

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

In re: :
PREMPRO PRODUCTS LIABILITY : MDL Docket No. 4:03CV1507 WRW
LITIGATION : ALL CASES

STIPULATED ORDER RE CONFIDENTIALITY OF WHI STUDY DATA

The parties to this matter through their counsel of record stipulate that the subjoined order may be entered by the court.

Dated this 10th day of June, 2009.

WILLIAMS & CONNOLLY LLP

WILLIAMS, LOVE, O'LEARY & POWERS,
P.C.

By

Attorneys for Wyeth

By

Michael Williams
Attorneys for Plaintiffs

LANE POWELL PC

By

Julie K. Campbell
Attorneys for Fred Hutchinson Cancer
Research Center

THIRD

~~CONFIDENTIAL~~ CONFIDENTIALITY ORDER RE WHI STUDY DATA

1. This Order is entered for the purpose of protecting the privacy rights of participants of the Women's Health Initiative ("WHI") study, the contractual rights and

obligations of Fred Hutchinson Cancer Research Center (“FHCRC”) and the publication rights of the WHI investigators, in connection with the WHI study conducted pursuant to contract between FHCRC and the National Institutes of Health (“NIH”), on stipulation of counsel for FHCRC, Wyeth and plaintiffs.

2. This Confidentiality Order relates to a second subpoena issued to FHCRC dated February 5, 2009, a copy of which is attached hereto. That subpoena requests data and documents for dates both prior to and after 2005. FHCRC has agreed to produce data in response to that subpoena, but only to the extent the data has already been released to the NHLBI in limited datasets. Generally, only data up through approximately August 2005 has been released to the NHLBI. *This order involves only such data that FHCRC has submitted in limited datasets to the NHLBI.* Data that post dates the 2005 submission to the NHLBI has also been requested in the subpoena, but the availability of that data will be considered separately either by agreement yet to be reached among the parties, or if necessary by this Court upon motion.

3. Data or documents produced by FHCRC as described in paragraph 2 will not contain the names, addresses, social security numbers, places of birth, cities of birth or contact data of the participants in the WHI study; the interviewer identification numbers; unedited, verbatim responses of participants; identification of family relationships and pedigrees; original study identification numbers (new identifiers will be assigned at Wyeth’s expense); clinical center identifiers (new identifiers will be assigned at Wyeth’s expense); “sensitive data” (as defined by the NHLBI guidelines); and dates (dates will be recoded relative to a specific reference point[i.e. enrollment date] with flags for the approximate dates of certain events such as letters to participants to the extent Wyeth requests such information) The parties in this

proceeding who receive the data from FHCRC will not undertake any efforts to determine the identity of the participants or the clinical center(s) associated with each participant.

4. FHCRC will bill and Wyeth will pay compensation for the reasonable and appropriate production costs incurred to produce the documents and data. FHCRC's reasonable and appropriate production costs will be paid in the first instance by Wyeth and will be shared among those other defendants requesting the documents and data in a manner agreed upon by them or by further Order of the Court.

5. A party may provide the documents and data to its retained experts, provided that such experts first receive a copy of this Order and sign the "Conditions of Disclosure" form attached to this order and that the party sends the signed forms to counsel for FHCRC "for her eyes only." The manufacturer defendants may make the documents and data available to executives or employees within their companies.

6. The manufacturer defendants may also provide the documents and data to the Food and Drug Administration in order to meet any requirement under the Federal Food, Drug, and Cosmetic Act or associated regulations.

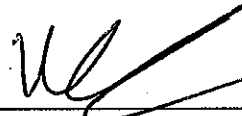
7. Nothing in this Order shall be construed as granting to or permitting the parties and their counsel an implied license in or right or option to use the intellectual property rights arising from any analysis or review of data by FHCRC or WHI investigators as may be produced in response to the attached subpoena, other than use in the hormone therapy litigation. However, any party has the right to publicly comment upon the data itself, including submission of articles or commentaries to medical journals or other media, so long as they first comply with any applicable National Heart Lung & Blood Institute (NHLBI) policies with respect to handling of the data.

8. Since that data referred to in paragraph 2 of this Order has already been released to the NHLBI, Wyeth and other parties may retain the data they may obtain via the attached subpoena after the culmination of this litigation.

9. Any person or entity who intentionally violates this Order will be subject to contempt of court and the imposition of civil sanctions, including reasonable attorneys' fees and costs.

10. Any unresolved issues relating to enforcement of any alleged violations of the terms of this Order will be resolved by this Court or, upon the termination of MDL-1507, any court with jurisdiction over the person against whom enforcement is sought.

SO ORDERED this 16th day of June, 2009.



UNITED STATES DISTRICT JUDGE
WM. R. WILSON, JR.