

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

IN RE: DIET DRUGS)
(PHENTERMINE/FENFLURAMINE)
DEXFENFLURAMINE) PRODUCTS) MDL No. 1203
LIABILITY LITIGATION) Judge Louis C. Bechtle
_____)

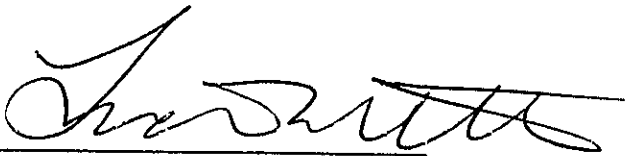
Pre-trial Order No. 718

ORDER DIRECTING ISSUANCE OF A LETTER ROGATORY

This matter having come for a hearing upon the motion of defendant American Home Products Corporation for a Letter Rogatory for Dr. Lucien Abenheim and/or a custodian of records to appear and produce documents for inspection and copying and it appearing that such a letter is appropriate,

NOW, THEREFORE, it is hereby ordered that the Clerk of the Court shall issue the Letter Rogatory in the form attached as Exhibit 1 to this Order.

June 17, 1999
Date



Judge Louis C. Bechtle
United States District Court

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FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS)

(PHENTERMINE/FENFLURAMINE)

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MDL No. 1203

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LETTER ROGATORY

FROM THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA TO THE MINISTRE DE LA JUSTICE
DU QUÉBEC A/S LE SERVICE JURIDIQUE, GREETING:

WHEREAS, a certain multidistrict civil litigation captioned In Re: Diet
Drugs (Phentermine/Fenfluramine Dexfenfluramine) Products Liability Litigation,
is pending in the United States District Court for the Eastern District of
Pennsylvania, Multidistrict Litigation Docket No. 1203 ("the Actions"), in which
American Home Products Corporation ("AHP") is a defendant, and

WHEREAS, the Actions in the multidistrict litigation docket are
consolidated for discovery purposes; and

WHEREAS, it has been suggested to us that justice cannot be
completely done between said parties without the documents in the possession

and/or control of Dr. Lucien Abenhaim, who works in Montreal, Québec, Canada, which is within your jurisdiction; and

WHEREAS, plaintiffs alleged that defendants are liable to them for alleged damages from ingestion of appetite-suppressant drugs, including the risk of developing primary pulmonary hypertension; and

WHEREAS, the International Primary Pulmonary Hypertension Study ("IPPHS") claims to have established an association between the use of appetite-suppressant drugs and the development of primary pulmonary hypertension; and

WHEREAS, Dr. Lucien Abenhaim is the lead researcher of the IPPHS and has in his possession and/or control the documents relating to the underlying data on which the IPPHS is based; and

WHEREAS, AHP seeks all documents related to the underlying data of the IPPHS as part of their defense that defendants' product does not cause primary pulmonary hypertension and that product labeling was legally adequate, including as to the risk of primary pulmonary hypertension; and

WHEREAS, AHP seeks to compel production of documents described in the annexed Appendix A for inspection and copying; and

WHEREAS, the documents sought from Dr. Lucien Abenhaim and/or a custodian of records are relevant, necessary and likely to be admissible at trial of the Action; and

WHEREAS, this Court is authorized by Rules 28(b) and 45 of the Federal Rules of Civil Procedure of the United States and by 28 U.S.C. § 1281 to

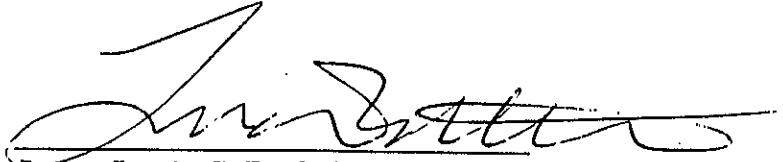
issue this Letter Rogatory to the Ministre de la Justice du Québec a/s Le service juridique in the Province of Quebec, Canada, to request an Order compelling Dr. Lucien Abenhaim to appear and produce the documents listed in Appendix A (redacted as necessary to preserve patient confidentiality); and

WE THEREFORE REQUEST that, in the interest of justice, you cause, by your proper and usual process, said Dr. Lucien Abenhaim and/or a custodian of records to appear before you or some competent officer authorized by you for that purpose, at a time and place to be determined by you, but no later than ~~May~~ ^{July} 1, 1999, and bring with him all of the documents as described in Appendix A pursuant to Rule 34 of the Federal Rules of Civil Procedure of the United States; and

IT IS FURTHER REQUESTED that, in the interest of justice, you cause the documents produced in response to this Letter Rogatory to be copied and returned to us under cover duly sealed and addressed to the Clerk of the District Court for the United States District Court for the Eastern District of Pennsylvania, and we shall be ready and willing to do the same for you in a similar case when required and we shall be ready and willing to reimburse you for any cost incurred in executing these requests.

Witness my hand and seal of said Court in the City of Philadelphia,

State of Pennsylvania, United States of America, on this 17th day of
June, 1999.

A handwritten signature in black ink, appearing to read "Louis C. Bechtle", written over a horizontal line.

Judge Louis C. Bechtle
United States District Judge

Appendix A

1. All documents, including but not limited to, raw data, medical records, abstracts of medical records, coding forms, interview memos, electronic files, data analysis files, case review files and all other documents or memos relating to the International Primary Pulmonary Study ("IPPHS") (redacted as necessary to preserve patient confidentiality).
2. All documents, including but not limited to, raw data, medical records, abstracts of medical records, coding forms, interview memos, electronic files, data analysis files, case review files and all other documents or memos relating to the initial findings and conclusions of the IPPHS, and any subsequent revisions to those findings.
3. All documents relating to the protocol or procedures used to conduct the IPPHS, including any drafts or revisions of the protocol or procedures.
4. All documents relating to the analysis and interpretation of the IPPHS data, including any change in the analyses and interpretations between the initial and final report, or at any other time.
5. All documents relating to the criteria and/or methodology used to identify and select study sites.
6. Any information or promotional materials provided to physicians or study sites about the IPPHS.
7. All documents relating to the identity, function and description of each study site.
8. All documents relating to the criteria and/or methodology used to identify the patients who participated in the study, including the basis for selecting each particular patient (redacted as necessary to preserve patient confidentiality).
9. All documents relating to the criteria and/or methodology used to identify the patients who participated in the control group, including the basis for selecting each particular patient (redacted as necessary to preserve patient confidentiality).
10. The medical records, abstract of medical records, and any documents relating to interviews, for each patient selected to participate in the study, including any patients who withdrew prior to the end of the study (redacted as necessary to preserve patient confidentiality).

11. The medical records, abstract of medical records, and any documents relating to interviews, for each patient selected to participate in the control group, including any patients who withdrew prior to the end of each study (redacted as necessary to preserve patient confidentiality).
12. Any documentation relating to decisions regarding eligibility to serve as a study or control group participant, including all information on individual participants (redacted as necessary to preserve patient confidentiality).
13. All documents relating to any exploratory or interim analysis of the data from the IPPHS.
14. All data analysis forms or records for the IPPHS.
15. All electronic files relating to the IPPHS.
16. All postcards, reports or other information received by the research teams from the study sites or any other source to report information relating to the study.
17. All documents, including but not limited to, correspondence, memoranda or telephone messages, used to report information to the research teams.
18. All references, including but not limited to, studies, articles, books, papers, and monographs, relied upon in the development, operation and and/or analysis of the IPPHS results.
19. All documents relating to the roles/responsibilities of each member of the research teams.
20. All correspondence with medical journals relating to the IPPHS, including copies of any drafts submitted for publication and reviews and/or comments received.
21. Any and all other underlying data related to IPPHS, which has not been specifically requested above.