

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE DIET DRUGS (Phentermine/
Fenfluramine/Dexfenfluramine) :
PRODUCTS LIABILITY LITIGATION : MDL Docket No. 1203

PRETRIAL ORDER NO. 420
(Discovery of Ongoing Studies)

AND NOW, this 6th day of January, 1998 upon consideration of Plaintiffs' Motion for an Order Compelling Discovery Concerning Ongoing Medical Studies, Defendants' responses thereto and the Agreement of the parties, it is hereby

ORDERED, ADJUDGED and DECREED that:

1. A study is a "Currently Ongoing Study" within the meaning of this Order if it is not subject to the conditions described in paragraph 2 herein and it is a study involving the collection and analysis of data pursuant to a written protocol and data are being actively collected pursuant to the terms of the written protocol and no more than 150 days have passed since the conclusion of such data collection activities.

2. A study is not a "Currently Ongoing Study" within the meaning of this Order if:

A The results of the study have been accepted for publication or otherwise presented publicly; or

B. Those sponsoring or conducting the study have formed an intent to cancel, terminate or otherwise abandon the study, provided that such a determination will be conclusively presumed if those sponsoring or conducting the study have not conducted any work concerning the study for a period of ninety (90) days.

3. To the extent that Plaintiffs' "Merits" Interrogatories Addressed to Defendants -- Master Set and Plaintiffs' "Merits" Request for Production of Documents Addressed to Defendants -- Master Set, including, without limitation, Plaintiffs' Document Production Request Nos. 32, 39, 46, 57 & 81-83 and Plaintiffs' Interrogatory Nos. 11 & 12 seek information and documents concerning tests, studies and the like which are not "Currently Ongoing Studies," as defined herein, defendants shall either produce the documents and information requested or, if such documents and information are withheld from production, shall describe the documents on the privilege logs which they are required to provide pursuant to the terms of PTO #22 and the terms of the Stipulation Regarding Objections and Responses to Plaintiffs' "Merits Interrogatories" and Requests for Production of Documents Addressed to Defendants -- Master Set (hereinafter "The Stipulation").

4. Within fifteen (15) days from the date of this Order, the parties shall produce the following information with respect to any Currently Ongoing Study to the extent that the party has access to such information:

(a) a written list of each such study which includes a description of the study, the names of the principal investigators for each study, the date on which each such study was initiated and the anticipated date on which each such study will be completed;

(b) the written protocol for each such study;

(c) the statistical plan for each such study;

(d) sample data entry forms for each such study; and

(e) a brief description of the current status of the study, *e.g.*, "enrollment of patients is now X percent complete," "data collection is now Y percent

complete,” “the code has been broken and data analysis is currently underway.”

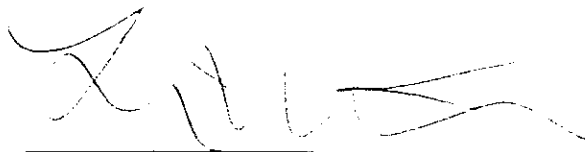
5. The parties shall provide supplemental disclosures containing the information required by the preceding paragraph in accordance with the schedule for providing supplemental discovery set forth in Pretrial Order No. 22.

6. If a study was a Currently Ongoing Study as of the date of this Order and thereafter ceases to be a “Currently Ongoing Study” within the meaning of this Order, then the defendants shall disclose all information and documents concerning the study which they are otherwise required to produce pursuant to plaintiffs’ Interrogatories and Document Production Requests or, to the extent that such information and documents are withheld from production pursuant to a bona fide claim of privilege or other protection from discovery, defendants shall describe the information and documents withheld from production on the privilege logs which they are required to furnish to the plaintiffs in accordance with the terms of Pretrial Order No. 22.

7. The names of the principal investigators disclosed pursuant to ¶ 4(a) and the progress reports disclosed pursuant to ¶ 4(e) of this Order shall be disclosed only to the members of the Plaintiffs’ Management Committee, the members of the PMC Discovery Committee, and the members of their law firms and, except upon Order of the Court for good cause shown, shall not be disclosed to any other person or used as a basis for discovery until such time as the study at issue ceases to be a “currently ongoing study” within the meaning of this Order.

8. Nothing in this Order shall be construed to require disclosure by any party of any materials prepared in anticipation of litigation, except as hereinafter provided. In particular, studies planned or conducted for a party, in anticipation of litigation, by a person within the scope of FRCP 26(b)(4)(B), shall not be subject to the disclosure requirements of ¶¶ 3 through 6 hereof, until and unless (i) such person is designated by such party as a testifying expert in MDL 1203 or in a state court action alleging damages as a result of the ingestion of diet drugs; or (ii) such party seeks to rely upon the results of such a study as evidence or as the basis of testimony by any person, in a trial of any action consolidated in MDL 1203 or in a state court action alleging damages as a result of the ingestion of diet drugs; or (iii) the party seeking disclosure makes the showing of substantial need required by FRCP 26(b)(3) or of exceptional circumstances required by FRCP 26(b)(4)(B); provided, however, the Court may preclude any party from introducing into evidence or otherwise relying on any study withheld from production pursuant to the terms of this paragraph on a showing that information concerning the study has not been disclosed in sufficient time to permit the opposing party a fair opportunity to obtain information and discovery concerning the study or to otherwise respond to or defend against such evidence.

9. This Order is without prejudice to the parties' rights to seek or oppose greater disclosure concerning Currently Ongoing Studies than provided for herein and shall not be construed to effect the burden of persuasion in connection with any such application to the Court.



Louis C. Bechtle
Chief Judge Emeritus

ENTERED: 1-7-99 _____
4

CLERK OF COURT

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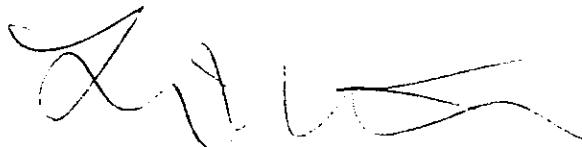
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Chief Judge Emeritus