

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

IN RE:	:	MDL DOCKET NO. 4:03-CV-1507-WRW
PREMPRO PRODUCTS LIABILITY	:	
LITIGATION	:	ALL CASES

ORDER Re: WHI EXTENSION STUDY DATA

After considering the parties' submissions, and hearing argument at the June 26, 2009, Status Conference, Wyeth's Second Motion to Compel Production of Documents by Fred Hutchinson Cancer Research Center ("FHCRC") (Doc. No. 2049) is GRANTED as set out below:

1. FHCRC must forthwith produce the data and documents ("the Data") requested by Wyeth in the February 5, 2009, subpoena.

2. FHCRC may bill (and, if billed, Wyeth must pay) for the reasonable and appropriate production costs incurred to produce the Data. These 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.

3. To protect the privacy rights of participants of the Women's Health Initiative ("WHI") study and such interests in the confidentiality of the Data as may exist:

a. The Data 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).

b. A party who receives the Data will not undertake any efforts to determine the identity of the participants or the clinical center(s) associated with each participant.

c. A party may provide the Data to its retained experts for use in the hormone therapy litigation only, provided that the experts first receive a copy of this Order, sign the “Conditions of Disclosure” form attached to this Order, and provide the signed forms to counsel for FHCRC “for her eyes only.”

d. The manufacturer defendants may make the Data available to executives or employees within their companies and to the Food and Drug Administration.¹

e. If the Data is disclosed to a deposition witness, the witness must be shown a copy of this Order and will be bound by the “Conditions of Disclosure” form. The portions of the deposition transcript and deposition exhibits related to the Data will be subject to this Order.

f. Submissions to the Court specifically mentioning the Data must be made under seal (submissions including only routine information need not be submitted under seal).

g. Nothing in this Order may 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 written analysis or review of the Data by FHCRC or WHI investigators other than use in the hormone therapy litigation.

4. Until FHCRC takes the position that the Data is no longer confidential, a party or persons subject to its control will not publish or seek to publish any analysis of the Data without permission of the Court.

¹In order to meet any requirement under the Federal Food, Drug, and Cosmetic Act or associated regulations, the Data may be provided to the FDA.

5. Before the termination of MDL-1507, the parties or FHCRC may petition the Court regarding whether the Data should be returned to FHCRC (or destroyed) at that time or whether continued use of the Data will be required on remand of cases to the transferor courts.

6. 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.

7. 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.

IT IS SO ORDERED this 13th day of July, 2009.

/s/ Wm. R. Wilson, Jr.
UNITED STATES DISTRICT JUDGE

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CONDITIONS OF DISCLOSURE

I, _____, do hereby certify that I have read the July 13, 2009, Confidentiality Order Re: WHI Extension Study Data (“Confidentiality Order”). Because it is necessary for me in connection with my participation in this case to have access to data subject to the Confidentiality Order, I have read the entire Confidentiality Order and understand and agree that I am bound and subject to all terms and provisions contained in the Confidentiality Order.

I understand that if I intentionally violate or attempt to violate any provision of the Confidentiality Order, I will be subject to contempt of court and the imposition of civil sanctions, including but not limited to reasonable attorneys’ fees and costs.

I acknowledge that Fred Hutchinson Cancer Research Center (“FHCRC”) asserts that the responsive data has inherent value, that the research being conducted by FHCRC is important to both FHCRC and its researchers, and that in order for the FHCRC researchers and others associated with WHI to fully exercise their contractual rights to publish the results of the WHI in peer reviewed journals, the responsive data must be kept confidential. I agree that, in the event that I use the data in violation of the Confidentiality Order, injunctive relief barring such misuse is warranted and may be issued by this Court or another Court of appropriate jurisdiction.

