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U.S. DISTRICT COURT  
EASTERN DISTRICT OF LA

UNITED STATES DISTRICT COURT  
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EASTERN DISTRICT OF LOUISIANA

LORETTA G. WHYTE  
CLERK

In re: VIOXX® \* MDL Docket No. 1657  
\*  
PRODUCTS LIABILITY LITIGATION \* SECTION L  
\*  
\* JUDGE FALLON  
\*  
\* MAG. JUDGE KNOWLES  
\*  
\* \* \* \* \*

THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER NO. 28**  
**(Prima Facie Evidence of Usage, Injury and Causation)**

This Order requires all parties who are (1) plaintiffs with personal injury claims pending in MDL Docket No. 1657 ("Plaintiff" or "Plaintiffs") as of November 9, 2007, or (2) claimants who have sought tolling pursuant to the tolling agreement dated June 1, 2005 (collectively "Claimant" or "Claimants") to produce specified information regarding their claims, unless the claim is eligible for, and has been submitted to, the Resolution Program. This Order, however, does *not* apply to plaintiffs who file claims after November 9, 2007 ("Post 11.09 Plaintiffs"). Post 11.09 Plaintiffs are covered by a separate order, Pretrial Order No. 29. Persons who represent themselves *pro se* in this proceeding shall comply fully with all obligations required of counsel by this Order, unless otherwise stated.

\_\_\_ Fee \_\_\_\_\_  
\_\_\_ Process \_\_\_\_\_  
 Dkt# \_\_\_\_\_  
\_\_\_ CtRmDep \_\_\_\_\_  
\_\_\_ Doc. No \_\_\_\_\_

**I. PRESERVATION NOTICE REQUIREMENT**

- A. Within sixty (60) days of entry of this Order, counsel for a Plaintiff or Claimant subject to this Order shall notify the following individuals or entities, by registered mail, that they may have records relevant to the Plaintiff's or Claimant's claim in this MDL Proceeding ("Claim") and that any records relating to the Plaintiff or Claimant must be preserved pursuant to Pretrial Order No. 1 entered by this Court on February 17, 2005 (the "Notice"), pending collection by the Plaintiff or Claimant:
1. All Pharmacies that dispensed any medications to the Plaintiff or Claimant for the period from January 1, 1995 to the present;
  2. All Physicians, Medical Facilities, other Healthcare Providers and/or other persons ("Other Providers") who Plaintiff or Claimant claims provided any samples of Vioxx to the Plaintiff or Claimant;
  3. All Physicians, Medical Facilities and/or other Healthcare Providers who prescribed Vioxx for the Plaintiff or Claimant;
  4. All Physicians and/or other Healthcare Providers who treated Plaintiff or Claimant for the period from January 1, 1995 to the present; and
  5. If Plaintiff or Claimant is seeking lost wages, all of his employers for the period from three years prior to the date for which he is seeking lost wages through the last day for which Plaintiff or Claimant is seeking lost wages.
- B. A copy of Pre Trial Order No. 1 shall be attached to the Notice and all copies of the Notice shall be preserved by Counsel for Plaintiff or Claimant for so long as the claim remains pending in this Proceeding.
- C. By no later than March 15, 2008, Plaintiff or Claimant shall serve a statement listing the names and addresses of all individuals or entities to which Notices were sent, along with copies of the Notices and a signed certification that the Notices were sent as required by this Order. Service by Plaintiffs shall be made in accordance with the service procedures of PTO No. 8 and paragraphs 5 through 7 of PTO 18C. Service by Claimants shall be made on Susan Giamportone at Womble Carlyle Sandrige & Rice, PLLC.
- D. Plaintiffs or Claimants who fail to fully comply with the requirements of this Order shall be given notice by e-mail or fax from Defendants' Liaison Counsel or his designee and shall be provided thirty (30) additional days to cure such deficiency ("Cure Period"). No other extensions will be granted, except for good cause shown. If Plaintiff or Claimant fails to cure the deficiency within the Cure Period, Defendant's Liaison Counsel shall file a Motion to Show Cause why the claim should not be dismissed with prejudice or, if tolled, why the tolling for that Claimant should not be terminated. Plaintiff or Claimant shall thereupon have thirty (30) days to respond to the Notice to Show Cause. Any failure to respond to

the Motion within the required period of time shall lead to the dismissal of the claim with prejudice or, if tolled, the termination of tolling for that claim, except for good cause shown.

- E. Plaintiff or Claimant may not seek to introduce into evidence at trial any document or information asserting that Vioxx was dispensed by a pharmacy or that Vioxx was provided to the Plaintiff or Claimant as a sample if a Notice were not sent to the Plaintiff's or Claimant's pharmacy, physician, other healthcare provider and/or Other Provider as required by this Order, except upon leave of court for good cause shown. A Plaintiff or Claimant who fails to comply with this Order may also be subject to other sanctions or orders.

## **II. DISCOVERY REQUIREMENTS**

- A. All Plaintiffs or Claimants who claim to have suffered an injury as a result of taking Vioxx must produce all of the information described in this Section II unless (a) the injury alleged is a Myocardial Infarction ("MI"), Sudden Cardiac Death ("SCD"), or Stroke as those terms are defined, *infra.*, in Section III, *and* (b) the Plaintiff or Claimant has submitted the claim to the Resolution Program:
1. All pharmacy records regarding the dispensing of drugs to the Plaintiff or Claimant for the period from January 1, 1995 to the present, along with a signed certification from the respective pharmacy or pharmacies indicating that the production is complete.
  2. If any death is claimed, a statement to that effect along with a copy of the death certificate and autopsy report, if one was performed.
  3. For Plaintiffs or Claimants alleging a MI, SCD or Stroke Injury, an Amended and Supplemental Plaintiff Profile Form ("ASPPF") and authorizations or "Claimant Profile Form" ("CPF") in a form attached hereto as Exhibit A unless Plaintiff or Claimant has as of the date of this Order submitted a Plaintiff Profile Form or Claimant Profile Form. Service by Plaintiffs shall be made in accordance with the service procedures of PTO No. 8 and paragraphs 5 through 7 of PTO 18C. Service by Claimants shall be made on Susan Giamportone at Womble Carlyle Sandrige & Rice, PLLC.
  4. For Plaintiffs not alleging a MI, SCD or Stroke Injury, an ASPPF and authorizations in the forms attached hereto as Exhibit A and served in accordance with the service methods of PTO 8 and paragraphs 5 through 9 of 18C.
  5. Answers to the Interrogatories set out as Exhibit B. Service by Plaintiffs shall be made in accordance with the service procedures of PTO No. 8 and paragraphs 5 through 7 of PTO 18C. Service by Claimants shall be made on Susan Giamportone at Womble Carlyle Sandrige & Rice, PLLC.

6. All medical records relating to the Plaintiff or Claimants from all healthcare providers requested in the Amended and Supplemental Plaintiff Profile Form for the period from January 1, 1995 to the present, along with a signed certification from each healthcare provider who has records relating to the Plaintiff indicating that all records in the possession, custody or control of the Provider have been produced. Service by Plaintiffs shall be made in accordance with the service procedures of PTO No. 8 and paragraphs 5 through 7 of PTO 18C. Service by Claimants shall be made on Susan Giamportone at Womble Carlyle Sandrige & Rice, PLLC.
  7. An affidavit signed by the Plaintiff or Claimant (i) attesting that records have been collected from all pharmacies that dispensed drugs to, or for, the Plaintiff or Claimant; (ii) attesting that all medical records described in subparagraph (6) above have been collected; and (iii) attesting that all records collected pursuant to subparagraphs A (1), (2) and (6) have been produced pursuant to this Order, along with an index or list identifying the source of the records. Service by Plaintiffs shall be made in accordance with the service procedures of PTO No. 8 and paragraphs 5 through 7 of PTO 18C. Service by Claimants shall be made on Susan Giamportone at Womble Carlyle Sandrige & Rice, PLLC.
  8. A Rule 26(a)(2) case specific expert report from a medical expert attesting (i) to a reasonable degree of medical probability that the Plaintiff or Claimant suffered an injury and (ii) that Vioxx caused the injury. The case specific expert report must include (i) an explanation of the basis of the attestation that Vioxx caused the Plaintiff or Claimant to suffer the injury, (ii) an identification of any other causes that were considered in formulating the opinion, (iii) a description of the specific injuries allegedly suffered; (iv) a description of the specific medical findings that support the diagnosis of those injuries; and (v) and identification of all documents relied on by the expert in forming his opinions.
- B. If any of the documents described in paragraphs (A) (1), (2) and (6) above do not exist, the Plaintiff shall state that fact in his or her affidavit and the reason why they do not exist and provide a certified "No Records Statement" from the pharmacy or healthcare provider.
- C. Plaintiffs and Claimants shall produce the items set forth above in this Section II in accordance the following schedule:
1. For Plaintiffs and Claimants whose last name begins with the letters A through L, on or before May 1, 2008;
  2. For Plaintiffs and Claimants whose last name begins with the letters M through Z, on or before July 1, 2008.

3. Plaintiffs shall serve the items set forth above in accordance with the service procedures of PTO 8 and paragraphs 5 through 7 of PTO 18C. Claimants shall serve the items set forth above on Susan Giamportone at Womble Carlyle Sandrige & Rice, PLLC
  4. Plaintiffs whose cases are subsequently transferred or removed to this Court shall produce the items set forth above within sixty (60) days of removal (measured from the date the notice of removal is filed in this Court) or transfer (measured from the date of filing in this Court of the Transfer Order issued by the Judicial Panel on Multidistrict Litigation) of their case to this proceeding.
- D. Plaintiffs or Claimants who fail to fully comply with the requirements of this Order shall be given notice by e-mail or fax from Defendants' Liaison Counsel or his designee and shall be provided thirty (30) additional days to cure such deficiency ("Cure Period"). No other extensions will be granted, except for good cause shown. If Plaintiff or Claimant fails to cure the deficiency within the Cure Period, Defendant's Liaison Counsel shall file a Motion to Show Cause why the claim should not be dismissed with prejudice or, if tolled, why the tolling for that Claimant should not be terminated. Plaintiff or Claimant shall thereupon have thirty (30) days to respond to the Notice to Show Cause. Any failure to respond to the Motion within the required period of time shall lead to the dismissal of the claim with prejudice or, if tolled, the termination of tolling for that claim.
- E. Nothing in this Order abrogates or replaces each Plaintiff's obligation to submit the Plaintiff Profile Form, authorizations, and other materials required under Pretrial Order 18C. The Plaintiff need not re-submit a Plaintiff Profile Form if one has already been submitted with respect to his or her claim.

### **III. DEFINITIONS**

- A. For purposes of this Order only, "Myocardial Infarction" ("MI") is defined as follows:
1. A final or discharge diagnosis in contemporaneous medical records of a myocardial infarction or heart attack; or
  2. A diagnosis or affirmative finding in the contemporaneous medical records (e.g., a report of consultation) by a cardiologist of a myocardial infarction or heart attack; or, within 14 days of discharge from the hospitalization related to the Event, an independent diagnosis by a treating cardiologist that the Event was a myocardial infarction or heart attack; provided that, in either instance, the final or discharge diagnosis does not rule out a myocardial infarction; or
  3. If the medical records are silent as to whether or not plaintiff had a myocardial infarction, new pathological Q waves in two or more contiguous leads; or

4. If the medical records are silent as to whether or not plaintiff had a myocardial infarction, (i) Signs and symptoms described in medical records of a heart attack (including but not limited to chest pain, pressure, tightness or discomfort, pain or discomfort in the upper areas of the body including but not limited to one or both arms, the back, neck, jaw or stomach, or shoulders; shortness of breath, weakness, dizziness, cold sweat, or excessive sweating, nausea, weakness, fatigue, loss of consciousness or posture, lightheadedness, feeling of faintness, heart-burn or indigestion sensations, feelings of restlessness or anxiousness, a sense of impending doom, disorientation, lips, hands or feet turning slightly blue, abnormal heart rhythms (arrhythmias), or loss of consciousness, cardiac arrest, blood pressure fluctuations or drops requiring medical intervention) or new ischemic ST-T wave changes on an electrocardiogram in two or more contiguous leads; AND (ii) a rise and fall of cardiac enzymes that includes a rise in serum creatine kinase MB (CK-MB) to greater than two times the upper limit of normal (based on the individual's laboratory's normal range) or a rise in serum cardiac troponin greater than two times the upper limit of normal that a given laboratory considers diagnostic for infarctions. (In the event that the laboratory records do not reflect the normal diagnostic range for troponin that is utilized by that specific laboratory, a rise in the troponin to greater than 1.5 ng/ml shall be deemed to indicate a myocardial infarction.)
  5. An event is not a myocardial infarction under definition Nos. 3 or 4 above, if myocardial infarction is ruled out as a diagnosis in the discharge summary or by an in-house cardiology consult at the time of the event, or the final diagnosis is angina or unstable angina.
- B. For purposes of this Order only, "Sudden Cardiac Death" ("SCD") is defined as a witnessed instantaneous or near-instantaneous unexplained death that occurs without warning or within one hour of non-diagnostic symptoms, or, an unwitnessed, unexpected sudden death in which criteria for a fatal coronary, cerebrovascular event or other cause or event are not met.
- C. For purposes of this Order only, "Ischemic Stroke" ("Stroke") is defined as:
1. A final or discharge diagnosis in contemporaneous medical records of an ischemic stroke or ischemic cerebrovascular event or accident (*i.e.*, ischemic stroke, intracranial thrombosis, cerebral embolism, thrombotic stroke, embolic stroke, lacunar infarct, lacunar stroke, thrombotic occlusion, cerebrovascular event or accident that is not a primary hemorrhagic event, and cerebral infarction; or a hemorrhagic stroke that is secondary to the terms previously listed); or
  2. If the final or discharge diagnosis is silent as to whether or not claimant had an Ischemic Stroke, a diagnosis or affirmative finding in the contemporaneous medical records (*e.g.*, a report of consultation) by a

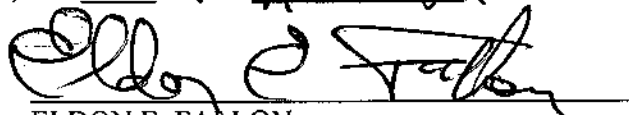
neurologist of an Ischemic Stroke; or, within 14 days of discharge from the hospitalization related to the Event, an independent diagnosis by a treating neurologist that the Event was an Ischemic Stroke.

3. For purposes of this Order only, an Event is **not** an Ischemic Stroke if:
- a. stroke or cerebrovascular accident is ruled out as a diagnosis in the discharge summary or by a treating neurologist within 14 days of discharge from the hospitalization related to the Event;
  - b. hemorrhagic stroke or hemorrhagic cerebrovascular accident is the diagnosis in the discharge summary or by a treating neurologist within 14 days of discharge from the hospitalization related to the Event. This definition does not include a hemorrhagic stroke that is secondary to an Ischemic Stroke; or
  - c. transient ischemic attack is the diagnosis in the discharge summary or is the diagnosis of a treating neurologist within 14 days of discharge from the hospitalization related to the Event.

#### IV. PENALTIES FOR FRAUD AND DECEPTION

Any Plaintiff (and his or her attorneys) who submits false or intentionally misleading information, or otherwise attempts to satisfy the documentation requirements of this Order through any form of deception, dishonesty or fraud shall be subject to appropriate sanctions (including monetary sanctions and costs) and dismissal with prejudice pursuant to Fed. R. Civ. P. 37.

New Orleans, Louisiana, this 9<sup>th</sup> day of November, 2007.



ELDON E. FALLON  
UNITED STATES DISTRICT JUDGE