

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

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

Master File No. 5:18-md-2809-KKC

MDL Docket No. 2809

ALL CASES

**CASE MANAGEMENT ORDER NO. 1  
REGARDING MASTER PLEADINGS AND PROPOSED DISCOVERY PLAN FOR  
PHASE ONE: GENERAL CAUSATION**

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The Court conducted a preliminary status conference in this matter on September 7, 2018 and ordered the parties to brief the issue of whether discovery in this matter should be conducted in two phases, with the first phase dedicated to general causation.

After considering the parties' submissions, the Court has determined that discovery in this matter will be conducted in two phases with the first phase addressing "general causation," *i.e.*, whether Onglyza or Kombiglyze XR is capable of causing any person to develop heart failure or other conditions alleged by the plaintiffs such as congestive heart failure, myocardial infarction and/or cardiovascular injury. General causation is a critical issue in this case, common to all actions. If the plaintiffs are unable to establish that Onglyza or Kombiglyze XR is capable of causing any person to develop heart failure or other conditions alleged by the plaintiffs, then the parties will not be required to undergo the time and expense of further discovery and litigation. Thus, addressing general causation before considering plaintiff-specific issues will best ensure the most efficient resolution of these actions and use of the parties' and the Court's resources.

Accordingly, the Court hereby ORDERS that plaintiffs' proposal (DE 168) to conduct concurrent discovery on all issues is DENIED. The Court further ORDERS as follows:

1. Both parties having proposed the filing of a Master Complaint, the Court hereby ORDERS that, on or before **November 19, 2018**, Plaintiffs must file a Master Complaint.
2. The Master Complaint may not be amended absent leave of the Court.
3. The Master Complaint will be the operative complaint in every individual action for the duration of these pretrial proceedings except that Defendants may respond to any individual complaint by way of motions permissible under Rule 12 of the Federal Rules of Civil Procedure. The Court will establish a deadline for such motions by subsequent order after reviewing the parties' proposed deadline(s).
4. If the parties wish to utilize Plaintiff Fact Sheets, authorization forms, and/or Defendant Fact Sheets, they must file proposed facts sheets and authorization forms and an accompanying motion for approval on or before **November 19, 2018**. If the parties are unable to agree on such fact sheets and forms, they may file separate proposals. **Any objections to the motion for approval must be filed within 14 days of the date the motion for approval is filed.**
5. On or before **December 19, 2018**, Defendants must file a Master Answer ("Master Answer") responding to the allegations of the Master Complaint.
6. Defendants will be deemed to have answered all cases pending in, filed in, or subsequently transferred to the MDL proceedings upon the filing of the Master Answer. The Master Answer will be deemed to deny any allegations contained in individual complaints that are not contained in the Master Complaint.
7. After the filing of the Master Answer, cases may only be voluntarily dismissed by order of the Court pursuant to Federal Rule of Civil Procedure 41(a)(2) or a stipulation pursuant to Federal Rule of Civil Procedure 41(a)(1)(ii), except that a

Complaint filed directly in the MDL may be voluntarily dismissed upon notice by Plaintiff within ten (10) days of the filing of the Complaint.

8. Neither the filing of the Master Answer, nor the filing of a Notice of Appearance, nor CM/ECF registration, nor the appearance of any party or counsel at a status conference constitutes a waiver of any defense including lack of personal jurisdiction, objections to service, jurisdiction or venue, and any defenses to any state law claims.
9. The plaintiffs may not file a reply to the Master Answer.
10. Both parties having proposed the use of a Short Form Complaint, no later than **December 19, 2018**, Plaintiffs' counsel must file a proposed Short Form Complaint and accompanying motion for approval stating the Short Form Complaint's proposed purpose and effect. **Any objections to the motion for approval must be filed within 14 days of the date the motion for approval is filed.**
11. On or before **January 15, 2019**, the parties must file a proposed plan containing:
  - a) the deadlines for filing counter-claims, cross-claims, and third-party complaints and for filing answers and motions responding to such claims and for responses and replies to such motions if different from the Local Rules;
  - b) the deadline for the filing of motions under Federal Rules of Civil Procedure 12 directed at individual complaints and for responses and replies if different from the Local Rules;
  - c) the deadline for the service of completed fact sheets and authorizations;
  - d) a proposed joint discovery plan for the first phase of discovery on the issue of general causation, *i.e.*, whether saxagliptin is capable of causing the

types of injuries alleged by the plaintiffs. The discovery plan must contain the following:

- i. The date such discovery may commence;
- ii. The date such discovery, including expert discovery, must conclude;
- iii. The deadline for plaintiffs and defendants to serve expert reports relating to the issue of general causation and the deadline for filing rebuttal expert reports;
- iv. The deadline for depositions of expert witnesses on the issue of general causation;
- v. The deadline for filing *Daubert* motions challenging expert witness testimony on the issue of general causation; the deadline for responses and replies to such motions; and the month for hearings to be conducted on the motions;
- vi. A plan for coordinating discovery and other appropriate pretrial proceedings with any related state-court litigation to the extent possible.

If the parties are unable to agree on a proposed plan, they may file separate proposals.

12. In any action that is (a) filed in or transferred to this Court after this Order is entered and (b) consolidated with this action for pretrial purposes, the Clerk need not separately file the Case Management Orders already entered in these MDL proceedings. However, the Clerk must include a statement in the initial notice to counsel that the Order Regarding Practice and Procedure Upon Transfer, this Case

Management Order, and all subsequent Case Management Orders govern all cases in the MDL proceedings.

Dated October 24, 2018.



*Karen K. Caldwell*

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