gastrointestinal problems" might be. Indeed, Plaintiffs' counsel characterized this action as a psychiatric injury action in their supplemental letter brief in support of their application for Mass Tort designation. See Plaintiffs' Supplemental Letter Brief, annexed to Rosenman Cert. at Exhibit B. Defendants submit that the inclusion of the phrase "gastrointestinal problems" is merely an attempt by Plaintiff to keep this action in Atlantic County.

<sup>2</sup> Plaintiffs Jessica Boers, Arie Boers, and Jane Boers voluntarily dismissed their claims against Defendants following a ruling on Arie and Jane Boers' motion for a protective order regarding the discoverability of their mental health histories for purposes of addressing alternate causation.

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filed, in late 2003. Most of the actions alleging gastrointestinal adverse events are in their infancy, having only just begun the discovery process.

**Plaintiffs' Application for Mass Tort Designation**

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This action is a pharmaceutical product liability actions that involves complex issues of liability and medical causation and shares similar claims and injuries with the five other psychiatric actions pending in Essex County. In the interests of justice and judicial economy, if this matter remains in New Jersey,<sup>5</sup> Defendants submit that the appropriate venue for this action is Essex County.

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<sup>5</sup> Defendants reserve the right to challenge the appropriateness of a New Jersey forum for this action.

## ARGUMENT

### IN THE INTERESTS OF JUSTICE AND JUDICIAL ECONOMY, THE PROPER NEW JERSEY VENUE FOR THIS ACTION IS ESSEX COUNTY

The Rules Governing the Courts of the State of New Jersey require venue to be laid by the plaintiff in accordance with the provisions of Rule 4:3-2. However, “[v]enue requirements are not jurisdictional...they are rules of practice designed to place litigation at a location convenient to parties and witnesses...Accordingly, an action may be changed from one venue to another where the convenience of parties and witnesses is not served by strict application of venue rules.” State of N.J., Dep’t of Env’t. Prot. v. Middlesex County Bd. of Chosen Freeholders, 206 N.J. Super. 414, 420 (Super. Ct. Ch. Div. 1985) (citing R. 4-3:3(a)(3)); Diodato v. Camden County Park Comm’n, 136 N.J. Super. 324, 327-328 (App. Div. 1975); Doyley v. Schroeter, 191 N.J. Super. 120, 123, 126-28 (Super. Ct. Law Div. 1983); Engel v. Gosper, 71 N.J. Super. 573 (Super. Ct. Law Div. 1962)). Thus, notwithstanding a plaintiff’s discretion to select the place of venue in the first instance, the Rules expressly permit change of venue “for the convenience of parties and witnesses in the interest of justice.” R. 4:3-3(a).

As noted above, five other cases alleging psychiatric injuries are pending before Judge Schott in Essex County. Like this case, the five Essex County cases are pharmaceutical product liability actions alleging that plaintiffs’ ingestion of Accutane® caused psychiatric adverse events. Like this case, the five Essex County cases each involve the same complex issues of liability and medical causation, including whether the product warnings regarding potential psychiatric injuries are adequate and whether Accutane® is capable causing psychiatric injuries. Like this case, the five Essex County cases assert causes of action for failure to warn, negligence, misrepresentation, and violations of the New Jersey Product Liability Act. Given the obvious similarities between the Essex County cases and the instant matter, it makes economic and practical sense for this case to be managed by Judge Schott in Essex County.

Change of venue will undoubtedly serve the interests of judicial economy. Having all cases alleging psychiatric injuries located in Essex County before one judge will conserve judicial resources by having only one judge become familiar with and adjudicate the complex scientific and medical issues germane to the alleged psychiatric adverse events.

For the last six years, the aforementioned psychiatric cases have been efficiently and effectively managed in Essex County. Since the filing of the first Essex County action alleging that Accutane® caused plaintiffs to suffer from psychiatric injuries, massive amounts of discovery, including document production and depositions, have taken place in the Essex County psychiatric cases. Additionally, many orders have been entered in the psychiatric actions, all of which create the law of these cases. The prior presiding judge in the Accutane® psychiatric cases pending in Essex County, the Honorable Mary C. Jacobson, alone entered nine consecutive Case Management Orders that, inter alia, defined the scope of discovery. In the last year, Judge Schott has decided key discovery issues unique to the psychiatric actions, such as permitting Defendants to obtain plaintiffs' parents' records relating to their mental health histories pertinent to the issue of whether Accutane®, or other factors such as genetics, caused each plaintiff's psychiatric problems. A number of the psychiatric cases pending before her are now proceeding to expert discovery. Judge Schott's hands-on approach to managing the psychiatric cases to the advanced stage at which they are today ensures that she will be intimately familiar with the complex issues regarding whether the product warnings are adequate and whether Accutane® is capable causing psychiatric injuries. Therefore, Judge Schott is uniquely qualified to manage the instant action.

This Court, in connection with the pending gastrointestinal cases, will address whether, as a matter of law, the Accutane® package insert, which has contained information regarding gastrointestinal symptoms for more than twenty years, provided adequate information to the prescribing physicians. Meanwhile, Judge Schott has been and continues to be immersed in the legal, factual and scientific details of the actions alleging psychiatric injuries. In the cases

pending before Judge Schott, the issue will be whether the package insert adequately warned the prescribing physicians of potential psychiatric adverse events and whether there is a causal link between the ingestion of Accutane® and psychiatric injuries - issues that are factually and scientifically distinct from those in the gastrointestinal action.

In addition to addressing these issues in the trial set cases, currently pending before Judge Schott is a motion for summary judgment in Turney et al. v. Hoffmann-La Roche Inc. et al., which motion seeks a determination that the package insert was adequate as a matter of law. Clearly, changing the venue of the instant action from Atlantic County to Essex County, where the issues in this case are advanced and being actively adjudicated, will serve the interests of judicial economy.

Finally, Plaintiff cannot assert prejudice by a change in venue. Plaintiff is a resident of the State of Texas and, therefore, it is of no consequence to him in which county in New Jersey this matter will proceed.<sup>6</sup> Meanwhile, Defendants' principal place of business is in Nutley, New Jersey, which city is in Essex County.

Therefore, in the interests of judicial economy and justice, Defendants respectfully request that venue be changed to Essex County.

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<sup>6</sup> Although a plaintiff has discretion to chose his or her forum, courts disapprove of inappropriate forum shopping or, in this case, venue-shopping, particularly where, as here, it appears the foreign Plaintiff's ties to the forum are tenuous.

**CONCLUSION**

For the foregoing reasons, Defendants respectfully request that, pursuant to Rule 4:3-3, the Court change the venue in this matter from the Law Division, Atlantic County to the Law Division, Essex County.

Respectfully submitted,

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By: 

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