

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: PROPULSID : **MDL NO. 1355**
PRODUCTS LIABILITY LITIGATION : **SECTION: L**
 : **JUDGE FALLON**
 : **MAG. JUDGE AFRICK**
THIS DOCUMENT RELATES TO ALL CASES :
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**PRE-TRIAL ORDER No. 13
(ONGOING STUDIES)**

ON JOINT MOTION OF PLAINTIFFS’ LIAISON COUNSEL AND DEFENDANTS’ LIAISON COUNSEL IT IS HEREBY ORDERED that all discovery, including, but not limited to, subpoenas, requests for production of documents, interrogatories, requests for admissions, and depositions seeking documents and information concerning ongoing scientific and medical studies, inclusive of all domestic and foreign studies, shall be subject to this Order.

1. A study is an “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 collected actively 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 an “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 presumed conclusively if those sponsoring or conducting the study have not conducted any work concerning the study for a period of ninety (90) days.

3. Within 15 (fifteen) days of this Order, the parties shall produce the following information with respect to any 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 study commenced and the anticipated date on which each study should be completed;
 - b) the written protocol for each study;
 - c) the statistical plan for each study;
 - d) sample entry data forms for each study; and
 - e) a brief description of the current status of each study, e.g. “enrollment of patients is now X percent complete;” “data collection is now Y percent complete;” and “the code has been broken and data analysis is now underway.”

4. The parties shall provide supplemental disclosures containing the information required by the preceding paragraph consistent with Fed.R.Civ.P.26(e).
5. The names of the principal investigators disclosed pursuant to ¶ 3(a) and the progress reports disclosed pursuant to ¶ 3(e) of this Order shall be disclosed only to Defendants' Co-Lead Counsel and/or Defendants' Liaison Counsel and/or Plaintiffs' Liaison Counsel and/or Plaintiffs' Steering Committee, and members of their law firms and, except upon Orders 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 "ongoing" within the meaning of this Order.
6. If a study was an "Ongoing Study" as of the date of this Order and thereafter ceases to be an "Ongoing Study" within the meaning of this Order, then the party who has asserted a privilege or other protection from discovery shall disclose all information and documents concerning the study which they are otherwise required to produce pursuant to discovery procedure, or to the extent that such documents are withheld from production pursuant to a valid claim of privilege or other protection from discovery, the party withholding the documents shall describe the information and documents withheld from production on the privilege logs, as required by Pre-Trial Order No. 5.
7. 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

8. a person within the scope of FRCP 26(b)(4)(B), shall not be subject to the disclosure requirement of ¶ 3 through ¶ 6 hereof, until and unless
- a) such person is designated by such party as a testifying expert in MDL 1355 or in a state court proceeding alleging damages as a result of the ingestion of Propulsid®; or
 - b) 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 1355 or in a state court proceeding alleging damages as a result of the ingestion of Propulsid®; or
 - c) 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 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.

New Orleans, Louisiana, this 29th day of November, 2001.

/s/ Eldon E. Fallon
JUDGE ELDON E. FALLON
UNITES STATES DISTRICT JUDGE