UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE : ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	MDL No. 1:15-md-2657-FDS This document relates to: All Actions

DEFENDANT GLAXOSMITHKLINE LLC'S
MOTION FOR SEQUENCED DISCOVERY

Pursuant to Rules 16 and 26 of the Federal Rules of Civil Procedure and Local Rules 16.1(f) and 26.3, Defendant GlaxoSmithKline LLC ("GSK") respectfully moves for entry of [GSK's Proposed] Case Management Order on Sequenced Discovery, attached as Exhibit A. The proposed case management order would focus the next phase of discovery on general causation and federal preemption. GSK contemporaneously submits a Memorandum in Support of Its Motion for Sequenced Discovery

WHEREFORE, GSK respectfully requests that this Court grant its Motion for Sequenced Discovery for the reasons set forth in its Memorandum.

LOCAL RULE 7.1(A)(2) CERTIFICATION

Pursuant to Local Rule 7.1(a)(2), the undersigned counsel hereby certifies that, on June 1, 2016, Counsel for GSK sent [GSK's Proposed] Case Management Order on Sequenced Discovery to Plaintiffs' Lead Counsel and invited further discussion. Counsel for GSK and Plaintiffs' Lead Counsel conferred by phone on June 2, 2016 and June 3, 2016, in a good faith attempt to narrow the issues of dispute without success. Plaintiffs' Lead Counsel indicated their opposition to the Proposed Order.

Respectfully submitted,
GLAXOSMITHKLINE LLC,
By its attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

/s/ Madeleine M. McDonough
Madeleine M. McDonough

Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION,	)	**MDL. No. 1:15-md-2657-FDS**
This Document Relates To:	)	
All Cases	)	

[GSK's PROPOSED] MDL Order No. X
June XX, 2016

DISCOVERY AND SCHEDULING ORDER

I. GENERAL MATTERS

A. Scope and Applicability

1. The following protocols and limitations in this Order shall apply to all cases in MDL No. 2657.

2. Any order entered in a transferor court prior to consolidation in this MDL is vacated to the extent it relates to scheduling or discovery. Scheduling and discovery shall be governed only by this and other orders entered in these MDL proceedings. This provision is not intended to affect prior orders entered in these MDL proceedings.

3. In the interests of efficiency and conservation of resources, the parties will endeavor to coordinate discovery and other appropriate pretrial proceedings with any related state court litigations to the greatest extent possible.

4. No party may conduct any discovery not expressly authorized by an Order of the Court, absent further direction from the Court or express agreement of the parties.

5. All discovery on Defendants shall be taken by Plaintiffs' Lead Counsel ("PLC"), as set forth in MDL Order No. 3, or their designee, on behalf of all plaintiffs in the MDL. An individual plaintiff's counsel may suggest discovery to the PLC, but may not conduct discovery independently or in her own name.

6. Nothing in this Order shall prevent any party from moving for a stay of discovery or other proceedings.

B. Protective Order. The protection of confidential documents and information and the inadvertent production of confidential and/or privileged information shall be subject to the terms of the Protective Order Governing Confidential and Privileged Materials (MDL Order No. 13).

C. Records Collection. The parties shall share the cost of collection of medical, pharmacy, insurance, educational, and other relevant third-party records in the MDL proceedings. Records will be accessible through a records collection vendor, and Defendants will not be required or expected to provide separate or additional copies thereof to any Plaintiff.

D. Format of Production. The protocol for and format of production of documents shall be in accordance with the terms of an Order Governing Production Format of Document and Electronically Stored Information.

E. Deposition Protocol. The protocol for depositions shall be in accordance with the terms of an Order Governing Deposition Guidelines.

F. Initial Disclosure Obligations. For all cases in the MDL proceedings, the parties are relieved from complying with the requirements of Federal Rule of Civil Procedure 26(a)(1).

G. Pre-Transfer Discovery. Any request for discovery or notice of deposition served in a case before it was transferred to the MDL proceedings and currently suspended pursuant to MDL Order No. 1 is deemed withdrawn.

H. Discovery Disputes. Any discovery dispute – other than a dispute arising in the course of a deposition or involving invocation of a privilege or work product protection – will be submitted to the Court as follows: (a) the movant will serve a brief of not more than five double-spaced pages setting forth its position; (b) the responding party may serve a responsive brief of no more than five double-spaced pages within 14 days; and (c) the movant may submit a reply of no more than three double-spaced pages within seven days of the responding brief. The parties may apply to the Court for additional time or pages for good cause.

II. DISCOVERY PLAN AND PROCEDURES

A. Phase 1 Discovery – Basic Case Specific Information. The first phase of discovery shall be limited to: (1) production of Product Identification Fact Sheets, Plaintiff Fact Sheets, Defendant Fact Sheets for GlaxoSmithKline LLC ("GSK"), and the documents and materials referenced therein (MDL Order Nos. 10, 11, and 12); and (2) collection of records pursuant to authorizations and releases provided by Plaintiffs.

B. Phase 2 Discovery – General Causation and Preemption.

1. *Scope.* Phase 2 of discovery shall be limited to non-privileged matters proportional to the needs of the case in accordance with Fed. R. Civ. P. 26(b)(1) and relevant to: (1) the general causation element of Plaintiffs' claims, and (2) federal preemption. "General causation" refers to the question of whether Zofran® or ondansetron causes the specific types of

birth defects and injuries alleged in these proceedings. Discovery into federal preemption is initially limited to whether "GSK was in exclusive possession of information not previously submitted to the FDA indicating the need for a new or strengthened warning," (Dkt. #139, p. 6), as Plaintiffs have alleged and GSK has denied. If that initial inquiry reveals evidence that shows that GSK was, in fact, in exclusive possession of relevant and material information not previously submitted to the FDA regarding whether Zofran® or ondansetron could cause birth defects, further discovery may proceed regarding "how the FDA would have responded to a [Changes Being Effected] proposal had GSK submitted one." (Dkt. #139, p. 6.) If discovery does not reveal any such information, the parties shall not conduct additional discovery without good cause shown.

2. *Timing.* Phase 2 shall commence upon the filing of Master Complaints in accordance with the terms of the Order on Master Pleadings (MDL Order No. 14).

3. *Science Day.* On November 10, 2016, the parties shall appear before the Court for a "Science Day." This appearance will be the parties' opportunity to present to the Court on the basic scientific facts and issues that are important to establishing general causation.

4. *Custodial and Non-Custodial Files.* Phase 2 discovery shall include the Zofran® regulatory files, which total approximately 530,000 pages and which GSK has voluntarily produced to Plaintiffs. Plaintiffs may request

an additional 7 custodial or non-custodial files in the areas of regulatory, clinical, preclinical, safety and epidemiology that are relevant to general causation and federal preemption.

5. *Written Discovery.* Absent an Order of the Court upon a showing of good cause or written agreement of the parties, no party shall serve more than 20 requests for production, 20 interrogatories, and 20 requests for admission, including all subparts, relevant to general causation and preemption. Responses and objections shall be served within 60 days of service of the requests.

6. *Depositions.* Absent an Order of the Court upon a showing of good cause or written agreement of the parties, no party shall take more than 7 fact depositions relevant to general causation and preemption, whether noticed under Fed. R. Civ. P. 30 or 31, each limited to seven hours in length.

7. *Experts.* Expert discovery regarding general preemption and causation shall follow the schedule set forth below. At least 10 business days before an expert's deposition, the parties must produce all facts, data and other materials reviewed by the expert in rendering his or her opinion, any working files maintained by the expert with respect to this matter, and all communications discoverable pursuant to Rule 26(b)(4) to the opposing party.

8. *Dispositive Motions.* Defendant(s) may renew or file dispositive motions within 45 days after the resolution of Phase 2 *Daubert* motions. Nothing in this Order shall restrict the ability of a Defendant to renew or file

dispositive motions before the resolution of Phase 2 *Daubert* motions or during any future phase of discovery.

9. *Schedule.*

Event	**Deadline**
Science Day	November 10, 2016
Close of Phase 2 Fact Discovery	February 28, 2017
Plaintiffs' Phase 2 Expert Reports	March 31, 2017
Depositions of Plaintiffs' Phase 2 Experts	May 31, 2017
Defendants' Phase 2 Expert Reports	June 30, 2017
Depositions of Defendants' Phase 2 Experts and Close of Phase 2 Expert Discovery	August 31, 2017
Daubert Motions on Phase 2 Experts	September 29, 2017
Oppositions to *Daubert* Motions	30 days after the filing of *Daubert* motions
Replies in Support of *Daubert* Motions	15 days after the filing of oppositions to *Daubert* motions

C. Additional Phases – Other Remaining Issues. Should any claims remain following the resolution of *Daubert* and dispositive motions as part of Phase 2, discovery on other remaining issues and additional case-specific discovery may commence upon future Order of the Court.

D. Extension of Discovery Deadlines. Nothing in this Order shall be interpreted to restrict the ability of the parties to stipulate in writing to an extension of discovery deadlines or to move for an extension of discovery deadlines as permitted by the Rules. If any discovery extension would impact non-discovery deadlines in this case, the parties must obtain Court approval.

So Ordered.

F. Dennis Saylor IV
United States District Judge

Dated: June __, 2016