THE HONORABLE BARBARA J. ROTHSTEIN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

IN RE: PHENYLPROPANOLAMINE (PPA) PRODUCTS LIABILITY LITIGATION This document relates to the actions listed on Attachment A	MDL No. 1407 FINAL MDL PRETRIAL ORDER

FINAL MDL PRETRIAL ORDER

This Final MDL Pretrial Order describes the events that have taken place in MDL 1407 and those items that require further action by the transferor court. A copy of this Final MDL Pretrial Order, along with the case file and materials, will be provided to the transferor court.

I. INTRODUCTION

On August 28, 2001, the Judicial Panel for Multidistrict Litigation ("JPML") designated this Court as the transferee court for all individual, consumer class and other federal cases arising out of the sale or use of over-the-counter cough/cold and appetite suppressant products containing phenylpropanolamine ("PPA") for pre-trial consolidation and coordination. *In re: Phenylpropanolamine ("PPA") Products Liability Litigation*, MDL No. 1407.

The proceedings in this MDL 1407 began in earnest with the Order re: Initial Conference dated November 1, 2001, requiring plaintiffs and defendants to submit proposed committee rosters, and scheduling the initial conference for November 16, 2001. Since then: (1) generic fact discovery has been completed or substantially completed as to most MDL defendants (including written discovery, document production and review, discovery depositions and requests for admissions); (2) a procedure for case-specific fact discovery in each case has been implemented, and discovery has been underway since 2002; (3) Rule 26 disclosures of generic experts have been made, the discovery depositions of those experts have been completed, and a process to permit the adoption of those experts' opinions in other cases transferred or being transferred to this MDL has been adopted; (4) trial preservation depositions of several of plaintiffs' and defendants' generic experts are underway or have been taken; (5) and the Court has resolved *Daubert* motions challenging plaintiffs' expert opinions solely as to general causation.

Beginning in August 2005, the Court entered emergency orders temporarily staying proceedings in cases within the MDL affected by Hurricanes Kathrina and Rita. All such stays and extensions thereto have now expired.

Given the foregoing, the Court is satisfied that this MDL has sufficiently matured and the Court has issued a Suggestion of Remand for the cases listed on Attachment A to facilitate their remand by the JPML to their transferor courts for further case-specific proceedings, including designation and discovery of case-specific experts, independent medical examinations, pre-trial motion practice and final disposition.

Below is a more detailed overview of the proceedings in MDL 1407 to date.

II. ADMINISTRATION OF CASES

A. Lead and Liaison Counsel.

By order entered on November 20, 2001, this Court appointed and assigned certain responsibilities to Lead and Liaison Counsel for Plaintiffs and Defendants. (Order Appointing Lead and Liaison Counsel (signed Nov. 19, 2001, entered Nov. 20, 2001). The responsibilities of each are delineated in Memorandum in Support of Proposed Language Ordered by the Court in its November 1, 2001, "Order re: Initial Conference" (Nov. 14, 2001) (hereinafter, "Memo Nov. 14, 2001")). On January 22, 2007, the Court entered CMO 21, relieving certain attorneys and firms of their responsibilities under the November 2001 Order.

B. Committees.

The Court approved and appointed members to various committees designed to manage and advance the litigation, including the Plaintiff's Steering Committee ("PSC"). (Order Appointing Members to Plaintiffs' and Joint Committees (Jan. 17, 2002) (hereafter "Order Jan. 17, 2002")). As part of its duties and responsibilities, the PSC assists all plaintiffs in MDL 1407 by overseeing discovery (including conducting extensive discovery of each defendant), by communicating with plaintiff lawyers, by appearing before this Court, by attending status conferences and by preparing motions and responses regarding case-wide discovery matters. The PSC acts on behalf of or in consultation with Plaintiffs' Lead Counsel in the management of the litigation. (Order Jan. 17, 2002; Plaintiffs' Lead Counsels' Status Report No. 1 (Nov. 30, 2001)); Memo Nov. 14, 2001).

C. Common Benefit Fund.

In order to provide for costs and attorneys' fees that the PSC (and its appointed subcommittees) may be entitled to receive for providing case-wide services over the last several years, the court provided for sequestration of four (4%) percent of all payments made

by defendants in settlements or in satisfaction of judgments of cases transferred to MDL 1407, to be placed in escrow into the common benefit fund (a/k/a MDL 1407 Fee and Cost Trust Account). Similarly, in those state court cases where plaintiffs have agreed to coordinate with and use the MDL 1407 work product, the court provided for sequestration of three (3%) percent of all such payments. (The 4% and 3% payments are referred to collectively herein as "MDL Assessment"). The MDL Assessments are to be deposited by defendants into the common benefit fund and the total dollar amounts of these assessments are confidential. The common benefit fund will provide payment to PSC members and other common benefit attorneys for the PSC's work product to the extent that the court ultimately determines that the service was authorized, necessary and beneficial to plaintiffs. The MDL Assessment requirement applies to all MDL 1407 payments made by defendants to plaintiffs, regardless of whether a plaintiff's case is disposed of while on the MDL 1407 docket or following remand to the transferor court.

The Common Benefit fund is governed by Amended CMO 8 (Establishing Plaintiffs' Litigation Expense Fund to Compensate and Reimburse Attorneys for Services Performed and Expenses Incurred for Common Benefit), CMO 16 (Establishing MDL 1407 Fee and Cost Trust Account and Procedures) and CMO 20 (Establishing Common Benefit Fee Committee, Procedures, and Standards to Determine Compensable Fees and Costs). CMO 16 effectuates CMO 8 and details the procedures for (1) assessing and depositing these funds into the account; (2) protecting the confidentiality of the information submitted to and from the Trustee; (3) insuring the accuracy of the information provided; (4) reporting by the Trustee to Liaison Counsel; and (5) resolving assessment disputes. (CMO 16). CMO 20 establishes the Common Benefit Fee Committee, and sets forth (1) procedures for the review of common benefit fee and cost applications and subsequent responsibilities, and (2) standards for the review of common benefit fees and costs. (CMO 20).

D. State/Federal Coordination.

It became evident in the beginning of MDL 1407 that the extensive parallel state and federal PPA litigation, involving many of the same defendants and the same plaintiffs' counsel in both state and federal courts, warranted particular emphasis on coordinated discovery. To this end, the parties in state and federal court have jointly succeeded in reducing costs and expenses to themselves and the court system by coordinating most generic discovery proceedings. For example, depositions of defendant representatives and employees were all cross-noticed and, with few exceptions, witnesses were deposed only once for purposes of all cases in the country. Such was also the case during expert discovery. Finally, the parties' presentation of expert testimony under *Daubert* (*see infra* Part III.C.) was coordinated with many state court judges overseeing state court coordinated proceedings. Overall, serious efforts were made by the parties and this Court to achieve meaningful coordination, which were met with considerable success.

E. Denial of Class Certification.

The Court denied class certification in eight nationwide and one Louisiana statewide personal injury actions and in seven economic injury actions. (Order granting Defendants' Motion to Strike Class Allegations and Deny Class Certification (Jan. 5, 2002); Order Extending Court's June 5, 2002 Order Denying Class Certification to Additional Cases (Feb. 24, 2003); Order Denying Plaintiffs' Motion for Class Certification Pursuant to Rule 23(B)(3) for Economic Injury Claims (Sept. 4, 2003); (Order Denying Plaintiffs' Renewed Motion for Class Certification Pursuant to Rule 23(B)(3) for Economic Injury Claims (Feb. 7, 2003); Order Denying Certification of Kentucky Economic Injury Class (Nov. 5, 2003)).

III. DISCOVERY

This MDL has proceeded in a relatively quick and stream-lined fashion, thanks in large measure to the cooperation of the parties. Shortly after commencing this case in the winter

of 2001, the court began issuing Case Management Orders ("CMOs") to govern most case-wide issues, as well as case-specific orders. The Court entered 21 CMOs, as well as supplements to them. Some of the specific CMOs are discussed, *infra*, expanding on their specific subject matter. All CMOs are accessible at the Court's website, (www.wawd.uscourts.gov/ wawd/mdl.nsf/main/page.) The primary orders that governed the pretrial management of the discovery in this litigation are CMO Nos. 1, 2, 3, 6, 6A, 10, ~~and~~ 19 and 19A.

- CMO 1: established a protocol for generic fact discovery (governing, *inter alia*, written discovery, document production and depositions of defendants' corporate representatives and employees);
- CMO 2: set forth a confidentiality order;
- CMO 3: provided a document preservation order; and
- CMO 6, 6A, 10, 19 and 19A: established a protocol for case-specific fact discovery (governing, *inter alia*, written discovery (including a Fact Sheet and Records Authorizations, document production and depositions of plaintiffs and case-specific fact witnesses).

A. Generic Fact Discovery.

1. Document Discovery. Extensive fact discovery was conducted against defendants and was substantially completed against most defendants by mid-2003. In an effort to attain consistency and to avoid undue duplication, the parties negotiated and agreed substantially upon master sets of requests for production and interrogatories ("Master Set of Written Discovery") which are attached to CMO 1. No further general document requests or interrogatories were allowed to be propounded on defendants without leave of Court. To the extent that any defendant had previously produced documents and/or made responses to document requests or interrogatories also contained in the Master Set of Written Discovery

prior to January 21, 2002, those productions and/or responses were deemed responsive to the same requests contained in the Master Set of Written Discovery. (CMO 1 Parts V.E., V.F.).

Discovery was also conducted be the parties from Yale University and the various hospitals participating in the Hemorrhagic Stroke Project, from the trade association, the Consumer Healthcare Products Association, and from the U.S. Food and Drug Administration.

The PSC created a document depository located in Minneapolis, Minnesota, where millions of documents produced by defendants were stored, reviewed and digitized for use in discovery and for purposes of creating "trial packages" for all plaintiffs who were interested and who agreed to the set-aside percentage.

2. Depositions of Common Fact Witnesses. The basic principles governing the taking of depositions of defendants' non case-specific (generic) fact witnesses were set forth in CMO 1. Cross-notices between state court proceedings and the MDL proceedings were encouraged. (CMO 1 Part V.G.). In the interest of efficiency and federal-state coordination, several defendants cross-noticed the depositions of company witnesses, HSP Investigators and CHPA employees in their respective state court proceedings.

B. Case-Specific Fact Discovery.

The basic principles of governing the taking of fact discovery of plaintiffs were set forth in CMO 6 (case-specific fact discovery procedure and plan). Under CMO 6, later modified by CMO 10, cases docketed in the MDL by February 12, 2002, had case-specific discovery cut-off dates of February 28, 2003. Cases docketed after February 28, 2003, were to have case-specific discovery completed within 12 months of the docket date. (CMO 6 Part VI.). As discussed further below, however, due to numerous delays many of these case-specific discovery cut-off dates were extended.

1. Case-Specific Fact Discovery of Plaintiffs.

a. Plaintiff Fact Sheets (PFSs). Under CMO 6, plaintiffs in every case transferred to MDL 1407 were ordered to complete a plaintiff fact sheet (PFS). (CMO 6 Part II.A.). Plaintiffs were required to complete and serve on defendants' liaison counsel fact sheets. In the event of a plaintiff's failure to serve a completed PFS, defendants' liaison counsel was to send a warning letter to that plaintiff. If, within 30 days of a warning letter, the plaintiff had still failed to serve a completed PFS, defendants were able to seek appropriate relief from the Court if a meet and confer did not otherwise resolve the issue. (CMO 6 Part III.A.).

Under CMO 10, entered seven months after CMO 6, the Court ordered that no case would be considered for remand if any plaintiff had not completely complied with the discovery requirements of its prior orders, including the completion of a PFS. (CMO 10 ¶ 1). Failure to provide complete PFS responses tolled the period for completion of fact discovery, which would not run until one year after defendants' receipt of a completed PFS and its accompanying authorizations. (CMO 10 ¶ 3).

Finally, CMO 19 and 19A provide that defendants may file motions to dismiss based on a plaintiff's failure to timely file a PFS or cure a PFS that is not complete in all respects within fifteen days of notice of deficiencies.

b. Other Written Discovery. In addition to the PFS, defendants were entitled to propound ten (10) interrogatories and ten (10) requests for production (non-duplicative of any issue raised via PFS) on each plaintiff during the case-specific fact discovery time period. (CMO 6 Parts III.B.-III.C.). Plaintiffs were to serve responses to each type of request within 45 days of service of them. Upon remand, the parties may obtain updated medical records.

c. Depositions. Defendants were entitled to conduct ten (10) depositions of fact witnesses ("fact witnesses" include plaintiffs' treating physicians) as part of their case-specific discovery. (CMO 6 Part III.D.). Defendants were allowed to take additional depositions upon a showing of good cause. Upon remand, the parties may move the transferor court to take additional depositions including newly identified fact witnesses regarding plaintiff's current medical condition for good cause and necessity. In the event good cause and necessity is shown to update the plaintiff's deposition, shortened time limits may be imposed, depending on the circumstances.

2. Case-Specific Fact Discovery of Defendants. Plaintiffs were allowed to propound on defendants no more than ten (10) case-specific interrogatories and ten (10) case-specific document requests. (CMO 6 Part IV.A.-IV.B.). Plaintiffs were also allowed to conduct case-specific depositions of witnesses affiliated with defendants. (CMO 6 Part IV.C.).

B. Expert Discovery.

1. Generally. Expert discovery was divided into two main categories: generic experts (testifying regarding issues of general applicability, including general causation) and case-specific experts (testifying on behalf of a specific plaintiff). The Court ordered that only generic expert discovery would be conducted in the MDL, leaving case-specific expert discovery for completion upon remand. Under the process established by the MDL Court, experts were disclosed by certain members of the PSC and by defendants. Individual plaintiffs could then adopt those expert disclosures or disclose their own experts. If a plaintiff adopted the experts disclosed by certain members of the PSC with respect to any issues of widespread applicability, that plaintiff may nevertheless later designate different experts to testify at trial on the same issues provided: (1) the later-designated experts rely upon the same or substantially the same evidence, opinions and/or theories relied upon by the

PSC expert(s) adopted by that plaintiff; and (2) such opinions, evidence and/or theories have not been previously determined by the MDL to be scientifically unreliable or otherwise inadmissible. Similarly, a defendant may later may later designate expert(s) different from the generic expert(s) disclosed by defendants to testify at trial on the same issues provided that the later-designated expert(s) rely upon the same or substantially the same evidence, opinions and/or theories relied upon by defendants' previously disclosed generic expert(s). Expert-specific challenges, such as to the qualifications or specific causation opinions to the later-designated experts, are preserved. These issues are addressed more specifically in prior MDL Orders, including without limit MDL Order entered September 9, 2002.

Numerous general causation experts on behalf of both plaintiffs and defendants testified at their depositions. Discovery as to these experts was to be completed by March 10, 2003, with subsequently transferred cases subject to the provisions of CMO 9 which provides for the adoption of, or designation of experts on issues of general applicability. (Order re: Expert Discovery Schedule (Mar. 22, 2002) and CMO 9). Several general causation experts also testified at the *Daubert* hearing. A copy is attached hereto.

2. ***Daubert.*** On April 28 – May 1, 2003, the Court conducted hearings regarding the admissibility of plaintiffs' expert opinions as to general causation pursuant to Federal Rules of Evidence 702 and 703 and *Daubert v. Merrell Dow Pharms., Inc.* 509 U.S. 579 (1993). The Court entered its findings in its Order Granting in Part and Denying in Part MDL Defendants' Motion to Preclude Plaintiffs' Expert Opinions as to General Causation Pursuant to Fed. R. Evid. 702 and 703 and *Daubert,* on June 18, 2003.

3. **Case-Specific Expert Discovery.** Upon remand of the cases back to the transferor courts, case-specific expert discovery must be conducted. This will include scheduling of plaintiffs' and defendants' designations of case-specific experts, service of reports by the case-specific experts, depositions of case-specific experts and motion practice

relating to those experts. Case-specific experts consist of experts rendering opinions about the medical condition of specific plaintiffs, life-care planners, economists and other case-specific experts rendering non-medical opinions. This discovery may include independent medical examinations of plaintiffs. In contrast to the expert discovery in the MDL relating solely to general causation, case-specific experts will opine among other things on specific causation with regard to individual plaintiffs as well as damages.

IV. PRODUCT IDENTIFICATION ORDERS

A. Identification of Defendants and Products Ingested (CMO 13).

There were numerous cases pending in MDL 1407 that assert claims of individuals who allege to have ingested one or more PPA-containing products. Certain cases and/or plaintiffs listed numerous manufacturing defendants but failed to state with specificity which products they allegedly ingested and failed to identify the manufacturers of the products that allegedly caused their injuries. On May 2, 2003, the Court entered CMO 13 which required each plaintiff in a multi-defendant case to file and serve (within 30 days of entry of the order) an affirmation setting forth the PPA product he/she allegedly ingested and the manufacturer of that product. Defendants could then seek dismissals under CMO 13 for the claims of any plaintiffs who failed to identify them in the PFS, if any, and in their affirmations. (CMO 13).

Because of the potentially burdensome and unnecessary filings of numerous pages and documents, the parties submitted a proposed CMO 13A to the Court to streamline the dismissal process and minimize the amount of filings to obtain dismissals. CMO 13A provided the defendants whose products are not identified in a plaintiff's affirmation a mechanism for getting dismissed from the claims made by that plaintiff. (CMO 13A).

B. Severance of Multiple-Plaintiff Cases (CMO 15).

There were numerous cases pending in MDL 1407 that joined the unrelated claims of numerous plaintiffs who allege to have taken a PPA-containing product. The plaintiffs in these multi-plaintiff cases failed to specify which products they allegedly ingested and failed to identify the manufacturers of the products that allegedly caused their injuries. On May 29, 2003, the Court entered CMO 15, which required each plaintiff in a multi-plaintiff[1] case to file and serve an individual new complaint within 30 days of entry of the order. Under CMO 15, plaintiffs' individual complaints were to provide specific allegations regarding: (1) the products allegedly ingested; (2) the dates on which the products were ingested; (3) the injury alleged; and (4) the dates of injury. (CMO 15).

CMO 15A served as an adjunct to CMO 15 to give the parties a mechanism to resolve "non-compliant" served complaints and dismissal of original multi-plaintiff complaints. CMO 15A allowed defendants to move to dismiss with prejudice the original case as to those plaintiffs who failed to properly file an individual new complaint and as to those plaintiffs who filed an individual new complaint which did not identify a product manufactured by the moving defendant. (CMO 15A).

V. PROCEDURES FOR REMAND

A. Discovery to be Conducted Prior to Remand.

The Court entered CMO 17C, amended by CMO 18D, which details the procedures and conditions before a case will be considered "ripe for remand." (CMO 17C). The Court only considers a case ripe for remand if the discovery permitted by CMOs Nos. 1, 6, 6A, 10, 13, 13A, and 15 ("and any additional orders" entered by the Court) has been completed. All other generic fact and expert discovery permitted by the Court is considered time barred.

[1] "Multi-plaintiff cases" refer to cases that involve more than one plaintiff who alleges that they ingested a product containing PPA. This term does not refer to plaintiffs with derivative claims.

The remand process is initiated by defendants, on a monthly basis, filing a list of cases they believe have become ripe for remand during the preceding month. A plaintiff may also submit cases believed to be ripe. The Court then issues an Order to Show Cause why the cases listed on the Order should not be suggested for remand, setting dates for responses and replies. Once the Magistrate Judge has ruled on the objections to remand, the Court issues a Suggestion of Remand Order which is forwarded to the Judicial Panel On Multi-District Litigation. The Court will subsequently designate this Final MDL Pretrial Order, along with any supplements and/or amendments thereto, as the Final Pretrial Order in all cases for which the Panel issues an Order for Remand. (CMO 17C).

B. Remaining Discovery After Remand.

Case-specific expert discovery has been deferred pending remand. The transferor court has jurisdiction over setting the case-specific expert discovery schedule, any other case-specific discovery and any other pre-trial matters not addressed by this Court. (*See supra* Part III.C.3.).

C. MDL Mediation.

The parties have agreed upon a number of mediators from the following areas: California, Texas, Louisiana, Alabama, Mississippi, North Carolina, South Carolina, Tennessee, Northeast, Midwest and Northwest.

VI. SUMMARY OF ACTIVITIES UPON REMAND

The following activities remain to be completed upon remand of the cases listed on Attachment A and include but are not limited to:

- Case-specific expert designation and discovery;
- Independent medical examinations;
- Obtain updated medical records and, upon a showing of good cause and necessity, updating the plaintiff's deposition, and/or deposing additional or newly identified fact

witnesses. In the event good cause and necessity is shown to update the plaintiff's deposition, shortened time limits may be imposed, depending on the circumstances;

- Pending case-specific motions;
- Pretrial motion practice, including specific causation motions; and
- Final disposition.

VII. DOCUMENTS TO BE SENT TO TRANSFEROR COURT

The clerk of the transferee court will forward to the transferor court (electronically where feasible) a copy of: (1) this Pretrial Order and attachments; (2) the docket sheet for the particular case being remanded and all documents identified on that docket sheet; and (3) the docket sheet for MDL 1407. The docket sheet for each particular case being remanded will be deemed to include and incorporate all matters on the MDL 1407 docket sheet that refer or pertain to "all cases" or that otherwise refer or pertain to the particular case being remanded.

In the event a party believes that the docket sheet for a particular case being remanded is not correct or complete for any reason, a party to that case may, with notice to all other parties to the action, file with the transferor court a Designation Amending the Record. Upon receiving that Designation, the transferor court will make any needed changes to the docket. If the docket is revised to include additional documents, the parties should provide those documents to the transferor court.

VIII. CONCLUSION

This MDL Pretrial Order does not expand or modify any prior order of the Court. The Plaintiffs' Steering Committee and defendants have agreed that, upon receipt from the Judicial Panel of a final remand order for a particular case, this Pretrial Order is to be provided to the appropriate transferor court without the necessity of a motion by any party to that case.

DATED at Seattle, Washington this 7th day of September, 2007.

Barbara Jacobs Rothstein
U.S. District Court Judge