

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY  
CENTRAL DIVISION  
LEXINGTON**

**IN RE: ONGLYZA (SAXAGLIPTIN)  
AND KOMBIGLYZE XR  
(SAXAGLIPTIN AND METFORMIN)  
PRODUCTS LIABILITY LITIGATION**

Master File No. 5:18-md-2809-KKC  
**MDL No. 2809**  
ALL CASES

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**CASE MANAGEMENT ORDER NO. 2  
Regarding Plaintiff Profile Forms, Plaintiff Fact Sheets, and Defendant Fact Sheets**

The Court hereby ORDERS that the joint motion (DE 183) filed by the plaintiffs and certain defendants (AstraZeneca Pharmaceuticals, LP; Bristol-Myers Squibb Company; and McKesson Corporation) is GRANTED. The Court further hereby ORDERS as follows:

**I. PLAINTIFF PROFILE FORM**

This Case Management Order governs the production of Plaintiff Profile Forms (PPF) for all cases now included in MDL No. 2809 and any cases subsequently added to MDL No. 2809. Each personal injury plaintiff or plaintiff suing in a representative capacity in MDL No. 2809 is required to deliver to the defendants a completed and verified PPF and accompanying materials. The PPF to be used is filed in the record at Docket Entry 183-2.

For all cases included in MDL No. 2809 or any case added to MDL No. 2809 on or before January 15, 2019, the completed PPF and accompanying materials, including executed authorizations and required documents and things, are due by March 1, 2019. For any case added to MDL No. 2809 after January 15, 2019, the PPF and accompanying materials are due

within seventy-five (75) days of the date the case is added to MDL No. 2809.<sup>1</sup> The PPF and accompanying materials shall be sent to defendants' counsel, Emily Ullman, at eullman@cov.com. Representatives of Plaintiffs' Co-lead Counsel shall be copied on all PPF submissions at BMeyers@thesandersfirm.com and ESmizer@thesandersfirm.com.

Responses to the PPF shall be treated as answers to interrogatories under Federal Rule of Civil Procedure ("FRCP") 33 and requests for the production of documents under FRCP 34 and shall be supplemented in accordance with FRCP 26. The questions contained in the PPF are non-objectionable and shall be answered without objection. Each answer in the PPF must be as complete and straightforward as the information reasonably available to the responding plaintiff permits. If an information request and/or question in the PPF cannot be answered completely, it shall be answered to the extent possible. If the responding plaintiff does not have personal knowledge sufficient to respond fully to an information request and/or question in the PPF, that plaintiff shall so state, but shall make a reasonable and good faith effort to obtain the information, except where the information is equally available to the defendants. The responding plaintiff must verify his or her response to the PPF under oath, certifying and declaring under penalty of perjury under the laws of the United States that his or her responses are true and correct.

All documents or things that are responsive to the document requests in the PPF and that are in the possession, custody, or control of the responding plaintiff shall be produced with the PPF response. Each plaintiff shall also provide a signed records authorization to his or her individual counsel. Plaintiff's individual counsel shall provide to defendants' counsel a

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<sup>1</sup> A case shall be deemed added to MDL No. 2809 either (a) on the date that the certified copy of the Conditional Transfer Order issued by the JPML is entered on the docket of this Court; or (b) where transfer is contested, the date of transfer in any subsequent order from the JPML; or (c) the date the case is directly filed in MDL No. 2809.

completed authorization for each provider identified in the PPF. Defendants shall not obtain records from a plaintiff's mental health provider pursuant to such authorizations absent further order of the Court or agreement of the parties. Defendants shall make records received pursuant to the authorizations available by a mutually-agreed method to Plaintiffs' Co-Lead Counsel and individual plaintiff's counsel as identified in the PPF. The parties shall apportion the costs of making such records available to plaintiffs' counsel in a manner to be determined by the parties.

## **II. PRODUCTION OF RECORDS SHOWING USE AND INJURY**

Each plaintiff alleges that use of Onglyza® or Kombiglyze XR® (collectively, "Onglyza") caused him or her to develop heart failure (or aggravation or worsening of heart failure) or caused his or her decedent to develop heart failure (or aggravation or worsening of heart failure). As part of his or her PPF, a plaintiff must produce documentation that shows: (1) use of Onglyza; and (2) subsequent heart failure or aggravation or worsening of heart failure.

With respect to records that plaintiff contends show use of Onglyza, a plaintiff must produce with his or her PPF all documents in plaintiff's possession, custody, or control showing proof of use, which may include any of the following: (1) pharmacy records demonstrating that a prescription for Onglyza was filled by a retail or hospital pharmacy for use by the plaintiff or his or her decedent; (2) records showing that samples were given or provided by a physician for use by the plaintiff or his or her decedent; (3) medical record(s) denoting a prescription to plaintiff for Onglyza or notation of Onglyza as a current medication; (4) an affidavit from a healthcare provider attesting that he or she prescribed Onglyza to plaintiff; or (5) pill bottle(s) for use by the plaintiff or his or her decedent.

The parties agree that the scope of the allegations in these cases is limited to heart failure claims including wrongful death claims resulting from heart failure. With respect to records showing plaintiff's injury, a plaintiff must produce, with his or her PPF, medical

record(s) demonstrating that he or she, after exposure to Onglyza, experienced new, aggravating, or worsening heart failure.

### **III. DEFICIENCY NOTICE AND ENFORCEMENT PROCEDURES**

The following procedures shall apply to failure to comply with the PPF requirements, including by failing to provide a response entirely or failing to produce documents showing use and injury:

Within forty-five (45) days of receiving plaintiff's PPF or, if no PPF has been received, the deadline by which the PPF should have been submitted, defendants must notify individual plaintiff's counsel by e-mail specifically enumerating alleged deficiencies in plaintiff's responses to the PPF ("Deficiency Notice"). The relevant plaintiff shall have forty-five (45) days from the date of the Deficiency Notice to cure the identified deficiency or deficiencies. Once cured, defendants shall send confirmation to individual plaintiff's counsel that the PPF is no longer deficient. Plaintiffs' Co-Lead Counsel, Timothy Clark (TClark@thesandersfirm.com; BMeyers@thesandersfirm.com) and Jennifer A. Moore (jmoore@gminjurylaw.com; klane@gminjurylaw.com), shall be copied on all Deficiency Notices and responses.

If the deficiency is not cured, counsel for the defendants may move the Court to issue an order requiring the plaintiff to file a response within thirty (30) days showing cause why the case should not be dismissed with prejudice. If the plaintiff files such a response, defendants may file a reply. Any such reply must be filed within fourteen (14) days of the date the response is filed.

If a plaintiff who is ordered to do so fails to show cause why the case should not be dismissed with prejudice, the Court must dismiss the case with prejudice.

Defendants should move the Court in an omnibus fashion for show-cause orders for multiple plaintiffs whenever possible to encourage efficiency and judicial economy.

Any filings regarding an order to show cause shall not prevent any party from filing a subsequent motion to dismiss or for summary judgment and/or motion for summary adjudication on any issue.

**IV. PLAINTIFF FACT SHEET AND DEFENDANT FACT SHEET.**

The parties shall negotiate a Plaintiff Fact Sheet and a Defendant Fact Sheet. During the period in which the Court is evaluating *Daubert* motions regarding expert witness testimony on the issue of general causation, the parties shall file the proposed PFS, the proposed DFS, and an accompanying proposed Case Management Order which will contemplate the submission of completed PFS and DFS shortly thereafter. During this time period the parties plan to reach consensus on a pool of cases that will be required to submit PFS and DFS.

Dated January 9, 2019.



*Karen K. Caldwell*

KAREN K. CALDWELL, CHIEF JUDGE  
UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY