UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING,
SALES PRACTICES AND PRODUCTS
LIABILITY LITIGATION

MDL 1871

07-MD-1871

THIS DOCUMENT RELATES TO:
ALL ACTIONS

:

PRETRIAL ORDER NO. 56

RULES AND PROCEDURES RELATING TO THE AUTHORIZATION FOR RELEASE OF MEDICAL, HEALTHCARE, PHARMACY AND OTHER RECORDS RELATING TO CLAIMANTS IN THE AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

This matter is before the Court upon the joint application of the Plaintiffs' Steering Committee ("PSC") and GlaxoSmithKline ("GSK") for an Order aiding in the collection and distribution of medical records in compliance with this Court's previous Orders. After consideration of this joint request and finding that such an Order would facilitate the orderly, uniform and cost-effective acquisition of relevant information and materials for this litigation, this 20th day of April, 2009, it is ORDERED as follows:

1. The basis for this Order. Pursuant to this Court's Order dated June 9, 2008 (PTO No. 7), a plaintiff is required to complete and serve a Plaintiff Fact Sheet within sixty (60) days of filing and serving a Complaint or entering into a Tolling Agreement with GSK. In addition to the Fact Sheet, Plaintiffs are required to sign and serve a Health Insurance Portability and Accountability Act ("HIPAA") compliant authorizations as well as any medical records then in his/her possession. Some healthcare providers, pharmacies and other entities having custody of these records (including, where applicable, employment, military and social security records), however, have refused to release such records unless specific forms prepared by the particular entity are used. Requiring specific forms prepared by individual entities causes a delay in the exchange of relevant information in this litigation. In order to facilitate the timely exchange of medical and other information, the PSC and GSK have prepared four (4) Authorization Forms that are fully compliant with HIPAA. The four (4) Authorization Forms are attached collectively as Exhibit A. The purpose of this Order is to provide for a simple, uniform and cost-effective process for the collection of records relevant to claims pending before this Court. Accordingly, this Order is issued pursuant to the Court's authority to direct and control the coordinated

discovery in this litigation pursuant to 28 U.S.C. § 1407, Fed.R.Civ.P. 16 and Fed.R.Civ.P. 26(b), and the Court's inherent authority regarding case-specific discovery in the MDL.

- 2. Claimants Affected By This Order. This Order applies to all claims pending before this Court under MDL 1871. This includes cases originally transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to its Order of October 16, 2007 or as tagalong actions, and all related cases originally filed in this Court or transferred or removed to this Court. This Order also applies to all cases tolled pursuant to Tolling Agreements entered into between plaintiffs' counsel and GSK.
- 3. **Discovery Affected By This Order.** This Order applies to the procurement of information and materials from entities (including, but not limited to, physicians, healthcare providers, pharmacies, educational facilities, former and present employers, insurance providers, all branches of the military and any other federal, state and/or local government agencies) relating to claimants referred to in Paragraph 2 above.
- 4. Duty To Accept Court-Approved Authorization To Release Medical Records And Employment Records. The Authorization Forms attached to this Order are HIPAA compliant and have been approved for use in all claims affected by this Order. Accordingly:
 - (a) All physicians, healthcare providers, pharmacies, pharmacy benefits managers ("PBM"), educational facilities, former and present employers, insurance providers, all branches of the military, any federal, state, and/or local government agencies, or any other entity asked to produce records relating to a plaintiff or employee (all referred to as "Entities") shall accept the Authorization Forms as valid for all claims affected by this Order;
 - (b) Entities may not request or insist upon different forms or terms different from the Authorization Forms;
 - (c) When signed by a patient or employee and plaintiff in claims affected by this Order, the Authorization Forms shall be relied upon by all Entities to authorize the release of all records, including all medical and psychiatric records;
 - (d) No facility-specific or different form shall be necessary for production of any records relating to a current or former patient or employee;
 - (e) A photocopy or .pdf image of the Authorization Forms shall be accepted;
 - (f) No original signatures shall be required on the Authorization Forms for production of any records relating to a current or former patient or employee;
 - (g) Any Authorization Form dated after October 16, 2007, shall be effective for production of any records relating to a current or former patient or employee and no differently dated Authorization shall be necessary or

requested by the Entities;

- (h) Entities may not impose any waiting period for the production of records; and
- (i) Entities may not condition the release of requested records upon the payment of unreasonable "processing" or "handling" fees.
- 5. Deceased Plaintiffs. Due to the difficulties the parties are experiencing in obtaining pertinent medical records on behalf of those clients who are deceased, the Court finds it necessary for the efficient procurement of those records to have specific rules pertaining to claims involving deceased plaintiffs. For the sole and limited purpose of obtaining records associated with a claim covered by this Order, Plaintiff's counsel is considered the "personal representative" of an estate he/she represents and may sign a Court-Approved Authorization to obtain records. All Entities are hereby Ordered to accept an Authorization for a deceased plaintiff signed by Plaintiff's counsel.

It is so **ORDERED**.

CYNTHIA M. RUFE, J.
/s/ Cynthia M. Rufe
BY THE COURT: