

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

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<b>IN RE: ZOLOFT (SERTRALINE</b>	<b>:</b>	<b>MDL NO. 2342</b>
<b>HYDROCHLORIDE) PRODUCTS</b>	<b>:</b>	<b>12-MD-2342</b>
<b>LIABILITY LITIGATION</b>	<b>:</b>	
<hr/>	<b>:</b>	<b>HON. CYNTHIA M. RUFÉ</b>
	<b>:</b>	
<b>THIS DOCUMENT RELATES TO</b>	<b>:</b>	
<b>ALL ACTIONS</b>	<b>:</b>	
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**PRETRIAL ORDER NO. 23  
(AMENDMENT TO PRETRIAL ORDER NOS. 15 AND 20)  
JOINT DISCOVERY AND SCHEDULING PLAN**

1.     **AND NOW**, this 1st day of April 2013, in recognition that discovery and trial issues are most efficiently handled by the entry of Pretrial Orders, and upon consideration of Report and Recommendation No. 1 of the Special Discovery Master, Andrew A. Chirls, the Court hereby enters this Pretrial Order amending Pretrial Order Nos. 15 and 20, to govern discovery and scheduling concerning this MDL, subject to entry of subsequent Pretrial Orders modifying or supplementing this Pretrial Order.<sup>1</sup>

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

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<sup>1</sup> This Pretrial Order recites deadlines and milestone dates that have already passed so that the public may have ready access to information about the progress and management of this litigation. 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.

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.<sup>2</sup> Pfizer has agreed that by December 7, 2012, it will provide amended written responses and objections to the remaining 28 identified Requests for Production,<sup>3</sup> 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 **provided** Pfizer with 30(b)(6) deposition notices directed at ESI, corporate organization/structure, and Greenstone. By November 30, 2012, Pfizer identified witnesses and proposed dates for such depositions to take place, which proposed dates were to 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 was also to 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 were to 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 were to 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 was to serve any objections to the scope of such notices (including both topics and documents). The parties will

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<sup>2</sup> 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.

<sup>3</sup> 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.

continue to meet and confer to define the topics within these broad, general categories, as well as the dates and procedures for depositions. By April 4, 2013, Pfizer will identify witnesses and propose target dates for depositions to take place for 30(b)(6) deponents on marketing and pharmacovigilance. 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 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 and material 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 including Zolofit general causation<sup>4</sup> and *Daubert* motions directed at Zolofit general causation experts:

July 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. <sup>5</sup>
September 3, 2013	Pfizer will serve opening expert reports on general causation.
September 16, 2013	Plaintiffs will serve rebuttal expert reports on general causation. <sup>6</sup>
September 30, 2013	Pfizer will serve rebuttal expert reports on general causation.
November 14, 2013	Pfizer will complete depositions of the PSC's general causation experts.
November 29, 2013	PSC will complete depositions of Pfizer's general causation experts.
December 16, 2013	<i>Daubert</i> motions and opening briefs shall be due.
January 13, 2014	Responses to <i>Daubert</i> motions shall be due.
February 3, 2014	Reply briefs in support of <i>Daubert</i> motions shall be due.
Date(s) to be set by the Court	Hearings on <i>Daubert</i> motions.

<sup>4</sup> A few cases involve, in addition to Zolofit 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 Zolofit 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.

<sup>5</sup> 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.

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



**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.

**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) The deadline for Plaintiffs in the Initial Discovery Group to respond to the expanded Plaintiff's Fact Sheet is extended from April 15, 2013 to May 6, 2013 for the 12 PSC Selections and is extended from April 22, 2013 to May 22, 2013 for the 13 Pfizer Selections and (b) the time within which Pfizer shall respond 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 is extended from May 28, 2013 to June 24, 2013. 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 Zoloft or sertraline to the minor Plaintiff's or decedent's mother for the pregnancy at issue, (vi) no more than two healthcare providers 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.<sup>7</sup> Pfizer may also serve up to 25 Requests for Admissions on the plaintiffs in the Initial Discovery Group. The date by which all threshold discovery of the Initial Discovery Group shall be completed, previously scheduled for November 15, 2013, is hereby established as December 16, 2013.

**8. INITIAL TRIAL SETTING:** The first trial is tentatively set to begin no later than October 13, 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 after completion of generic causation *Daubert* briefing. By January 11, 2013, the parties submitted joint or competing proposals governing selection of Initial Discovery Group Cases. By May 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. The deadline for this submission is extended from April 15, 2013.

**IT IS SO ORDERED.**

**BY THE COURT:**

  
CYNTHIA M. RUFÉ, J.

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<sup>7</sup> 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 Plaintiffs' limit of two depositions in this category.