

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

<hr/>	:	MDL NO. 2342
IN RE: ZOLOFT (SERTRALINE	:	12-MD-2342
HYDROCHLORIDE) PRODUCTS	:	
LIABILITY LITIGATION	:	
<hr/>	:	HON. CYNTHIA M. RUFÉ
	:	
THIS DOCUMENT APPLIES TO:	:	
ALL ACTIONS	:	
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PRETRIAL ORDER NO. 8
(PROTECTIVE ORDER)

AND NOW, this 23rd day of July 2012, in order to expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, adequately protect confidential material, and ensure that protection is afforded only to material so entitled, and upon consideration of the stipulated request of the parties, through Lead Counsel, the Court enters this Protective Order pursuant to Rule 26 of the Federal Rules of Civil Procedure.

1. **Purpose.** Preparation for trial of these actions may require the discovery of certain documents and testimony that the producing party reasonably and in good faith believes should be subject to a protective order under Federal Rule of Civil Procedure 26(c)(1)(G) or other state or federal law, including: (a) a Plaintiff's personal identifying information, financial information, and medical/insurance information, as well as other confidential information, and (b) a Defendant's trade secret or other confidential research, development, or commercial information, and patient-or-reporter-identifying information. Such materials may include (a) documents in the Zolofit Investigational New Drug Application ("IND") and New Drug Application ("NDA") files and any Supplemental, Amended, and Abbreviated NDAs; (b) documents and information made confidential pursuant to statute, law, or regulation of any

jurisdiction; (c) all other documents and information that contain trade secrets or other confidential research, development, or commercial information and that Defendant marks as “confidential;” and (d) all material, data, and information obtained, derived, or generated from such materials. Such documents, testimony, and information are referred to below as “Confidential Information.” Specifically excluded from Confidential Information are (a) any documents that have been, or in the future will be, designated as not confidential by order of any court and (b) any documents obtained, in the past or in the future, by any person or entity through procedures established under the Freedom of Information Act. In the event of a dispute as to whether a document is available through the Freedom of Information Act, the issue will be resolved by Plaintiffs' counsel making an appropriate request for the release of such documents from the United States Food and Drug Administration (referred to herein as “FDA”).

2 . **Designation by Producing Party.**

(a) For purposes of this Order, the term “document” means all written, recorded, or graphic material as described and defined in Rule 1001 of the Federal Rules of Evidence and shall include electronically stored information. A party producing documents or serving written discovery responses that such party determines, after appropriate review by an attorney or by a person working under the supervision of an attorney, contain Confidential Information shall designate such documents or information as confidential by placing a stamp or marking on the documents stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN ZOLOFT PRODUCTS LIABILITY LITIGATION**. Such markings will not obscure, alter, or interfere with the legibility of the original document. Documents so marked are referred to in this Order as

“Protected Documents.”

(b) Portions of interrogatory answers, responses to requests for admissions, deposition transcripts and exhibits, pleadings, motions, affidavits, and briefs that quote, summarize, or contain Confidential Information shall be Protected Documents, but, to the extent feasible, shall be prepared in such a manner that the Confidential Information is bound separately from that not entitled to protection; these portions that quote, summarize, or contain materials entitled to protection will remain Protected Documents regardless of labeling.

(c) Confidential Information disclosed by a third party shall be covered by this Order if a party notifies all other parties within 30 days of receipt of such information that the information or portions thereof constitute or contain Confidential Information. Until the expiration of 30 days following receipt of such information, the information disclosed by any such third party shall be treated as Confidential Information under this Order.

3 . **Depositions.** Protected Documents may be used or marked as exhibits in depositions but shall remain subject to this Order. If deposition testimony discloses Confidential Information, counsel for the deponent or any party shall inform the deposing counsel of the confidentiality of any such testimony not later than 20 days after receiving a copy of the deposition transcript or by making the confidential designation as to the specific testimony in question on the record at the deposition to be separately marked by the court reporter. Until expiration of the 20-day period, the entire deposition will be treated as a Protected Document under this Order. If no party or deponent timely designates Confidential Information in a deposition, then none of the transcript or its exhibits shall be treated as confidential. If a designation is made, all such testimony, each deposition transcript, recording, or portion thereof,

and each exhibit that is so designated, shall be treated as Confidential Information unless otherwise agreed to by the parties or directed by order of the Court.

4. **Non-Disclosure of Confidential Information.**

(a) Confidential Information shall not be disclosed in any way to anyone for any purpose other than as required for the preparation and trial of the above-captioned litigation or other Zoloft (sertraline hydrochloride) litigation as defined in Paragraph 7(b) below. Access to and disclosure of Confidential Information shall be limited to those persons designated as Qualified Persons below. All Qualified Persons given access to Confidential Information shall keep all such information confidential from all other persons except as specifically provided in this Order.

(b) To avoid security risks currently inherent in certain current technologies and to facilitate compliance with the terms of this Order, including, without limitation, the provisions of Paragraphs 7(d), 9, and 10, and unless the party whose confidential information is at issue agrees otherwise in writing, and except as set forth immediately below with respect to limited electronic mail communications, all Qualified Persons with access to Confidential Information shall be and are prohibited from storing or transmitting any Confidential Information in or via any online or web-based storage location or service, when such storage location or service is managed or maintained by any third-party service provider, including any provider of so-called “cloud computing” services, other than a reputable litigation support service provider with a secure document hosting facility that uses encrypted web-enabled software that allows for secure and protected sharing and collaboration concerning said documents amongst only authorized counsel and that does not employ so-called “cloud computing” services.

Notwithstanding the foregoing provision, a Qualified Person, as defined in the following paragraph, shall not be prohibited from transmitting to any other Qualified Person a reasonably limited number of files containing Confidential Information through electronic mail, as attachments to an electronic mail in the form of separate PDF files (and not as zip files or links to files), as long as the person transmitting the files takes reasonable steps to protect the confidentiality of the files.

5. **Qualified Persons.** Confidential Information may be disclosed only to the following persons (hereinafter referred to as “Qualified Persons”):

(a) When produced by Pfizer Inc (“Pfizer”) or other corporate defendants, the Plaintiffs and their attorneys in the above-captioned litigation and, pursuant to the provisions set forth in Paragraphs 7(a) and 7(b) below, the plaintiffs and their attorneys in other Zolofit (sertraline hydrochloride) litigation as defined in Paragraph 7(b), provided they have agreed to be bound by this Order. Persons encompassed by the preceding sentence include the attorneys’ employees (including outside copy services, organizations involved in organizing, filing, coding, converting, storing, or retrieving data or designing programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system, and stenographers);

(b) When produced by Plaintiffs, Defendants and their inside and outside counsel. This includes the attorneys' employees (including outside copy services, organizations involved in organizing, filing, coding, converting, storing, or retrieving data or designing programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system, and stenographers);

(c) Experts, consultants, and case-specific medical treaters (“consultants”) whose assistance is necessary to assist counsel in the preparation of a case or cases, or to testify, except that disclosure shall not be made to any consultant if counsel for the party retaining that consultant has actual knowledge that the consultant has been found to have violated the terms of a protective order in any litigation or legal proceeding;

(d) A deponent or a witness at deposition, trial or hearing, other than those who are otherwise covered by paragraph 5(c), provided there is a reasonable basis to believe that the witness will give relevant testimony regarding the Confidential Information or that disclosure is necessary to prepare the witness for the testimony. If a party wishes to show Confidential Information to such a deponent or witness before or during a deposition, hearing, or trial, the deponent or witness must be informed of this Protective Order and either sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit “A” or consent under oath to abide by its provisions. The parties agree that this provision does not preclude the producing party from objecting to or moving to preclude disclosure to any deponent or witness, or to seek amendment of this provision in the future, if it believes it has a good faith basis for such objection or motion;

(e) A person identified in the document as a subject of the communication, or having authored or previously received the document;

(f) Any person mutually agreed upon among the parties; and

(g) The Court or any Court personnel, including any court reporters.

6. **Non-Disclosure to Competitors.** Notwithstanding the foregoing, without express written consent, in no event shall any disclosure of Confidential Information be made to any competitor of a defendant producing party or to any person who, upon reasonable and good faith

inquiry, could be determined to be a current employee of or consultant doing research on anti-depressant drugs for a competitor of a defendant producing party irrespective of whether such competitor or person is retained as an expert in this action. "Competitor" shall mean any manufacturer of or manufacturer involved in the sale of anti-depressant medications or current employee of such entity. If a party seeks to disclose Confidential Information to a Competitor of a producing defendant, the party seeking disclosure shall follow the notice provisions set forth in Paragraph 8 below.

7. Qualified Persons Bound by Order.

(a) Before being given access to any Confidential Information, each Qualified Person, other than the Court, the employees and staff of the Court, counsel of record, and the direct employees of counsel of record, and other than as set forth above with respect to those witnesses who are shown Confidential Information at a deposition, trial or hearing as identified in paragraph 5(d), shall be advised of the terms of this Order, shall be given a copy of this Order, shall agree in writing to be bound by the terms of this Order by signing a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A," and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order. Counsel for each party shall maintain a list of all Qualified Persons to whom they or their client(s) have provided any Confidential Information, which list shall be available for inspection by the Court.

(b) Counsel for Plaintiffs in the above-captioned litigation may share Confidential Information produced pursuant to this Order with counsel of record representing plaintiffs in other litigation (that is, actions other than those that are part of this MDL) who, at the

time of the proposed sharing, specifically allege injury to an infant as a purported result of the mother's use of Zoloft (sertraline hydrochloride) during pregnancy, pursuant to the following provisions: (1) Any attorney in the above-captioned litigation who proposes sharing shall, before sharing any Confidential Information, obtain from the attorney with whom sharing is proposed a signed copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" and provide the name of each such attorney to Defendants' Lead Counsel; and (2) Disclosure shall not be made to any attorney who has been found to have violated the terms of a protective order in any litigation or legal proceeding.

(c) The witness who is a Qualified Person pursuant to Paragraph 5(d) but who has not signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" may be shown Confidential Information before or during his or her testimony, but shall not be given a copy of the documents containing such Confidential Information to keep. The witness will review his or her transcribed testimony containing the Confidential Information for purposes of completing the errata sheet within 30 days of receiving a copy of the deposition transcript from the court reporter but may not keep any portion of the transcript that discusses the Confidential Information. The witness must return the portions of the transcript containing the Confidential Information, as well as any exhibits to that portion of the transcript, to the court reporter once the witness has completed the errata sheet. Any documents used at the deposition which contain Confidential Information (including marked exhibits) shall not be kept or maintained by the witness or his or her counsel except that Qualified Persons described in paragraph 5(c) may retain their depositions and exhibits until the completion of the Qualified Person's consultation or representation in this case, at which time he or she shall follow the procedures set forth in

paragraph 7(d) below.

(d) Any Confidential Information distributed or disclosed to a Qualified Person who is a signatory of Exhibit “A” shall be returned to the party's counsel who provided it to the Qualified Person or, with the consent of the party producing the Confidential Information, destroyed at the completion of the Qualified Person's consultation or representation in this case. Upon the request of the producing party or the Court, each such Qualified Person shall execute an affidavit stating that all such documents and copies thereof have been returned or destroyed as required.

(e) The Court shall retain jurisdiction over any person or organization authorized, as set forth above, to receive Confidential Information as necessary to enforce the provisions of this Order.

8 . Challenges to Redaction and Confidentiality Designation, or Notice of Intended Disclosure to Competitors. The party designating information, documents, materials or items as Confidential Information bears the burden of establishing confidentiality. Nothing in this Order shall constitute a waiver of any party's right to object to the designation or non-designation of a particular document as a Protected Document. If a party contends that any document has been erroneously or improperly designated or not designated as Confidential Information, the document at issue shall be treated as confidential until either the parties reach a written agreement or this Court issues an order determining that the document is not confidential and shall not be given confidential treatment.

If a party in good faith wishes to challenge either a disclosing party's redaction of any information or a party's designation of information or documents as confidential or if a party

in good faith desires to provide Confidential Information to a Competitor, the party shall:

(a) Notify the party that designated the information as confidential in writing reasonably identifying the information (if Protected Documents by identifying the production number of the documents at issue) and, in addition, if seeking to provide information or documents to a Competitor, the identity of the Competitor;

(b) The parties shall meet and confer in an effort to reach agreement regarding the information at issue;

(c) If, after 14 days of the objecting party's notification to the designating party, the parties cannot reach agreement on whether some or all of the information should remain redacted, should remain designated as confidential, or should be provided to a Competitor, the party challenging the redaction or designation or seeking to provide the information to a competitor may move the Court for an order stating that the information designated as "Confidential" is not "Confidential Information" within the meaning of this Order and is not entitled to the protections of this Order. If the objecting party does not file such a motion within 60 days after expiration of the 14-day period for negotiation and the designating party has not agreed to extend the time for filing such a motion, the information designated as "Confidential" shall be treated as "Confidential Information" within the meaning of this Order, without waiver by the objecting party to renew its objection in good faith and without unreasonable delay at a future date, following the procedure set forth above. With respect to any motions relating to the confidentiality of documents or related information, the burden of justifying the designation shall lie with the designating party. All parties retain the right to appeal the decision of the Court.

9. **Authorized and Unauthorized Uses of Confidential Information.**

(a) Confidential Information shall not be used for any business, competitive or other non-litigation purpose without the express written consent of counsel for the designating party or by order of the Court. Nothing in this Protective Order shall limit any producing party's use of its own documents or shall prevent any producing party from disclosing its own Confidential Information to any person. Nothing herein shall prevent a plaintiff from viewing or receiving and retaining copies of his/her own medical records and from sharing such medical records with that plaintiff's physicians, regardless of whether or not the documents have been designated as confidential. Such disclosures shall not affect any confidential designation made pursuant to the terms of this Protective Order so long as the disclosure is made in a manner that is reasonably calculated to maintain the confidentiality of the information.

(b) Use of Confidential Information In Court. The parties will use the following procedure, absent further Court Order, for submitting to the Court papers consisting of, containing, or attaching Confidential Information: Confidential Information is not to be filed with the Court except when required in connection with motions or other matters pending before the Court. The party seeking to file Confidential Information in support of a motion or other matter pending before the Court may first notify the producing party of its intent to file Confidential Information and seek agreement to de-designate such information. Absent a written agreement to the contrary by the designating party, any Confidential Information of any type filed in support of a motion or other matter pending before the Court shall be filed under seal by first filing a motion with the Court pursuant to Local Rules 5.1.5 and 5.1.2(7) and, upon an Order granting such motion and consistent with Local Rule 5.1.2(7), filing such Confidential

Information, together with the Order granting the motion to seal, in paper form in an envelope delivered to the clerk of the Court and marked with the title and caption of this Action, the title of each document being filed, and a statement substantially in the following form: Pursuant to the Order of the Court dated _____, this envelope containing the above-entitled documents filed by [the name of the party] is not to be opened nor the contents thereof displayed or revealed, except by the Court, or in accordance with an Order of the Court.

(c) **Security of Confidential Information.** Except as specifically provided in this Order, counsel shall keep all Confidential Information and Protected Documents produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.

10 . **Subpoena by Other Courts or Agencies.** If another court or an administrative agency requests, subpoenas, or orders production of Protected Documents or Confidential Information from a party that has obtained those materials under the terms of this Order, the party shall promptly notify the producing party of the pendency of such subpoena or other process. The subpoenaed party will not oppose the producing party's effort to intervene in the proceeding, quash the subpoena, or take other reasonable action to seek appropriate relief, with the cost of such opposition to the subpoena to be borne by the producing party unless otherwise agreed to be the parties.

11 . **Re-Designation.** On a monthly basis in any month in which any Protected Document has its confidentiality designation changed to non-confidential, beginning on a date to be agreed upon by the parties, the parties shall produce a log that identifies any Protected

Document whose confidentiality designation has been so changed. The log shall be produced in a searchable electronic format that can be used with commercially available database software identifying the following information for each document produced in this Action: the document's (a) beginning and ending production numbers; (b) date; (c) title; and (d) confidentiality status (e.g., "Confidential" or "Non-Confidential").

12 . **Disposition of Confidential Information.** Upon the request of any party after the final conclusion of this action (including without limitation any appeals and after the time for filing all appellate proceedings has passed), each party so requested shall return all Confidential Information to counsel for the party that produced it, shall destroy it, or otherwise shall comply with an applicable order of the Court. The return or destruction of Confidential Information under this paragraph shall include, without limitation, all copies, and duplicates thereof. The parties shall certify, within 60 days of receipt of a written request for certification, that all Confidential Information required to be returned or destroyed has been so returned or destroyed. Unless otherwise ordered by the Court, counsel may retain: (a) copies of pleadings or other papers that have been filed with the Court and that contain Confidential Information; (b) their work product; and (c) official transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel.

13 . **Order Survives Termination of Action.** After the termination of this action by entry of a final judgment or order of dismissal, the provisions of this Order shall continue to be binding. This Order is, and shall be deemed to be, an enforceable agreement between the parties, their agents, and their attorneys. The parties agree that the terms of this Order shall be interpreted and enforced by the MDL 2342 Court, including as to all persons and entities bound

by this Order pursuant to paragraph 14, and the parties will discuss with the MDL Court any necessary modification of this provision upon the transfer or remand of any action in this litigation.

14 . **Persons and Entities Bound by Order.** This Order shall be binding upon the parties, upon their attorneys, upon all signatories to Exhibit “A,” and upon their successors, personal or legal representatives, subsidiaries, divisions, employees, agents, and independent contractors.

15 . **No Waiver of Objections.** Neither this Order nor any of the procedures described above affects or constitutes a waiver of any party's right to object to the relevancy, admissibility or discoverability of any information or document or to seek an order that discovery or admissibility be had only subject to appropriate limits or restrictions, as provided by the Federal Rules of Civil Procedure, the Federal Rules of Evidence, the Local Rules of this Court, or other applicable rules or law.

16 . **No Waiver of Any Privilege.**

(a) This Order does not constitute a waiver of any party's right to withhold or redact information protected from disclosure by the attorney-client privilege, physician-patient privilege, work product doctrine, or other applicable privilege, protection, law, or regulation. Furthermore, in discovery in this lawsuit, the parties have agreed that they do not intend to disclose information subject to a claim of attorney-client privilege or attorney work product protection. If, nevertheless, a party (the “Disclosing Party”) inadvertently discloses such privileged or work product information (“Inadvertently Disclosed Information”), such disclosure shall not constitute or be deemed a waiver or forfeiture of any claim of attorney-client privilege

or work product immunity that the Disclosing Party would otherwise be entitled to assert with respect to the Inadvertently Disclosed Information and its subject matter. All parties will provide a privilege log in accordance with the requirements of the federal rules of civil procedure. A privilege log shall be provided within 90 days after each production of documents by a party except that a receiving party shall be permitted to request from the producing party, through Plaintiffs' or Defendants' Lead or Liaison Counsel and on reasonable notice, that a privilege log for a particular production be provided within a shorter time period if the receiving party has a good faith basis for such a request in connection with a scheduled deposition.

(b) If a Disclosing Party notifies the Receiving Party of Inadvertently Disclosed Information, the Receiving Party shall return or destroy, within ten business days, all copies of such information and provide a certification of counsel that all such Inadvertently Disclosed Information has been returned or destroyed. From the moment a party provides notice of inadvertent production, a receiving party shall not copy, distribute, or otherwise use in any manner the disputed documents or information, and shall instruct all persons to whom the receiving party has disseminated a copy of the documents or information that the documents or information are subject to this Order and may not be copied, distributed, or otherwise used pending the motion and further notice from the Court.

(c) Within 20 business days after providing notification of Inadvertently Disclosed Information, the Disclosing Party shall produce a privilege log listing such information.

(d) The Receiving Party may move the Court for an Order compelling production of the Inadvertently Disclosed Information. Such motion shall be filed under seal and shall not assert as a ground for entering such an Order the fact or circumstances of the inadvertent

production. On any such motion, the Disclosing Party shall retain the burden of establishing its privilege or work product claims. Nothing in this paragraph shall limit the right of any party to petition the Court for an in camera review of the Inadvertently Disclosed Information.

17 . **Inadvertent Production or Disclosure of Confidential Information.** In the event that a party inadvertently produces Confidential Information without the required legend, the producing party shall contact the receiving party within 30 days of the discovery of the inadvertent production, or as promptly as reasonably possible thereafter, and inform the receiving party or parties in writing of the inadvertent production and the specific material at issue. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of confidentiality, either as to specific documents and information disclosed or on the same or related subject matter. Upon receipt of such notice, the receiving party or parties shall treat the material identified in the notice as confidential until (a) the parties agree to non-confidential treatment of the subject material, or (b) the Court, on motion of any party, issues an order addressing the appropriate treatment of the subject material. Each receiving party shall further notify every person or organization that received copies of or access to the material identified in the notice that such material contains Confidential Information.

18 . **Modification Permitted.** Nothing in this Order shall prevent any party or other person from seeking modification of this Order, or from objecting to discovery that it believes to be otherwise improper.

19 . **Use of Confidential Information at Trial.** Nothing in this Order shall preclude a party from introducing into evidence at trial or hearing any Confidential Information or Protected Document that is admissible under the Federal Rules of Evidence. At trial or

evidentiary hearings, the Court may take such measures as the Court deems appropriate, to protect the claimed confidential document or information sought to be admitted.

It is so **ORDERED**.

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFÉ, J.

EXHIBIT A to PRETRIAL ORDER NO. 8 (PROTECTIVE ORDER)

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

IN RE: ZOLOFT (SERTRALINE	:	MDL NO. 2342
HYDROCHLORIDE) PRODUCTS	:	12-MD-2342
LIABILITY LITIGATION	:	
_____	:	HON. CYNTHIA M. RUFÉ
	:	
THIS DOCUMENT APPLIES TO:	:	
ALL ACTIONS	:	

The undersigned hereby acknowledges that [print or type full name:]

_____ has read the Protective Order

(Pretrial Order No. 8) entered in this action, that (s)he understands the terms thereof, that (s)he agrees to be bound by such terms, and that (s)he agrees not to disclose any confidential information to any person other than as permitted by the Protective Order. The undersigned consents to the exercise of personal jurisdiction by the above Court in any proceeding(s) to enforce the terms of the Protective Order.

Signature

Date