

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

In re: AVANDIA MARKETING, SALES
PRACTICES AND PRODUCTS LIABILITY
LITIGATION

:
: AVANDIA MDL 1871
: 2007-MD-1871
:
:

THIS DOCUMENT RELATES TO:
ALL ACTIONS

:
: HON. CYNTHIA M. RUFÉ
:
:

PRETRIAL ORDER NO. 121

AND NOW, this 15th day of November, 2010, upon review of Defendant's Motion for a Lone Pine Order [Doc. No. 769], Plaintiffs' Responses thereto [Doc. No. 798, 800], and Defendant's Reply [Doc. No. 839], the Court notes it shares Defendant's concern that the Plaintiff Fact Sheets are often unsupported by submitted documents and Plaintiffs have not provided significant support for their stated position that cases can be fairly evaluated based on those Fact Sheets. It is now clear to the Court additional support for Plaintiff's claims is necessary in furtherance of settlement agreements, for the selection of cases for bellwether trials, and for the timely remand of cases to the sending courts for resolution.¹ The Court's overriding concern is the need to objectively identify which of the many thousand plaintiffs have injuries which can credibly be attributed to Avandia usage, as alleged in their complaints (or Plaintiff Fact Sheets if the filing of a complaint has been tolled). The Order issued below merely requires information which plaintiffs and their counsel should have possessed before

¹ "Lone Pine orders are designed to handle the complex issues and potential burdens of defendants and the courts in mass tort litigation. In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under Fed. R. Civ. P. 16." Acuna v. Brown & Root, Inc. et. al., 200 F.3d 335, 340 (5th Cir. 2000).

filing their claims: proof of Avandia usage, proof of injury, information about the nature of the injury, and the relation in time of the injury to the Avandia usage. Accordingly, the Court hereby **GRANTS** Defendant's Motion in part, and **DENIES** the Motion in part, as follows:

1. Physician Certification of Avandia Usage and Injury. In addition to all existing pre-trial disclosure obligations, each plaintiff and claimant, including each personal representative of an estate of any deceased or any incompetent user of Avandia (collectively, "plaintiff") shall, within the time limits set forth in Paragraph 3 below, serve upon counsel for GSK a signed certification from a licensed physician that includes the following:

- a. plaintiff's name, address, and date of birth;
- b. a determination that the plaintiff used Avandia, along with a listing of the records reviewed by the physician that document such usage and the dates of such usage;
- c. either (1) a determination that the plaintiff suffered one or more injuries listed in Exhibit A to this Order during Avandia usage or within one year of cessation of Avandia usage, or (2) a determination that (i) the plaintiff suffered one or more injuries listed in Exhibit A to this Order more than one year after cessation of Avandia usage and (ii) the Avandia usage caused such injury or injuries;
- d. an identification of the injury or injuries set forth in Paragraph 1.c; a listing of the records reviewed by the physician that document such injury or injuries; and the dates of the records that document such injury or injuries; and
- e. copies of all records listed in Paragraphs 1.b and 1.d.

2. Documentation of Avandia Usage. At the same time that each plaintiff serves on counsel for GSK the Physician Certification described in Paragraph 1,

each plaintiff must serve GSK counsel with records documenting all period(s) of Avandia usage.

3. Schedule for Serving Physician Certification Pursuant to Paragraph 1 and Usage Documents Pursuant to Paragraph 2:

a. For all cases filed or made subject to a tolling agreement on or after January 1, 2010 and before the date of this Order, the Physician Certification and Documents shall be served within 60 days of the filing of this Order.

b. For all cases filed or made subject to a tolling agreement on or after January 1, 2009, and before January 1, 2010, the Physician Certification and Documents shall be served within 90 days of the filing of this Order.

c. For all cases filed or made subject to a tolling agreement on or after January 1, 2008, and before January 1, 2009, the Physician Certification and Documents shall be served within 120 days of the filing of this Order.

d. For all cases filed or made subject to a tolling agreement before January 1, 2008, the Physician Certification and Documents shall be served within 150 days of the filing of this Order.

e. For all cases filed or made subject to a tolling agreement on or after the date of this Order, the Physician Certification and Documents shall be served within 60 days of the filing or the date on which the claim was made subject to a tolling agreement.

f. If any plaintiff is unable to comply with the foregoing deadlines after making reasonable efforts to do so, that plaintiff may apply to the Special Master for an extension of the deadlines for good cause shown; provided, however, that

any request for an extension must be made in writing and submitted to the Special Master at least 15 days before the deadline for submission of the Physician Certification and Documents.

4. Dismissal of Plaintiffs Who Fail to Provide Required Documents.

When any plaintiff fails to provide the documents required by this Order by the required deadline, the Court may, on GSK's motion, dismiss plaintiff's claims with prejudice.

5. Rule 26 Expert Obligations. The Physician Certification required

by this Order is not a substitute for any Rule 26 expert obligations required under the law or separate order of the Court. No physician who completes a Physician Certification pursuant to this Order is subject to fact or expert discovery solely because of his or her role in completing the Physician Certification.

Dated: *November 5th,*
2010

IT IS SO ORDERED.

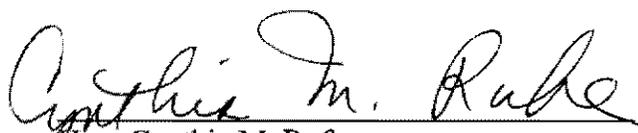

Hon. Cynthia M. Rufe
United States District Judge

EXHIBIT A

The following contains a list of injuries alleged by plaintiffs to be related to Avandia use. There may be other specific injuries alleged by plaintiffs, not listed below, that are covered by the "other" category below. GSK has disputed, and continues to dispute, these allegations, and this list has not been endorsed in whole or in part by GSK.

Myocardial Infarction	Ischemic Heart Disease
Acute Coronary Syndrome	Percutaneous coronary intervention (PCI)/Coronary Angioplasty
Angina Pectoris	Angiogram
Angina Unstable	Dyspnea
Postinfarction Angina	Edema
Prinzmetal Angina	Cardiovascular Accident (Stroke)
Coronary Artery Vasospasm	Transient ischemic attack
Arteriospasm Coronary	Heart failure
Coronary Artery Occlusion	Fluid retention
Coronary Artery Reocclusion	Fracture
Coronary Artery Thrombosis	Hepatic effects
Coronary Artery Disorder	Percutaneous transluminal renal angioplasty (PTRA), other renal injuries
Coronary Artery Disease or Syndrome	Hypoglycemia
Coronary Bypass Thrombosis	Hyperlipidemia/Dyslipidemia
Stenting	Hypertension
Coronary Artery Bypass Grafting	Macular edema
Myocardial Ischemia	Atrial Fibrillation
Arrhythmia	Percutaneous transluminal coronary angioplasty
Subendocardial Ischemia	Coronary clot extraction
Abnormal ECG/EKG	Thrombolytic therapy
Ventricular Tachycardia	Liver injury
Ventricular Fibrillation	Other (identify)
Ventricular Asystole	
Chest Pain	
Cardiac Arrest	
Death	