

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

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:				
	:				
	:				MDL No. 1871
	:				07-md-01871-CMR

**THIS DOCUMENT APPLIES TO:
ALL ACTIONS**

**PRETRIAL ORDER NO. 10
(PROTECTIVE ORDER)**

AND NOW, this 10th day of June 2008, in order to expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, adequately protect confidential material, and ensure that protection is afforded only to material so entitled, the Court enters this Protective Order pursuant to Rule 26 of the Federal Rules of Civil Procedure.

1. Discovery Materials

This Order applies to all products of discovery and all information derived therefrom, including, but not limited to, all documents, objects or things, deposition testimony and interrogatory/request for admission responses, and any copies, excerpts or summaries thereof, obtained by any party pursuant to the requirements of any court order, requests for production of documents, requests for admissions, interrogatories, or subpoena (“Discovery Materials”). This Order is limited to the litigation or appeal of any action brought by or on behalf of plaintiffs, alleging personal injuries or other damages arising from plaintiffs’ purchase and/or ingestion of rosiglitazone

maleate, commonly known as Avandia®, or any combination product containing Avandia, including Avandaryl® or Avandamet®, referred to herein collectively as “Avandia” (“Litigation”), and includes any state court action where counsel for the plaintiff has agreed to be bound by this order.

2. Use of Discovery Materials

With the exception of documents or information that have become publicly available without a breach of the terms of this Order, or any other legal obligation to safeguard and maintain confidentiality, all documents, information or other Discovery Materials produced or discovered in this Litigation, and that have been designated “Confidential Discovery Materials,” shall be used by the receiving party solely for the prosecution or defense of this Litigation, to the extent reasonably necessary to accomplish the purpose for which disclosure is made, and not for any other purpose, including any other litigation or judicial proceedings, or any business, competitive, governmental, commercial, or administrative purpose or function.

3. “Confidential Discovery Materials” Defined

For the purposes of this Order, “Confidential Discovery Materials” shall mean any non-public information that the producing party reasonably and in good faith believes is properly protected under Federal Rule of Civil Procedure 26(c)(1)(G).

Where large volumes of Discovery Materials are provided to the requesting party’s counsel for preliminary inspection and designation for production, and have not been reviewed for confidentiality purposes, the producing party reserves the right to so designate and redact appropriate Discovery Materials after they are designated by the requesting party for production. During the preliminary inspection process, and before production, all Discovery Materials reviewed by the requesting party’s counsel shall be treated as Confidential Discovery Materials.

4. Designation of Documents as “Confidential”

a. For the purposes of this Order, the term “document” means all tangible items, whether written, recorded or graphic, whether produced or created by a party or another person, whether produced pursuant to subpoena, to discovery request, by agreement, or otherwise.

b. Any document which the producing party intends to designate as Confidential shall be stamped (or otherwise have the legend recorded upon it in a way that brings the legend to the attention of a reasonable examiner) with a notation substantially similar to the following:

Avandia MDL 1871: Confidential-Subject to Protective Order

Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying. The stamp shall be affixed in such a manner as not to obliterate or obscure any written material.

5. Non-Disclosure of Confidential Discovery Materials

Except with the prior written consent of the party or other person originally producing Confidential Discovery Materials, or as hereinafter provided under this Order, no Confidential Discovery Materials, or any portion thereof, may be disclosed to any person except as set forth in section 6 below.

6. Permissible Disclosures of Confidential Discovery Material

Notwithstanding paragraph 5, Confidential Discovery Materials may only be disclosed to and used by:

a. the parties and their counsel of record in this Litigation who have agreed to be bound by the terms of this Protective Order. For counsel of record, this includes his/her partners, associates, secretaries, legal assistants, and employees to the

extent considered reasonably necessary to render professional services in the Litigation;

b. in-house counsel of the parties, to the extent reasonably necessary to render professional services in the Litigation;

c. court officials involved in this Litigation (including court reporters, persons operating video recording equipment at depositions, and any special master appointed by the Court);

d. any person designated by the Court in the interest of justice, upon such terms as the Court may deem proper;

e. where produced by a plaintiff, in addition to the persons described in subsections (a) and (b) of this section, a defendant's in-house paralegals and outside counsel, including any attorneys employed by or retained by defendant's outside counsel who are assisting in connection with this Litigation, and the paralegal, clerical, secretarial, and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by defendant's outside counsel;

f. where produced by defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), in addition to the persons described in subsections (a) and (b) of this section, plaintiff attorneys in other filed litigation alleging personal injuries resulting from the use of and/or other damages arising from plaintiffs' purchase of Avandia including their paralegal, clerical, secretarial and other staff employed or retained by such counsel;

g. where produced by any defendant, outside counsel for any defendant, including any attorneys employed by or retained by any defendant's outside counsel who are assisting in connection with this Litigation, and the paralegal, clerical, secretarial, and other staff

employed or retained by such outside counsel;

h. where produced by any defendant, in addition to the persons described in this section, and to the extent not expressly prohibited, plaintiff attorneys in other filed litigation alleging personal injuries resulting from the use of and/or other damages arising from plaintiffs' purchase of Avandia including their paralegal, clerical, secretarial and other staff employed or retained by such counsel;

i. persons noticed for depositions or designated as trial witnesses, or those who counsel of record in good faith expect to testify at deposition or trial, to the extent reasonably necessary in preparing to testify;

j. outside consultants or outside experts retained for the purpose of assisting counsel in the Litigation, with the exception of David Egilman, M.D., for whom the parties shall agree on specific additional protections prior to the disclosure of any Confidential Discovery Materials to said individual;

k. employees of counsel involved solely in one or more aspects of organizing, filing, coding, converting, storing, or retrieving data or designating programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system;

l. employees of third-party contractors performing one or more of the functions set forth in (k) above;

m. any employee of a party or former employee of a party, but only to the extent considered necessary for the preparation and trial of this action;

n. any person who is an author, copyee or addressee of Confidential

Discovery Materials, however, the person seeking access to Confidential Discovery Materials under this subsection is expressly limited to those Confidential Discovery Materials that the person has authored or on which he/she is a copyee or addressee and only to the extent considered reasonably necessary for the preparation and trial of this action; and

- o. any other person, if consented to in writing by the producing party.

Any individual to whom disclosure is to be made under subparagraphs (d) through (o) above, shall sign, prior to such disclosure, a copy of the Endorsement of Protective Order (*see* Exhibit A). Counsel providing access to Confidential Discovery Materials shall retain copies of the executed Endorsement(s) of Protective Order. Any party seeking a copy of an Endorsement may make a demand setting forth the reasons therefor to which the opposing party will respond in writing. If the dispute cannot be resolved, the demanding party may move the Court for an order compelling production upon a showing of good cause. For testifying experts, a copy of the Endorsement of Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the Confidential Discovery Materials to which the expert has access, at the time the expert's designation is served, or at the time the Confidential Discovery Materials are provided to the testifying expert, whichever is later.

Before disclosing Confidential Discovery Materials to any person listed in subparagraphs (d) through (o) who is a Customer or Competitor (or an employee of either) of the party that so designated the Confidential Discovery Materials, but who is not an employee of a party, the party wishing to make such disclosure shall give at least three (3) business days advance notice in writing to the counsel who designated such Discovery Materials as confidential, stating that such disclosure will be made, identifying by subject matter category the Confidential Discovery

Materials to be disclosed, and stating the purposes of such disclosure. If, within the three (3) business day period, a motion is filed objecting to the proposed disclosure, disclosure is not permissible until the Court has denied such motion. As used in this paragraph, (a) the term “Customer” means any direct purchaser of products from GSK, or any regular indirect purchaser of products from GSK (such as a pharmacy generally purchasing through wholesale houses), and does not include physicians; and (b) the term “Competitor” means any manufacturer or seller of prescription medicines.

The notice provision immediately above applies to consultants and/or independent contractors of Competitors to the extent the consultants or contractors derive a substantial portion of their income, or spend a substantial portion of their time working for a pharmaceutical company that manufactures prescription medicines or products in the endocrine science area or that are used to treat the condition of diabetes.

7. Production of Confidential Discovery Materials by Non-Parties

Any non-party who is producing Discovery Materials in the Litigation may agree to and obtain the benefits of the terms and protections of this Order by designating as “Confidential” the Discovery Materials that the non-party is producing, as set forth in section 4.

8. Inadvertent Disclosures

a. The parties agree that the inadvertent production of any Discovery Materials that would be protected from disclosure pursuant to the attorney-client privilege, the work product doctrine or any other relevant privilege or doctrine shall not constitute a waiver of the applicable privilege or doctrine. If any such Discovery Materials are inadvertently produced, the recipient of the Discovery Materials agrees that, upon request from the producing party, it

will promptly return the Discovery Materials and all copies in its possession, delete any versions of the Discovery Materials on any database it maintains and make no use of the information contained in the Discovery Materials; provided, however, that the party returning such Discovery Materials shall have the right to apply to the Court for an order that such Discovery Materials are not protected from disclosure by any privilege. The person returning such material may not, however, assert as a ground for such motion the fact or circumstances of the inadvertent production.

b. The parties further agree that in the event the producing party or other person inadvertently fails to designate Discovery Materials as confidential, it may make such a designation subsequently by notifying all persons and parties to whom such Discovery Materials were produced, in writing, within thirty (30) days of the producing party's or other third person's discovery of the inadvertent failure to designate. After receipt of such timely notification, the persons to whom production has been made shall treat the designated Discovery Materials as confidential, subject to their right to dispute such designation in accordance with paragraph 9.

9. Declassification

a. Nothing shall prevent disclosure beyond that limited by this Order if the producing party consents in writing to such disclosure.

b. If at any time a party (or aggrieved entity permitted by the Court to intervene for such purpose) wishes for any reason to dispute a designation of Discovery Materials as "Confidential" made hereunder, such person shall notify the designating party of such dispute in writing, specifying by exact Bates number(s) the Confidential Discovery Materials in dispute. The designating party shall respond in writing within ten (10) business days of receiving this notification. Notification of any such dispute does not in any way suspend the operation of this

Order.

c. If the parties are unable to amicably resolve the dispute, the proponent of confidentiality may apply by motion to the Court for a ruling that Discovery Materials stamped as “Confidential” are entitled to such status and protection under Rule 26 of the Federal Rules of Civil Procedure and this Order, provided that such motion is made within thirty (30) days from the date the challenger of the Confidential designation challenges the designation. The designating party shall have the burden of proof on such motion to establish the propriety of its Confidential designation.

d. If the time for filing a motion, as provided in paragraph 9(c), has expired without the filing of any such motion, or ten (10) business days have elapsed after the appeal period for an order of this Court that the Discovery Materials shall not be entitled to confidential status, the Confidential Discovery Materials shall lose their designation.

10. Confidential Discovery Materials in Depositions

a. Counsel for any party may show Confidential Discovery Materials to a deponent during deposition and examine the deponent about the materials. Confidential Discovery Materials shown to any witness during a deposition shall not lose its confidential status through such use, and counsel shall exercise their best efforts and take all steps reasonably required to protect its confidentiality during such use.

b. The party noticing a deposition shall obtain each witness’ endorsement of the protective order in advance of the deposition and shall notify the designating party at least three (3) business days prior to the deposition if it has been unable to obtain that witness’ endorsement. The designating party may then move the Court for an Order directing that the

witness abide by the terms of the protective order, and no confidential document shall be shown to the deponent until the Court has ruled. Deponents shall not retain or copy portions of the transcript of their depositions that contain Confidential information not provided by them or the entities they represent unless they sign the form described, and otherwise comply with the provisions in paragraph 6. While a deponent is being examined about any Confidential Discovery Materials or the confidential information contained therein, persons to whom disclosure is not authorized under this Order shall be excluded from being present.

c. Parties (and deponents) may, within thirty (30) days after receiving the final transcript of a deposition, designate pages of the transcript (and exhibits thereto) as Confidential. Until expiration of such thirty (30) day period, the entire transcript, including exhibits, will be treated as subject to protection under this Order. Subject to the procedures outlined in Section 8(b), if no party or deponent timely designates a transcript as confidential, then none of the transcript or its exhibits will be treated as confidential.

11. Confidential Discovery Materials Offered as Evidence at Trial

Confidential Discovery Materials and the information therein may be offered in evidence at trial or any court hearing, provided that the proponent of the evidence gives notice to counsel for the party or other person that designated the Discovery Materials or information as confidential in accordance with the Federal Rules of Evidence and any local rules, standing orders, or rulings in the Litigation governing identification and use of exhibits at trial. Any party may move the Court for an order that the evidence be received *in camera* or under other conditions to prevent unnecessary disclosure. The Court will then determine whether the proffered evidence should continue to be treated as confidential and, if so, what protection, if

any, may be afforded to such Discovery Materials or information at trial.

12. Filing Confidential Discovery Materials With The Court

Confidential Discovery Materials shall not be filed with the Clerk except when required in connection with matters pending before the Court. If filed, they shall be filed in a sealed envelope, clearly marked:

“THIS ENVELOPE CONTAINS DOCUMENTS MARKED AS CONFIDENTIAL THAT ARE THEREFORE COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT”

and shall remain sealed while in the office of the Clerk for so long as they retain their status as Confidential Discovery Materials. In the event a challenge is made to the sealing of the documents by a third-party or the Court, it shall be the burden of the party who has made the “Confidential” designation (not the party who filed the documents under seal, if a different party) to defend that designation. Nothing herein shall supersede or interfere with the parties’ right to designate documents under Paragraph 9 of this Order.

Said Confidential Discovery Materials shall be kept under seal until further order of the Court; however, said Confidential Discovery Materials and other papers filed under seal shall be available to the Court, to counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Order.

13. Client Consultation

Nothing in this Order shall prevent or otherwise restrict counsel from rendering advice to

their clients in this Litigation and, in the course thereof, relying on examination of Confidential Discovery Materials; provided, however, that in rendering such advice and otherwise communicating with such client, counsel shall not make specific disclosure of any item so designated except pursuant to the procedures of paragraph 6.

14. Subpoena by other Courts or Agencies

If another court or an administrative agency subpoenas or otherwise orders production of Confidential Discovery Materials which a person has obtained under the terms of this Order, the person to whom the subpoena or other process is directed shall promptly notify the designating party in writing via fax and overnight delivery to liaison counsel for GSK, as specifically identified in Case Management Order No. 1, of all of the following: (1) the Discovery Materials that are requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. In no event shall Confidential Discovery Materials be produced prior to the expiration of five (5) business days following confirmation of receipt of written notice by the designating party. The person receiving the subpoena or other process shall cooperate with the producing party in any proceeding related thereto.

Additionally, the person subpoenaed must inform the subpoena's issuer of this Order and provide the subpoena's issuer with a copy of this Order. Furthermore, with respect to any subpoena, the designating party has the burden and the expense of seeking the protection in

the applicable court. No party will object to the designating party having a reasonable opportunity to appear in any litigation or proceeding commanding disclosure of such protected material for the sole purpose of seeing to prevent or restrict disclosure thereof.

15. Non-termination

The provisions of this Order shall not terminate at the conclusion of this Litigation. Within ninety (90) days after final conclusion of all aspects of this Litigation, counsel shall, at their option, return or destroy Confidential Discovery Materials and all copies of same. If counsel elects to destroy Confidential Discovery Materials, they shall consult with counsel for the producing party on the manner of destruction and obtain such party's consent to the method and means of destruction. All counsel of record shall make certification of compliance herewith and shall deliver the same to counsel for the party who produced the Confidential Discovery Materials not more than one hundred twenty (120) days after final termination of this Litigation. Counsel of record, however, shall not be required to return or destroy any pretrial or trial records as are regularly maintained by that counsel in the ordinary course of business, which includes: (i) one full set of copies of all pleadings, affidavits, declarations, briefs, memoranda, expert reports, exhibits and other papers filed in this action; and (ii) one set of transcripts of all testimony taken at any depositions, hearings or trial (with exhibits). Any such materials that are not returned or destroyed shall remain subject to this Order, and the Court shall retain jurisdiction to ensure that the terms hereof are not violated.

16. Modification Permitted

Nothing in this Order shall prevent any party or other person from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

17. Responsibility of Attorneys; Copies

The attorneys of record are responsible for employing reasonable measures, consistent with this Order, to control and record duplication of, access to, and distribution of Confidential Discovery Materials, including abstracts and summaries thereof.

No duplications of Confidential Discovery Materials shall be made except for providing working copies and for filing in Court under seal; provided, however, that copies may be made only by those persons specified in sections (a), (b) and (c) of paragraph 6 above. Any copy provided to a person listed in paragraph 6 shall be returned to counsel of record upon completion of the purpose for which such copy was provided. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order and new counsel shall sign this Order.

18. No Waiver of Rights or Implication of Discoverability

a. No disclosure pursuant to any provision of this Order shall waive any rights or privileges of any party granted by this Order.

b. This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation; nor shall this order imply that Confidential Discovery Materials are properly discoverable, relevant, or admissible in this or any other litigation. Each party reserves the right to object to any disclosure of information or production of any documents that the producing party designates as Confidential Discovery Materials on any other ground it may deem appropriate.

c. The entry of this Order shall be without prejudice to the rights of the parties, or any one of them, or of any non-party, to assert or apply for additional or different

protection. Nothing in this Order shall prevent any party from seeking an appropriate protective order to further govern the use of Confidential Discovery Materials at trial.

19. Improper Disclosure of Confidential Discovery Material

Disclosure of Confidential Discovery Materials other than in accordance with the terms of this Protective Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate.

It is so **ORDERED**.

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFÉ, J.

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

_____	:	
IN RE: AVANDIA MARKETING, SALES	:	
PRACTICES AND PRODUCTS LIABILITY	:	MDL No. 1871
LITIGATION	:	07-md-01871-CMR
_____	:	
	:	
THIS DOCUMENT APPLIES TO:	:	
ALL ACTIONS	:	
_____	:	

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to the Protective Order dated _____, 2008 (the "Order"), in the above-captioned litigation ("Litigation"); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my receipt or review of any information or documents designated as Confidential ("Confidential Discovery Materials") pursuant to the Order.

I further agree that I shall not disclose or distribute to others, except in accord with the Order, any Confidential Discovery Materials, in any form whatsoever, and that such Confidential Discovery Materials and the information contained therein may be used only for the purposes authorized by the Order.

I further agree to return all copies of any Confidential Discovery Materials I have received to counsel who provided them to me upon completion of the purpose for which they were provided, and to do so no later than within thirty (30) days of the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material 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

Order, 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 Eastern District of Pennsylvania for the purposes of any proceedings relating to enforcement of the Order.

I further agree and attest to my understanding that I am not permitted to make any changes, amendments or edits to the terms of this Endorsement without the written approval of counsel for all parties to the above-captioned matter, and that any such changes, amendments or edits made without the approval of counsel for all parties shall have no effect.

I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____

By: _____