



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 \_\_\_\_\_ day of \_\_\_\_\_, 2009.

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

By \_\_\_\_\_

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By



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By \_\_\_\_\_

June K. Campbell  
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Research Center

SECOND 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

between FHCRC and the National Institutes of Health (“NIH”), on stipulation of counsel for FHCRC, Wyeth and plaintiffs.

2. This Confidentiality Order governs the production of data by FHCRC in response to a Wyeth subpoena to FHCRC, dated February 5, 2009 attached hereto. Statistical information derived from or collected from the study and described in paragraph 1 of the subpoena will be referred to as “data”, whereas correspondence, emails, internal documents generated by FHCRC or WHI investigators as described in paragraph 2 of the subpoena will be referred to as “documents”.

3. Neither data nor documents produced by FHCRC will 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 for use in the hormone therapy litigation only, 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 paragraphs 1 or 2 of the subpoena, other than use in the hormone therapy litigation. However, to the extent that such analysis has been published, any party has the right to comment upon said published opinions or data. Any party acquiring the data by reason of this subpoena will comply with any applicable National Heart Lung & Blood Institute (NHLBI) policies with respect to handling of the data.

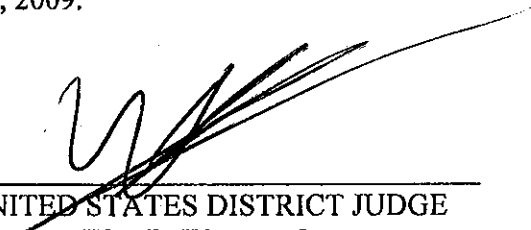
8. Wyeth may retain any data it obtains by this subpoena in response to paragraph 1 of the subpoena, to the extent said data has been made available in limited datasets to the NIH. FHCRC seeks the return (or the destruction) of the documents, to include internal FHCRC or WHI documents such as emails, correspondence, or notes produced in response to paragraph 2 of the subpoena at the conclusion of the litigation, unless already released to the scientific

community at large or prohibited by law. Before the conclusion of these proceedings by a final suggestion of remand or otherwise, the Court will seek the advice of the parties and FHCRC as to whether these documents should be returned to FHCRC (or destroyed) at that time or whether continued use of the documents will be required on remand of cases to the transferor courts.

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 9<sup>th</sup> day of June, 2009.

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