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March 10, 2005

CIVIL PRACTICE

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 Group¹ 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

¹ 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 judges², 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") (psychiatric³ and gastrointestinal conditions (virtually all inflammatory bowel disease (IBD)⁴ 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

² 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.

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

⁴ 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).

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

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.⁵

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

⁵ 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.⁶ 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)

⁶ 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 Wright⁷ 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

⁷Virginia 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)⁸.

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.

⁸ 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*⁹ 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*

⁹ *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*¹⁰, 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

¹⁰ 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

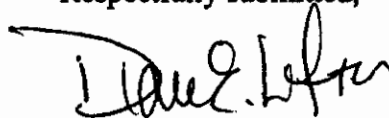
Hon. Philip S. Carchman, J.A.D.

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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)

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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 _____)
7 TAYLOR,)
8 Plaintiff,) DOCKET NO. ESX-L-5645-03
9 Vs.)
10 HOFFMAN-LA ROCHE, INC.,)
11 Defendant.)
12 _____)
13 WEBER,)
14 Plaintiff,) DOCKET NO. ESX-L-1965-03
15 Vs.)
16 HOFFMAN-LA ROCHE, INC.,)
17 Defendant.)

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

20 Date: January 18, 2005
21 Volume 2 of 2

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

Sound Recorded
Recording Operator,

1 THE COURT: Let's do this, we'll make it for
2 Friday, February 18th 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

FILED

JAN 26 2004

CAROL E. HIGBEE, J.S.C.

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Hoffmann-La Roche Inc. and
Roche Laboratories Inc.

ANDREW McCARRELL,

Plaintiff,

vs.

HOFFMANN LA ROCHE, INC. and ROCHE
LABORATORIES INC.

Defendants.

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 26th 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~~ 4, 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

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 19th 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.

FILED

FEB 01 2005

CAROL E. HIGBEE, J.S.C.

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

CASE MANAGEMENT ORDER NO. 3

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
EILBEN FIELDS,

Plaintiffs,

v.

HOFFMANN-LA ROCHE INC. and
ROCHE LABORATORIES INC.

Defendants.

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 1st 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.

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 Crlaks	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
Jamie Nichole Fields and Elizabeth Eileen Fields	v.	Hoffmann-La Roche Inc. and Roche Laboratories Inc.	ESX-L-10325-03
Patrick Flaherty	v.	Hoffmann-La Roche Inc.; Roche Laboratories Inc.; F. Hoffmann-La Roche, Ltd.; and Roche Holding, Ltd.	ATL-L-3255-04

SCHEDULE A

Plaintiff		Defendant	
Gillian 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
Chakendra 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 Mayhom	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

		DEFENDANT	CASE NO.
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 Turcotte	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-3260-04
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	Cause of Action	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
MAYS LANDING, NJ 08330

DATE: FEBRUARY 8, 2005

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

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

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

PALAZZOLO,)
)
Plaintiff,)
)
vs.)
)
HOFFMANN-LAROCHE INC.,)
)
Defendant.)

TRANSCRIPT
OF
CASE MANAGEMENT
CONFERENCE

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

Date: February 18, 2005

BEFORE:

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

TRANSCRIPT ORDERED BY:

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

APPEARANCES:

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

MICHAEL RYAN, ESQ. (Pro Hac Vice)

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

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.

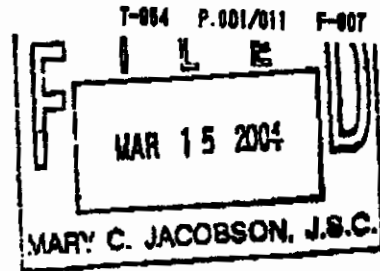
15 Just be sure and have that conversation
16 between yourselves and exchange between yourselves
17 prior to that management conference. And submit to me,
18 make it the Thursday before the conference an outline
19 of what areas remain what you agree remains in dispute
20 from what you might dispute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

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.,
Plaintiffs,

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ESSEX COUNTY

v.

DOCKET NO.: ESX-L-5498-99

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

CONSENT PROTECTIVE ORDER
REGARDING DISCLOSURE OF
CONFIDENTIAL DOCUMENTS

ROBERT ROWE,
Plaintiff,

v.

DOCKET NO.: ESX-L-2971-01

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

CASEY BALSHAM,
Plaintiff,

v.

DOCKET NO.: ESX-L-5808-01

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

DONNA CHEEK,
Plaintiff,

v.

DOCKET NO.: ESX-L-7983-01

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

DOUGLAS HOEFS, ET AL.,
Plaintiff,

v.

DOCKET NO.: ESX-L-8357-01

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

22-Mar-2004 11:18am From

T-054 P.002/011 F-007

MATTHEW M. TURNEY, ET AL.,

Plaintiffs,

v.

HOFFMANN-LA ROCHE INC., ET AL.,

DOCKET NO.: ESX-L-5143-02

Defendants

22-Mar-2004 11:18am From-

T-054 P.003/011 F-007

NICHOLAS E. PAMPELL,

Plaintiff,

v.

HOFFMANN-LA ROCHE INC., ET AL.,

Defendants

DOCKET NO.: ESX-L-5144-02

22-Mar-2004 11:10am From

T-984 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

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T-954 P.008/011 F-907

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

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T-854 P.004/011 F-007

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.

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T-854 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.

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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.

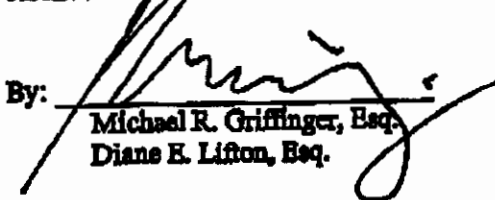
15. The disclosure of Confidential Material produced in this case or Confidential information contained therein to any person not qualified to receive such information pursuant to this Order and subject to its terms, or without following the terms and conditions of this Order, may subject the person 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-854 P.000/011 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 E. Lifton, Esq.

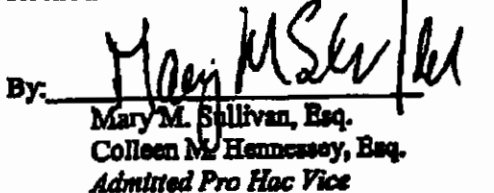
Dated:

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

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

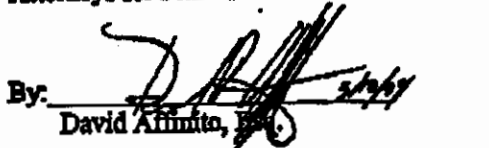
Dated:

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

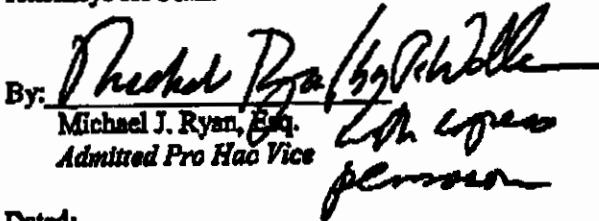
Dated:

DELL'ITALIA, AFFINITO, SANTOLA
Attorneys for Plaintiffs

By: 
David Affinito, Esq.

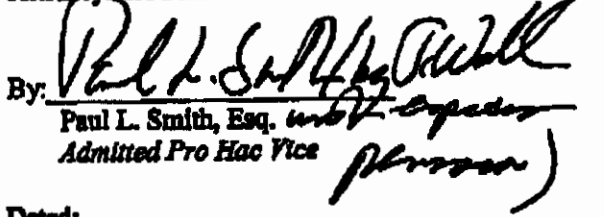
Dated:

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

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

Dated:

PAUL L. SMITH & ASSOCIATES
Attorneys for Plaintiffs

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

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 10:00

T-854 P.010/011 F-907

11-Mar-2004 07:30am From

T-724 P.010/010 F-004

LAW OFFICES OF PETER J. McNULTY
Attorneys for Plaintiffs

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

Date:

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

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

Date: 3-10-04

SO ORDERED:

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

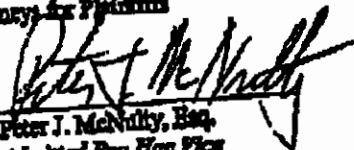
Date: 3-15-04

22-Mar-2004 11:12am From

T-954 P.011/011 F-007
P-734 P.010/010 F-004

11-Mar-2004 07:36am From

LAW OFFICES OF PETER J. McNULTY
Attorneys for Plaintiffs

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

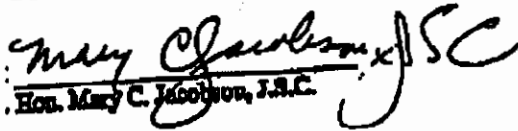
Date:

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

By: _____
Michael D. Hook, Esq.

Date:

SO ORDERED:


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

Date: 3-15-04