

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE
HYDROCHLORIDE) PRODUCTS
LIABILITY LITIGATION

MDL NO. 2342
12-MD-2342

HON. CYNTHIA M. RUFÉ

THIS DOCUMENT RELATES TO:
ALL ACTIONS

PRE-TRIAL ORDER NO. 15
JOINT DISCOVERY AND SCHEDULING PLAN

1. In recognition that discovery and trial issues are most efficiently handled by the entry of Pretrial Orders, this Pretrial Order shall govern discovery and scheduling concerning this MDL, subject to entry of subsequent Pretrial Orders modifying or supplementing this Pretrial Order.¹

2. **DOCUMENT DISCOVERY OF PFIZER:** The Plaintiffs' Steering Committee ("PSC") has previously served on Pfizer comprehensive written requests for production, to which Pfizer has served written responses and objections. In addition, Pfizer has begun a rolling production of documents in response to such requests, subject to objections, including the Investigational New Drug Application ("IND"), New Drug Application ("NDA"), and certain other categories of documents. The parties have continued to confer in an attempt to resolve their disputes over the scope of discovery and have agreed as follows: The PSC, on behalf of Plaintiffs, has agreed to withdraw the following numbered requests included in its Requests for Production previously served on Pfizer: 8, 11, 12, 13, 14, 15, 19, 21, 23, 25, 28, 31, 33, 34, 38, 44, and 45.² Pfizer has agreed that by December 7, 2012, it will provide amended written

¹ The parties have indicated to the Court that they are continuing to negotiate regarding the timing and sequence of discovery, including general and case-specific discovery, and plan to propose supplemental orders to this Court governing such issues. Such orders may require modification of some of the deadlines provided for by this Order.

² This withdrawal is without prejudice. That is, Plaintiffs may include some of these requests in their additional discovery requests discussed below, and Pfizer may respond and/or object.

responses and objections to the remaining 28 identified Requests for Production,³ and will continue its rolling production of documents in response to such requests. Without requiring further consent or Court Order, Plaintiffs may serve an additional 50 requests for production.

3. DEPOSITION DISCOVERY OF PFIZER: By November 15, 2012, the PSC will provide Pfizer with 30(b)(6) deposition notices directed at ESI, corporate organization/structure, and Greenstone. By November 30, 2012, Pfizer will identify witnesses and propose dates for such depositions to take place, which proposed dates will be before December 19, 2012, for deponents on ESI and corporate organization/structure, and before January 18, 2013, for the Greenstone deponent. By November 30, 2012, Pfizer will also serve any objections to the scope of the PSC's notices (including both topics and documents). These initial 30(b)(6) depositions on ESI, corporate organization/structure, and Greenstone will be limited to each witness's corporate capacity and to only the issues outlined in the 30(b)(6) notice.

By November 15, 2012, Plaintiffs will also re-serve amended Notices of 30(b)(6) depositions for the following areas, to the extent that they relate to the use of Zolofit by women of childbearing age, during pregnancy or lactation and/or any alleged association between Zolofit and adverse pregnancy outcomes or birth defects: sales, marketing, regulatory, pharmacovigilance, safety, and labeling. By November 30, 2012, Pfizer will serve any objections to the scope of such notices (including both topics and documents). The parties will continue to meet and confer to define the topics within these broad, general categories, as well as the dates and procedures for depositions. As to those topics and time frames where witnesses are available to Pfizer through reasonable efforts, witnesses will be made available for deposition by March 1, 2013. Generally, a 30(b)(6) deponent's testimony shall be limited to his or her corporate capacity and to only the issues outlined in the 30(b)(6) notice and Plaintiffs may later depose that witness as a fact witness. If, 45 days prior to a 30(b)(6) deposition, Pfizer has indicated that a fact witness designated by Plaintiffs will also testify as a 30(b)(6) witness, Pfizer

³ 1, 2, 3, 4, 5, 6, 7, 9, 10, 16, 17, 18, 20, 22, 26, 27, 29, 30, 32, 35, 36, 37, 39, 40, 41, 42, 43.

will make a good faith effort to produce, at least 30 days prior to the deposition, responsive documents (without waiving its objections), including documents from any custodial file review, for that witness. Plaintiffs agree not to seek a second deposition of such witness absent good cause shown (for example, numerous documents material and relevant to the witness are produced subsequent to the deposition).

No witness shall be considered a party or officer of a party for purposes of FRCP 45 merely because that person has been designated pursuant to 30(b)(6). Pfizer will make a good faith effort to produce documents relevant to such depositions at least one week prior to the deposition and will notify Plaintiffs' Lead Counsel at least one week before the deposition is scheduled to take place whether there are relevant documents of which it is aware that it is unable to produce within that timeframe.

Without requiring further consent or Court Order, Plaintiffs may take up to 30 fact witness depositions of Pfizer employees and/or former employees. Timing and other issues regarding the conduct of such depositions will be addressed in a subsequent order.

4. INTERROGATORIES AND REQUESTS FOR ADMISSION TO PFIZER:

Without requiring further consent or Court Order, Plaintiffs may serve up to 50 interrogatories and 50 Requests for Admission (not including Requests for Admission as to the admissibility or authenticity of documents).

5. GENERAL CAUSATION *DAUBERT* MOTIONS: The following schedule is established for exchange of expert reports regarding Zoloft general causation⁴ and *Daubert* motions directed at Zoloft general causation experts:

⁴ A few cases involve, in addition to Zoloft or sertraline, other medicines used by the mother plaintiffs during their pregnancy. This schedule, which is intended to address core discovery, does not apply to such products. Cases in which manufacturers of medicines other than Zoloft or sertraline have been joined as defendants will not be selected for the Initial Discovery Group and schedules for expert disclosures related to other products will be addressed and entered separately.

June 17, 2013	The PSC will submit general causation expert reports on the birth defect categories they intend to prosecute in this litigation. 45 days later plaintiffs can submit expert reports for injuries not included in the PSC's reports. ⁵
August 1, 2013	Pfizer will serve opening expert reports on general causation.
August 15, 2013	Plaintiffs will serve rebuttal expert reports on general causation. ⁶
August 29, 2013	Pfizer will serve rebuttal expert reports on general causation.
October 14, 2013	By this date, Pfizer will complete depositions of the PSC's general causation experts.
October 30, 2013	By this date, the PSC will complete depositions of Pfizer's general causation experts.
November 14, 2013	<i>Daubert</i> motions and opening briefs shall be due.
December 11, 2013	Responses to <i>Daubert</i> motions shall be due.
January 3, 2014	Reply briefs in support of <i>Daubert</i> motions shall be due.

Date(s) to be set by the Court Hearings on *Daubert* motions.

6. INITIAL DISCOVERY GROUP: By separate order, and after consideration of joint or competing proposals from the parties, to be submitted pursuant to paragraph 8 below, the Court will identify those cases that will be included in the Initial Discovery Group.

⁵ To the extent any such reports are served, the parties will meet and confer on an appropriate schedule to complete briefing as to such reports at the same time as the completion of briefing on the PSC's expert reports.

⁶ Rebuttal expert reports shall be responsive and not cumulative in nature and shall not change or add opinions.

7. **THRESHOLD PLAINTIFF DISCOVERY:** Without waiver of Pfizer's right to obtain discovery requested in its First Sets of Master Requests for Production to Plaintiffs (for both non-wrongful death and wrongful death actions), discovery from Plaintiffs in the Initial Discovery Group shall be presumptively limited to Threshold Discovery. Threshold Discovery includes the following: (a) Plaintiffs will respond by February 28, 2013, to an expanded Plaintiff Fact Sheet in a form to be agreed upon and set forth in a separate order; and (b) Pfizer shall respond by April 25, 2013, to Defendant Fact Sheets in a form to be agreed upon and set forth in a separate order for Plaintiffs in the Initial Discovery Group. In addition, without requiring further consent or Court Order, the following depositions may be noticed upon the identification of cases for the Initial Discovery Group: (i) the minor plaintiff's or decedent's mother, (ii) the minor plaintiff's or decedent's biological father, (iii) any legal guardians or court appointed representatives for the minor plaintiff or the decedent's estate, (iv) any other named plaintiff not included in the foregoing groups, (v) any healthcare provider(s) who prescribed Zolofit or sertraline to the minor plaintiff's or decedent's mother for the pregnancy at issue, (vi) no more than two healthcare provides who treated the minor plaintiff's or decedent's mother for her pregnancy, (vii) no more than two physicians who treated the minor plaintiff or decedent for the injuries alleged in this litigation, and (viii) no more than two Pfizer sales representatives who called on the mother's prescribing healthcare providers.⁷ Pfizer may also serve up to 25 Requests for Admissions on the Plaintiffs in the Initial Discovery Group. All threshold discovery of the Initial Discovery Group shall be completed by November 15, 2013.

8. **INITIAL TRIAL SETTING:** The first trial is tentatively set to begin no later than September 12, 2014, subject to the completion of all appropriate discovery and subject to further Order of the Court. However, the first trial will not commence less than eight months

⁷ If no sales representative who called on the mother's prescribing healthcare provider is available to be deposed, Plaintiffs may seek the deposition of the district or regional sales manager responsible for the sales representatives' territory. However, such deposition counts towards the plaintiffs' limit of two depositions in this category.

after completion of generic causation *Daubert* briefing. By January 11, 2013, the parties shall submit joint or competing proposals governing selection of Initial Discovery Group Cases. By March 15, 2013, the parties shall submit joint or competing proposals governing (1) selection of Trial Pool Cases, (2) the scope of general causation *Daubert*, (3) scheduling of summary judgment and specific causation *Daubert* motions in Trial Pool Cases, and (4) protocol for selection and scheduling of the first cases to be tried.

IT IS SO ORDERED.

Dated: November 15th, 2012


HON. CYNTHIA M. RUFÉ