UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE) PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:
All Cases

MAGISTRATE JUDGE HANNA

AMENDED CASE MANAGEMENT ORDER: FACT SHEET ANALYSIS

The Fact Sheet process having advanced substantially, this Court issues the following orders related to the use of information disclosed in the Fact Sheets to further these proceedings.

IT IS ORDERED, the **Defendants** shall provide the following particularized information, relating to each Plaintiff in the MDL, if contained in the relevant Plaintiff Fact Sheet, to the Special Masters and the Plaintiffs Steering Committee, who shall treat the information as confidential, subject to CASE MANAGEMENT ORDER: Protecting the Confidentiality of Discovery Materials (Rec. Doc. 1540). The Defendants shall produce the information in a manner and timeframe as ordered by the Court and conveyed to the Defendants by way of the Special Masters:

I. Actos User Background Information

- Name.
- Date of birth.
- Gender.
- Race.
- If applicable, date of death and cause of death as noted in the death certificate.

II. Exposure to Actos

- The date Actos use began, and in what dose.
- The date Actos use ceased.
- Total duration of Actos use.
- Any change made to the dosage of Actos over the course of its use, including the date any change was made.
- Cumulative Actos dose at the time of diagnosis of bladder cancer.
- Whether any generic Actos alternative was used, and if so, the date(s) of use of that alternative.

III. Medical History

- Any recurrent chronic infection or irritation of the urinary tract, and if known, the date(s) and duration of such infection or irritation.
- The date bladder cancer was diagnosed, according to a pathology report, and the type of cancer (e.g., muscular invasive or superficial).
- Any medically documented symptoms of bladder cancer occurring prior to diagnosis, and when medically noted.

IV. Treatment

- Any treatment for bladder cancer administered (e.g., TURBT/TURP, cystectomy, BCG), including the date(s) of treatment.
- Whether the bladder cancer recurred, and if so, the date(s) of recurrence; any treatment administered in response, including the date(s) of treatment and the nature of the recurrence (e.g., muscular invasive or superficial).

V. Risk/Causative Factors

- Smoking history, including secondhand smoke.
- Environmental exposures that the medical community agrees present a risk factor of bladder cancer (e.g., parasites, aristolochic acid), and if known, the date(s) and duration of exposure.
- Occupational exposures that the medical community agrees present a risk factor of bladder cancer (e.g., aromatic amines, arsenic), and if known, the date(s) and duration of exposure.
- Any medical history of genetic abnormality or history of hereditary predisposition presenting a risk factor for bladder cancer.
- Any other medically accepted risk factors for bladder cancer.[1]

IT IS FURTHER ORDERED, the **Plaintiffs' Steering Committee** shall provide the following particularized information, relating to each Plaintiff's case in the MDL, if contained in the relevant Defendant Fact Sheet, to the Special Masters in a manner and timeframe as ordered by the Court and conveyed to the Plaintiffs' Steering Committee by way of the Special Masters:

I. Actos User Background Information

- The Plaintiff's name.
- The Actos user's name (if different than the Plaintiff).
- The name of any physician who prescribed Actos to the Actos user.

II. Sales Representative Information

- The name of any Takeda or Eli Lilly sales representative who contacted a prescribing physician.

[1] Diabetes, while a disputed potential risk factor, need not be included in this list, as the Court assumes that every case in these MDL proceedings involves a Plaintiff or Decedent who has or had diabetes. If that assumption is incorrect as to any case in these proceedings, that fact should be noted.

- Whether the contacting sales representative was employed by a Takeda entity or Eli Lilly during the time of contact.

III. Contact with a Prescribing Physician

- Whether any "Dear Doctor" letter, or a document similar in purpose, was sent to a prescribing physician, and the date any such document was sent.
- Whether a "PIR" was received from a prescribing physician by any Takeda entity or Eli Lilly, and if so, from whom it was received and the date it was received; whether any response to a PIR was sent to a prescribing physician by a Takeda entity or Eli Lilly, and if so, the date it was sent.
- Whether any promotional material was provided to a prescribing physician by a Takeda or Eli Lilly sales representative, the nature of the material, and the date it was provided.
- Any other contact between a prescribing physician and Takeda or Eli Lilly or their sales representatives, the nature of the contact, and the date of the contact.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 6 day of February, 2015.

REBECCA F. DOHERTY
UNITED STATES DISTRICT COURT