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. RUFE**
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

SPECIAL DISCOVERY MASTER'S
REPORT AND RECOMMENDATION NO. 1
(Regarding Amendments To Pretrial Order Nos. 20 And 21)

On March 19, 2013, I met with the members of Plaintiffs' Executive Committee, including Plaintiffs' Liaison Counsel, and with Defendants' Liaison Counsel. This meeting followed submission to me by the two sides of written statements about the progress of discovery, selection of initial discovery groups, and related matters.

The Parties described the reasons why they agreed that it was appropriate to extend certain deadlines that are prescribed in Section 7 of Pretrial Order No. 20, which sets out a joint discovery and scheduling plan. The deadlines in Section 7 relate to the parties' obligations to provide Threshold Discovery Information with respect to Plaintiffs in the Initial Discovery Group. The deadlines are proposed to be extended by three weeks in one instance and a month in other instances.

The parties agreed, as well, that it was appropriate to extend by one month the deadline for completion of all threshold discovery of the Initial Discovery Group, and to extend the date for submission of proposals governing selection of Trial Pool Cases, the scope of causation issues, scheduling of certain motions, and the protocol for selection and scheduling of the first cases to be tried. This deadline is in Section 8 of Pretrial Order No. 20.

In no case would these extensions alter the deadlines set forth in Section 5 of Pretrial Order No. 20, relating to *Daubert* motions and to discovery on the issue of general causation. Nor would extension of the deadlines have any effect on the tentative date of the first trial, described in paragraph 8 of Pretrial Order No. 20.

The parties also described the reasons why they agreed that it would be helpful to extend by one month the date by which the defendants are to select thirteen cases for inclusion in the Initial Discovery Group. This deadline is in paragraph (3) of Pretrial Order No. 21. This change in the deadline would correspond to the changes proposed to deadlines in Paragraph 7 of Pretrial Order No. 20, described above.

I understand that extensions of the deadlines will be useful because they will allow the plaintiffs time to clarify and supplement some of the information provided in their fact sheets. This should give the defendants the ability to make more useful and targeted selections of cases for the Initial Discovery Group. Greater disclosure in connection with the fact sheets may also simplify subsequent discovery. This, in my view, constitutes good cause for the extensions that the parties are seeking.

I have considered whether it is realistic to move the immediately impending deadlines (related to threshold discovery) without also viewing it as inevitable that the milestones and deadlines of Section 5 of Pretrial Order No. 20 will have to be moved. It is realistic. The deadlines associated with presentation and litigation of causation issues and *Daubert* issues do not have to be moved as a result of extensions of time for threshold discovery. More important, the tentative initial trial date does not necessarily have to be moved because of extensions of time for threshold discovery. Section 8 of Pretrial Order No. 20 states, ". . . the first trial will not commence less than eight months after completion of generic causation *Daubert* briefing." This

eight month period appears to be important to allow for consideration of the *Daubert* issues, and this period remains available after the revisions to the schedule that the parties propose.

I am submitting a draft of Pretrial Order No. 23 (amending Pretrial Order Nos. 15 and 20) and a draft of Pretrial Order No. 24 (amending Pretrial Order Nos. 17 and 21), which embody these changes. I recommend that they be entered.

Respectfully submitted,

/s/ Andrew A. Chirls
Andrew A. Chirls,
Special Discovery Master
Attorney ID: 35422
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Telephone: 215-246-2200
Email: achirls@haines-law.com

Dated: March 28, 2013

CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2013, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

Respectfully submitted,

/s/ Andrew A. Chirls
ANDREW A. CHIRLS

EXHIBIT A

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. RUFE**
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

PRETRIAL ORDER NO. 23
(AMENDMENT TO PRETRIAL ORDER NOS. 15 AND 20)
JOINT DISCOVERY AND SCHEDULING PLAN

1. **AND NOW**, this ____ day of _____ 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.[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

[1] 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.[2] Pfizer has agreed that by December 7, 2012, it will provide amended written 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 **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 Zoloft by women of childbearing age, during pregnancy or lactation and/or any alleged association between Zoloft 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

[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.
[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.

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 Zoloft general causation[4] and *Daubert* motions directed at Zoloft 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.[5]
September 3, 2013	Pfizer will serve opening expert reports on general causation.
September 16, 2013	Plaintiffs will serve rebuttal expert reports on general causation.[6]
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	*Daubert* motions and opening briefs shall be due.
January 13, 2014	Responses to *Daubert* motions shall be due.
February 3, 2014	Reply briefs in support of *Daubert* motions shall be due.
Date(s) to be set by the Court	Hearings on *Daubert* motions.

[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.

[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.

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 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. 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:

_____

HON. CYNTHIA M. RUFE

[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 Plaintiffs' limit of two depositions in this category.

EXHIBIT B

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. RUFE**
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

PRETRIAL ORDER NO. 24
(AMENDMENT TO PRETRIAL ORDER NOS. 17 AND 21)
(Selection of Initial Discovery Group)

AND NOW, this ___ day of _____ 2013, pursuant to Pretrial Order No. 23 ("PTO 23") and to promote efficiency for the Court and the parties in the above-captioned matter, 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. 17 and 21 to set forth the protocol for selecting cases consolidated in MDL No. 2342 to be included in the Initial Discovery Group and proceed to Threshold Discovery as defined in PTO 23.

The Court agrees with the Parties that an Initial Discovery Group of 25 cases is appropriate. The method for selection of the 25 cases will be as follows[1]:

(1) In those cases where multiple Plaintiff firms are listed as attorneys for Plaintiff families,[2] those Plaintiffs' counsel **were to** advise Pfizer Inc. and Greenstone LLC (the "Pfizer Defendants") which firm is primary counsel to each Plaintiff family no later than January 31, 2013, and continue to update that list as new cases are filed thereafter.

[1] 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.
[2] As used herein, "Plaintiff family" means a minor Plaintiff or minor decedent, and that Plaintiff's or decedent's parents, guardians, and legal representatives.

(2) On or before March 15, 2013, the Plaintiff's Steering Committee ("PSC") selected 12 cases to be included in the Initial Discovery Group ("PSC Selections") and sent their list of cases (including Plaintiff name and MDL Docket No.) to Defendants and the Court. PSC Selections **were** distributed so that no Plaintiff firm is primary counsel for more than two cases among the PSC Selections.

(3) On or before April 22, 2013, the Pfizer Defendants will select 13 cases to be included in the Initial Discovery Group ("Pfizer Selections") and will send their list of cases (including Plaintiff name and MDL Docket No.) to the PSC and the Court. Pfizer Selections must be distributed so that no Plaintiff firm is primary counsel for more than two cases in the Pfizer Selections. This deadline is hereby extended from March 22, 2013.

(4) In the event that a Plaintiff family is dismissed from the PSC Selections prior to May 15, 2013, the PSC shall select another Plaintiff family with the same primary counsel.

(5) In the event that a Plaintiff family is dismissed from the PSC Selections prior to May 15, 2013, Pfizer shall select another Plaintiff family from any case in the MDL. In the event that a Plaintiff family is dismissed from the Pfizer Selections after May 15, 2013, Pfizer may, at its discretion, select another Plaintiff family to replace any such dismissed Plaintiff family.

(6) Replacement cases will be selected within 15 days of dismissal of the original case.

(7) Expanded Plaintiff Fact Sheets will be served for replacement cases within 30 days after notice of selection has been provided to the non-selecting party.

The deadline for Plaintiffs in the Initial Discovery Group to respond to the expanded Plaintiff 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.

Whenever notice to the opposing party is required to be given pursuant to this Order, notice by e-mail shall be sufficient. Notice to the Pfizer Defendants shall be directed to:

Mark.Cheffo@skadden.com
Catherine.Stevens@skadden.com

Notice to Plaintiffs shall be directed to the primary counsel for the plaintiff family whose action is affected and to:

DNast@NastLaw.com
beachlawyer51@hotmail.com

IT IS SO ORDERED.

BY THE COURT

_____
CYNTHIA M. RUFE, J.