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IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE)
PRODUCTS LIABILITY
LITIGATION

MDL Docket No. 2299

6:11-MD-2299

This Document Relates to All Cases

Hon. Rebecca F. Doherty
United States District Judge

Plaintiffs' Steering Committee on Behalf of All
Plaintiffs Herein,

Plaintiffs

v.

Takeda Pharmaceuticals America, Inc.; Takeda
Pharmaceuticals North America, Inc.; Takeda
California, Inc.; Takeda Pharmaceutical
Company Limited; and Eli Lilly and Company

Defendants.

**STIPULATED PROTECTIVE ORDER TO NON-PARTIES KAISER FOUNDATION
HOSPITALS, THE PERMANENTE MEDICAL GROUP, INC. AND KAISER
FOUNDATION HEALTH PLAN, INC.'S ANALYTICAL FILES AND OTHER HIGHLY
CONFIDENTIAL INFORMATION**

Pursuant to paragraph 17 of the Court's Case Management Order: Protecting the
Confidentiality of Discovery Materials in Civil Action No. 06-11-MD-2299 (W.D. La.) (the
"MDL Confidentiality Order"), Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R.
§ 164.512(e)(1), Plaintiffs' Steering Committee ("PSC") and non-parties Kaiser Foundation
Hospitals, The Permanente Medical Group, Inc. and Kaiser Foundation Health Plan, Inc.
(together "Kaiser") stipulate to a Protective Order as follows:

I. RECITALS

1. The PSC served a subpoena upon non-party Kaiser Foundation Hospitals in the above-entitled action on about September 2, 2014 ("September 2014 Subpoena.").

2. Thereafter, on February 19, 2015, the PSC filed certain motions to compel.

3. In response to the September 2014 Subpoena and the PSC's motion to compel, Kaiser has agreed to permit the PSC to designate certain individuals to access certain highly confidential and proprietary analytical files that contain portions of Kaiser's research data (the "Analytical Files") pertaining to the cohort study and nested case control study of Pioglitazone and bladder cancer in patients with diabetes mellitus (the "Actos-Bladder Cancer Study"), the manuscript prepared by researchers at Kaiser concerning the Actos-Bladder Cancer Study that has been submitted for publication, including drafts of the manuscript (collectively referred to as the "Manuscript"), and internal and external communications concerning the Manuscript (collectively the "Manuscript Communications") for the limited and exclusive purpose of litigating this MDL action.

4. In response to the Subpoena and the PSC's motion to compel, Kaiser, also, will provide responsive, non-privileged documents from custodial files of five Kaiser employees; Kaiser has advised that such documents have already been gathered through early November 2014 and can be promptly provided; responsive documents from November 2014 to the present will be provided on a rolling basis within 30 days from the signing of this Order.

5. The parties agree, the Analytical Files, as well as other materials requested by the September 2014 Subpoena, specifically including, but not limited to the nested cohort study questionnaires, contain personal and protected health information regarding or relating to individuals who have a privacy interest in such information and public disclosure thereof would

be contrary to the law and public interest. The PSC and Kaiser, also, understand and agree that such documents and information are subject to the Standards of Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); California Civil Code §§ 56 et seq.; or other similar statutory or regulatory privacy protections. The PSC and Kaiser agree that Kaiser may redact the Analytical Files and any other materials requested by the September 2014 Subpoena to the extent necessary to protect personal health information in accordance with HIPAA and that the PSC shall reimburse Kaiser's reasonable costs in providing access to and redacting the materials requested by the September 2014 Subpoena.

6. The PSC and Kaiser agree that once adopted this Stipulated Protective Order will constitute a "qualified protective order" under 45 C.F.R. 164.512(e).

7. The parties agree that Paragraph 17 of the MDL Confidentiality Order provides that its terms may be "amended or modified" "[b]y written agreement".

8. The parties agree that under Rule 26(c) of the Federal Rules of Civil Procedure, the Court may upon good cause issue protective orders.

9. The parties further agree such good cause exists for this Stipulated Protective Order given the highly confidential and proprietary nature of the Analytical Files, the Manuscript, the Manuscript Communications and the privacy interests of the patients whose information is contained therein.

10. The parties agree, that the PSC will submit this Stipulated Protective Order to the Court and request its entry before Kaiser must grant the PSC's designees access to the Analytical Files, the Manuscript or the Manuscript Communications. However, in order to promote expedient access to the Analytical Files, the Manuscript or the Manuscript Communications in

light of current litigation deadlines in this action, the PSC agrees to be bound by the terms of the Stipulated Order upon executing it by and through counsel and Kaiser may, therefore, permit access to the Analytical Files, the Manuscript or the Manuscript Communications before the Court formally enters this Stipulated Protective Order.

11. This Stipulated Protective Order hereby incorporates the terms and conditions of the Court's MDL Confidentiality Order such that all discovery materials Kaiser has produced and may further produce in this action may have at least the same protections as the "Confidential Discovery Materials" subject to that previous order. However, with regard to the Analytical Files, the Manuscript or the Manuscript Communications (sections II and III below) and discovery materials that Kaiser designates as "Attorneys' Eyes Only" (section IV below), the terms of this Stipulated Protective Order will govern and supersede the provisions of the MDL Confidentiality Order, and in the case of any conflict as between the two, this Order, Stipulated Protective Order to Non-Parties Kaiser Foundation Hospitals, the Permanente Medical Group, Inc. and Kaiser Foundation Health Plan, Inc.'s Analytical Files and Other Highly Confidential Information, shall govern.

12. The Takeda defendants may enter into a parallel Stipulated Protective Order with Kaiser that permits the Takeda Defendants to access the Analytical Files, the Manuscript or the Manuscript Communications in the same manner and under the same terms and conditions as the PSC's access to those files, and restricts the Takeda defendants' ability to disclose Kaiser's "Attorneys' Eyes Only" discovery materials.

II. ACCESS TO KAISER ANALYTICAL FILES AND WORK-PRODUCT ANALYSES AND REPORTS DERIVED THEREFROM

13. In order to protect against any unnecessary use or disclosure of the Analytical Files and the work-product analyses and aggregated data reports derived therefrom (the “Work-Product Files”), the PSC and Kaiser agree to the following terms and conditions:

14. The PSC may designate no more than four individuals from among its retained consultants or attorneys (the “Analytical-File Users”) to access Kaiser’s Analytical Files.

15. Kaiser shall develop a Remote Access Protocol that permits the Analytical-File Users to securely access and perform statistical analyses of the Analytical Files through the Internet. Kaiser shall not require the Analytical-File Users to disclose their identities to Kaiser in order to access the Analytical Files. Additional details of Kaiser’s Remote Access Protocol are set forth in the attached Exhibit 1. Up to two Analytical-File Users may simultaneously access the Analytical Files. Kaiser shall make the Analytical Files accessible to the PSC-designated persons at the earliest feasible time, and in no case longer than eighteen (18) days after entry of this Stipulated Protective Order by the Court.

16. Before Kaiser makes the Analytical Files available to the Analytical-File Users, Kaiser may remove any non-essential, individually-identifiable health information from the Analytical Files, including but not limited to, first name, last name and medical record number of individuals, so long as the integrity of the Analytical Files is sufficiently preserved for the Analytical-File Users to examine or analyze the Actos-Bladder Cancer Study. Kaiser must assign a unique numeric code to each unique patient in the Analytical Files, and ensure a basis of comparison and/or identification of these redactions against the original documents.

17. Kaiser’s Remote Access Protocol shall include the following features for handling Work-Product Files:

- a. the ability to create or modify user accounts;

- b. the ability to set file or folder permissions; and
- c. a file-zip program that can be used to encrypt and password-protect

designated files.

18. When an Analytical-File User has generated Work-Product Files and wishes to obtain them from Kaiser, the PSC's counsel shall notify Kaiser's counsel or other Kaiser designee via email. Upon receiving such notification, Kaiser shall have until 5 p.m. PST the next business day to email the designated work-product files to the PSC's counsel. Kaiser shall permanently destroy all copies of the designated Work-Product Files after emailing them to the PSC's counsel.

19. Kaiser shall not in any circumstance attempt to decrypt or otherwise view the contents of any Work-Product Files.

20. The PSC shall reimburse Kaiser its reasonable costs in preparing the Analytical Files and the Remote Access Protocol.

III. LIMITATIONS ON ACCESS, USE AND DISCLOSURE OF ANALYTICAL FILES, WORK-PRODUCT FILES, MANUSCRIPT AND MANUSCRIPT COMMUNICATIONS

21. The Analytical Files, the Work-Product Files, the Manuscript and Manuscript Communications, or any portions of any thereof, shall not be used or disclosed for any purpose other than litigation of this MDL action such as sales, marketing, research and development, contract negotiations, or any other commercial, competitive or business purpose.

22. The PSC shall not permit anyone other than their respective designated Analytical-File Users to access the Analytical Files through Kaiser's Remote Access Protocol and pending publication of the Manuscript the PSC will limit access to the Manuscript and the Manuscript Communications to members of the PSC and their testifying experts.

23. Prior to permitting the respective designated Analytical-File Users to access the Analytical Files through Kaiser's Remote Access Protocol, or prior to permitting anyone access to the Manuscript or Manuscript Communications, the PSC must provide those individuals with copies of this Stipulated Protective Order, the MDL Confidentiality Order and the applicable Attorneys' -Eyes-Only Notice and obtain their signatures on the Certificate of Confidentiality Obligation ("Certificate") attached here as Exhibit 2. For testifying experts, copies of any such Certificate executed by a testifying expert that accessed the Analytical Files, the Manuscript, or the Manuscript Communications shall be furnished to Kaiser upon request. The PSC shall take all other reasonable steps to ensure that the Analytical-File Users, or anyone with access to the Manuscript or Manuscript Communications do not use or disclose such information for any purpose other than litigation of this MDL action.

24. The Analytical-File Users shall not, in any circumstance:

- a. print or photograph the Analytical Files or any portions thereof;
- b. transfer or save the Analytical Files or any portions thereof to a CD, DVD, USB drive, hard drive or any other recordable device or medium; or
- c. attempt to re-identify the Analytical Files or any portions thereof.

Nothing in this paragraph shall prohibit the Analytical-File Users from performing statistical analyses of the Analytical Files or generating aggregated data reports from the Analytical Files.

25. Any use or disclosure of the Analytical Files to any person or entity other than to the Analytical-File Users for the purpose of this litigation as specified in paragraphs 14, 20 and 21 above is strictly prohibited unless:

- a. Kaiser consents to such use or disclosure; or
- b. the Court orders such use or disclosure.

Similarly, any use or disclosure of the Manuscript or Manuscript Communications to any person or entity other than to the PSC and its testifying experts for the purpose of this litigation as specified in paragraphs 15, 21 and 22 above is strictly prohibited unless:

- c. Kaiser consents to such use or disclosure; or
- d. the Court orders such use or disclosure.

26. Kaiser shall terminate its Remote Access Protocol upon the earlier of:

- a. written notification from the PSC's counsel that the Analytical-File Users have completed their work with the Analytical Files; or

- b. 180 calendar days from the date the Analytical-File Users first access the Analytical Files.

27. Should circumstances arise in the course of litigating this MDL action which requires the Analytical-File Users to regain access to the Analytical Files after Kaiser terminates its Remote Access protocol pursuant to paragraph 26 above, the PSC's counsel will advise Kaiser's counsel of those circumstances and request additional Remote Access to the Analytical Files for the Analytical-File Users. Kaiser will not unreasonably withhold such access and will arrange to provide access to the Analytical Files via the Remote Access Protocol for a mutually agreeable period of time. The PSC's counsel shall give Kaiser at least 5 business-days' notice of its request for additional access to allow Kaiser sufficient time to re-establish the Remote Access Protocol for the Analytical-File Users. However, Kaiser shall not under any circumstances be required to permit additional access to its Analytical Files beyond the end of the next trial proceeding in the MDL.

28. To the extent there exist any documents that contain or reflect the Analytical Files or portions thereof in Kaiser's production of documents and/or custodian-level ESI to the PSC,

Kaiser may designate those files as “HIGHLY CONFIDENTIAL ANALYTICAL FILES.”

Similarly, Kaiser may designate the Manuscript and any Manuscript Communications in

Kaiser’s production of documents and/or custodian-level ESI to the PSC as “HIGHLY

CONFIDENTIAL MANUSCRIPT FILES.” All documents so designated shall be subject to the

limitations on use and disclosure set forth in paragraphs 22 to 26 of this Stipulated Protective

Order.

29. The Work-Product Files, or any portions thereof, shall be entitled to the same protections as materials designated “ATTORNEYS’ EYES ONLY” pursuant to the MDL Confidentiality Order and section IV below.

IV. LIMITATIONS ON ACCESS, USE AND DISCLOSURE OF KAISER’S ATTORNEYS’-EYES-ONLY DISCOVERY MATERIALS

30. “ATTORNEYS’ EYES ONLY” information is defined as follows and shall include any information, document, or thing, or portion of any document or thing that Kaiser in good faith believes contains trade secrets, competitively sensitive technical, marketing, financial, sales, research and development, or other confidential business information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports, or other highly sensitive business or personal information, or unpublished manuscripts awaiting peer review and publication and communications related thereto, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of Kaiser.

31. “ATTORNEY’S EYES ONLY” information shall be afforded the same protections afforded to “Confidential Discovery Material” in the MDL Confidentiality Order.

32. In addition, discovery materials produced and marked as “ATTORNEYS’ EYES ONLY” may be disclosed only to outside counsel for the parties and their staff, and to the

persons identified in paragraphs 7(a)i, 7(a)vii and 7(a)viii of the MDL Confidentiality Order, except that such “ATTORNEYS’ EYES ONLY” materials may NOT be disclosed to any Plaintiff, or any other persons, or in any Other Actos Lawsuits outside of this MDL, or to counsel representing an Actos claimant with an unfiled claim, unless counsel for Kaiser agrees in advance or as ordered by the Court. Before disclosing “ATTORNEYS’ EYES ONLY” information to any Plaintiff, or any other persons, or in any Other Actos Lawsuits outside of this MDL, or to counsel representing an Actos claimant with an unfiled claim, the party making the disclosure must identify that person to Kaiser and either: (a) obtain Kaiser’s written approval, which must not be unreasonably withheld, and also (b) obtain each such person's execution of the non-disclosure agreement in the form attached to the MDL Confidentiality Order as Exhibit A after copies of the MDL Confidentiality Order and this Stipulated Protective Order is provided to such individuals; or (c) seek an order from the Court authorizing the disclosure.

33. Absent written consent from Kaiser, any person who receives access to “ATTORNEYS’ EYES ONLY” information shall not be involved in the prosecution of patents or patent applications relating to Pioglitazone or the methods, procedures, subjects, results or conclusions of the preclinical and clinical research or studies performed by Kaiser Permanente Northern California studying Pioglitazone, before any foreign or domestic agency, including the United States Patent and Trademark Office (“the Patent Office”). For purposes of this paragraph, “prosecution” includes directly or indirectly drafting, amending, advising, or otherwise affecting the scope or maintenance of patent claims. To avoid any doubt, “prosecution” as used in this paragraph does not include representing a party challenging a patent before a domestic or foreign agency (including, but not limited to, a reissue protest, ex parte reexamination or inter partes reexamination). This Prosecution Bar shall begin when access to “ATTORNEYS’ EYES

ONLY” information is first received by the affected individual and shall end two (2) years after final termination of this action.

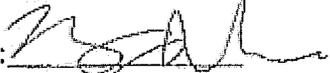
34. If Kaiser discovers that it has inadvertently or mistakenly disclosed information, documents or tangible items protected by attorney-client privilege or work product immunity, and brings that discovery to the attention of the Receiving Party, Kaiser and the Receiving Party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5). Such inadvertent or mistaken disclosure of such information shall not by itself prejudice or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such information. However, this does not restrict the right of the Receiving Party to challenge Kaiser's claim of privilege or work product protection if appropriate within a reasonable time after receiving notice of the inadvertent or mistaken disclosure.

Under Paragraph 8 concerning disputes to the designation of Confidential Discovery Material, if a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by Kaiser, the Receiving Party and Kaiser shall meet and confer to attempt to resolve the issue. If the Receiving Party and Kaiser are unable to reach an agreement as to the designation of the discovery material, the Receiving Party shall not have the right to serve a Challenge Notice as set forth in Paragraph 8 of the MDL Confidentiality Order with respect to the discovery materials produced by Kaiser. Instead, the Receiving Party shall file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the confidentiality designation. Any such motion shall be accompanied by a Motion for Leave to File Under Seal (“Sealing Motion”), in accordance with this Court's order concerning Sealing Motions. On such motion, Kaiser shall have the burden of proving that the material is entitled to protection, as if this Order has not been entered, pursuant to, Rule

26(c)(1)(G). On such a motion by the Receiving Party, Kaiser shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief. The Opposition shall be accompanied by a Sealing Motion.

Dated: March 2, 2015

Respectfully submitted,

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26(c)(1)(G). On such a motion by the Receiving Party, Kaiser shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief. The Opposition shall be accompanied by a Sealing Motion.

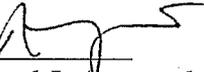
Dated: March 2, 2015

Respectfully submitted,

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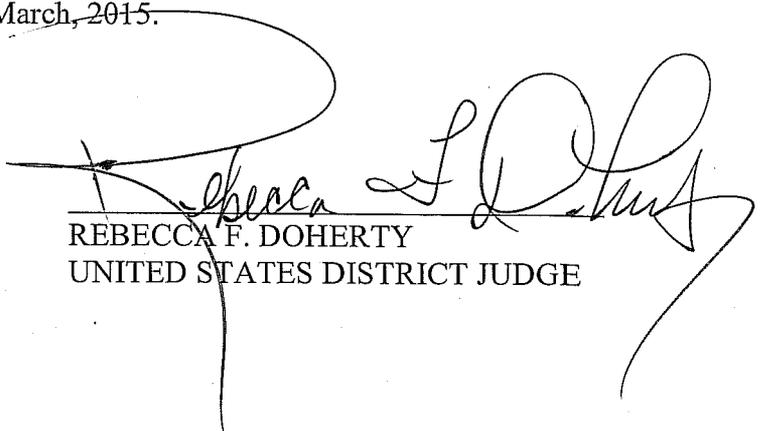
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*On behalf of the Plaintiffs' Steering
Committee*

SO ORDERED, this 3 day of March, 2015.



REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE

**EXHIBIT 1 WAS FILED UNDER SEAL
ATTACHED TO REC. DOC. 5325 (6:11-MD-2299)**

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE)
PRODUCTS LIABILITY
LITIGATION

MDL Docket No. 2299

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Hon. Rebecca F. Doherty
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Plaintiffs' Steering Committee on Behalf of All
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v.

Takeda Pharmaceuticals America, Inc.; Takeda
Pharmaceuticals North America, Inc.; Takeda
California, Inc.; Takeda Pharmaceutical
Company Limited; and Eli Lilly and Company

Defendants.

CERTIFICATE OF CONFIDENTIALITY OBLIGATION

I hereby attest to my understanding that I am being permitted access to one or more of the following: (1) a highly confidential and proprietary manuscript ("Manuscript"), (2) highly confidential communications relating to or concerning the Manuscript ("Manuscript Communications"), (3) highly confidential and proprietary research data analytical files (the "Analytical Files") and may generate statistical analyses and aggregated data from those analytical files (the "Work-Product Files") that contain information pertaining to patients, subject

to the terms and conditions of the following attached documents in the above-captioned litigation:

- Stipulated Protective Order Regarding the Plaintiffs' Steering Committee's Access to Non-Parties Kaiser Foundation Hospitals, The Permanente Medical Group, Inc. and Kaiser Foundation Health Plan, Inc.'s Analytical Files and Other Highly Confidential Information; and;
- Case Management Order: Protecting the Confidentiality of Discovery filed July 30, 2012. (together, the "Confidentiality Obligation Documents")

I have read the attached Confidentiality Obligation Documents and agree to be bound by their terms. I understand that my execution of this Certification is a prerequisite to my review and use of Kaiser's Analytical Files, the Manuscript and the Manuscript Communications. I agree that I shall not use or disclose the Analytical Files, Work-Product Files, the Manuscript and the Manuscript Communications or portions thereof, to others in any form whatsoever, except in accord with the terms and conditions of the attached, and that those files and the information contained therein may be used only for the purposes authorized by the Confidentiality Obligation Documents.

I further agree and attest to my understanding that my obligation to honor the confidentiality of the Analytical Files, Work-Product Files, the Manuscript and the Manuscript Communications and portions thereof will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Confidentiality Obligation Documents, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Western District of Louisiana, to the full extent allowed by law and to the full extent

determined by the United States Courts, for the purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the attached Confidentiality Obligation Documents as soon as I sign this Agreement, whether or not any of them have been entered as an Order of Court.

Date:

By: _____

Subscribed and sworn to before me this

_____ day of _____, 20 ____

NOTARY PUBLIC