

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA  
PRODUCTS LIABILITY LITIGATION

MDL No. 1596

THIS DOCUMENT RELATES TO:  
ALL ACTIONS

MOVANT'S COUNSEL IS DIRECTED  
TO SERVE A COPY OF THIS ORDER  
ON ALL PARTIES UPON RECEIPT

CASE MANAGEMENT

~~FEDERAL ORDER NO. 3 (PROTECTIVE 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, the Court enters this Protective Order pursuant to Rule 26 of the Federal Rules of Civil Procedure.

1. Discovery Materials

This Order applies to all products of discovery and all information derived therefrom, including, but not limited to, all documents, objects or things, deposition testimony and interrogatory/request for admission responses, and any copies, excerpts or summaries thereof, obtained by any party pursuant to the requirements of any court order, requests for production of documents, requests for admissions, interrogatories, or subpoena ("discovery materials"). This Order is limited to the litigation or appeal of any action brought by or on behalf of plaintiffs, alleging personal injuries or other damages arising from plaintiffs' ingestion of olanzapine, commonly known as Zyprexa® ("Litigation") and includes any state court action where counsel for the plaintiff has agreed to be bound by this order.

2. Use of Discovery Materials

With the exception of documents or information that has become publicly available without a breach of the terms of this Order, all documents, information or other

discovery materials produced or discovered in this Litigation and that have been designated confidential shall be used by the receiving party solely for the prosecution or defense of this Litigation, to the extent reasonably necessary to accomplish the purpose for which disclosure is made, and not for any other purpose, including any other litigation or judicial proceedings, or any business, competitive, governmental, commercial, or administrative purpose or function.

**3. "Confidential Discovery Materials" Defined**

For the purposes of this Order, "Confidential Discovery Materials" shall mean any information that the producing party in good faith believes is properly protected under Federal Rule of Civil Procedure 26(c)(7).

The terms of this Order shall in no way affect the right of any person (a) to withhold information on alleged grounds of immunity from discovery such as, for example, attorney/client privilege, work product or privacy rights of such third parties as patients, physicians, clinical investigators, or reporters of claimed adverse reactions; or (b) to withhold information on alleged grounds that such information is neither relevant to any claim or defense nor reasonably calculated to lead to the discovery of admissible evidence. If information is redacted on the basis it is neither relevant nor reasonably calculated to lead to the discovery of admissible evidence, the redacting party shall identify on a separate log that identifies the document subject to redaction and the reason for such redaction.

Where large volumes of discovery materials are provided to the requesting party's counsel for preliminary inspection and designation for production, and have not been reviewed for confidentiality purposes, the producing party reserves the right to so designate and redact appropriate discovery materials after they are designated by the requesting party for production. During the preliminary inspection process, and before production, all discovery materials reviewed by the requesting party's counsel shall be treated as Confidential Discovery material.

**4. Designation of Documents as "Confidential"**

a. For the purposes of this Order, the term "document" means all tangible items, whether written, recorded or graphic, whether produced or created by a party or

another person, whether produced pursuant to subpoena, to discovery request, by agreement, or otherwise.

b. Any document which the producing party intends to designate as Confidential shall be stamped (or otherwise have the legend recorded upon it in a way that brings the legend to the attention of a reasonable examiner) with a notation substantially similar to the following:

**Zyprexa MDL 1596: Confidential-Subject to Protective Order**

Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying. The stamp shall be affixed in such a manner as not to obliterate or obscure any written material.

c. A party may preliminarily designate as "Confidential" all documents produced by a third party entity employed by the party for the purposes of document management, quality control, production, reproduction, storage, scanning, or other such purpose related to discovery, by notifying counsel for the other party that all documents being produced are to be accorded such protection. Once said documents are produced by such third party vendor, the designating party will then review the documents and, as appropriate, designate them as "Confidential" by stamping the document (or otherwise having the legend recorded upon it in a way that brings its attention to a reasonable examiner) as such.

**5. Non-Disclosure of Confidential Discovery Materials**

Except with the prior written consent of the party or other person originally producing Confidential Discovery Materials, or as hereinafter provided under this Order, no Confidential Discovery Materials, or any portion thereof, may be disclosed to any person, including any plaintiff, except as set forth in section 6(d) below.

6. Permissible Disclosures of Confidential Discovery Material

Notwithstanding paragraph 5, Confidential Discovery Materials may be disclosed to and used only by:

- a. counsel of record for the parties in this Litigation and to his/her partners, associates, secretaries, legal assistants, and employees to the extent considered reasonably necessary to render professional services in the Litigation ,
- b. inside counsel of the parties, to the extent reasonably necessary to render professional services in the Litigation;
- c. court officials involved in this Litigation (including court reporters, persons operating video recording equipment at depositions, and any special master appointed by the Court);
- d. any person designated by the Court in the interest of justice, upon such terms as the Court may deem proper;
- e. where produced by a plaintiff, in addition to the persons described in subsections (a) and (b) of this section, a defendant's in-house paralegals and outside counsel, including any attorneys employed by or retained by defendant's outside counsel who are assisting in connection within this Litigation, and the paralegal, clerical, secretarial, and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by defendant's outside counsel. To the extent a defendant does not have in-house counsel, it may designate two individuals employed by such defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by plaintiff;
- f. where produced by defendant Eli Lilly and Company, in addition to the persons described in subsections (a) and (b) of this section, plaintiff's attorneys in other filed litigation alleging injuries or damages resulting from the use of Zyprexa® including their paralegal, clerical, secretarial and other staff employed or retained by such counsel, provided that

such counsel have agreed to be governed by the terms of this Order and shall sign a copy of the order;

g. where produced by any defendant, outside counsel for any other defendant, including any attorneys employed by or retained by any other defendant's outside counsel who are assisting in connection with this Litigation, and the paralegal, clerical, secretarial, and other staff employed or retained by such outside counsel;

h. persons noticed for depositions or designated as trial witnesses, or those who counsel of record in good faith expect to testify at deposition or trial, to the extent reasonably necessary in preparing to testify;

i. outside consultants or outside experts retained for the purpose of assisting counsel in the Litigation;

j. employees of counsel involved solely in one or more aspects of organizing, filing, coding, converting, storing, or retrieving data or designating programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system;

k. employees of third-party contractors performing one or more of the functions set forth in (j) above;

l. any employee of a party or former employee of a party, but only to the extent considered necessary for the preparation and trial of this action; and

m. any other person, if consented to by the producing party.

Any individual to whom disclosure is to be made under subparagraphs (d) through (m) above, shall sign, prior to such disclosure, a copy of the Endorsement of Protective Order, attached as Exhibit A. Counsel providing access to Confidential Discovery Materials shall retain copies of the executed Endorsement(s) of Protective Order. Any party seeking a copy of an endorsement may make a demand setting forth the reasons therefor to which the opposing party will respond in writing. If the dispute cannot be resolved the demanding party may move the Court for an order compelling production upon a showing of good cause. For testifying experts,

a copy of the Endorsement of Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the Confidential Discovery Materials to which the expert has access, at the time the expert's designation is served, or at the time the Confidential Discovery Materials are provided to the testifying expert, whichever is later.

Before disclosing Confidential discovery materials to any person listed in subparagraphs (d) through (m) who is a Customer or Competitor (or an employee of either) of the party that so designated the discovery materials, but who is not an employee of a party, the party wishing to make such disclosure shall give at least three (3) business days advance notice in writing to the counsel who designated such discovery materials as Confidential, stating that such disclosure will be made, identifying by subject matter category the discovery material to be disclosed, and stating the purposes of such disclosure. If, within the three (3) business day period, a motion is filed objecting to the proposed disclosure, disclosure is not permissible until the Court has denied such motion. As used in this paragraph, (a) the term "Customer" means any direct purchaser of products from Lilly, or any regular indirect purchaser of products from Lilly (such as a pharmacy generally purchasing through wholesale houses), and does not include physicians; and (b) the term "Competitor" means any manufacturer or seller of prescription medications.

The notice provision immediately above applies to consultants and/or independent contractors of Competitors to the extent the consultants or contractors derive a substantial portion of their income, or spend a substantial portion of their time working for a pharmaceutical company that manufactures prescription medical products in the neuroscience area.

**7. Production of Confidential Materials by Non-Parties**

Any non-party who is producing discovery materials in the Litigation may agree to and obtain the benefits of the terms and protections of this Order by designating as "Confidential" the discovery materials that the non-party is producing, as set forth in paragraph 4.

**8. Inadvertent Disclosures**

a. The parties agree that the inadvertent production of any discovery materials that would be protected from disclosure pursuant to the attorney-client privilege, the work product doctrine or any other relevant privilege or doctrine shall not constitute a waiver of the applicable privilege or doctrine. If any such discovery materials are inadvertently produced, the recipient of the discovery materials agrees that, upon request from the producing party, it will promptly return the discovery materials and all copies of the discovery materials in its possession, delete any versions of the discovery materials on any database it maintains and make no use of the information contained in the discovery materials; provided, however, that the party returning such discovery materials shall have the right to apply to the Court for an order that such discovery materials are not protected from disclosure by any privilege. The person returning such material may not, however, assert as a ground for such motion the fact or circumstances of the inadvertent production.

b. The parties further agree that in the event that the producing party or other person inadvertently fails to designate discovery materials as Confidential in this or any other litigation, it may make such a designation subsequently by notifying all persons and parties to whom such discovery materials were produced, in writing, as soon as practicable. After receipt of such notification, the persons to whom production has been made shall prospectively treat the designated discovery materials as Confidential, subject to their right to dispute such designation in accordance with paragraph 9.

**9. Declassification**

a. Nothing shall prevent disclosure beyond that limited by this Order if the producing party consents in writing to such disclosure.

b. If at any time a party (or aggrieved entity permitted by the Court to intervene for such purpose) wishes for any reason to dispute a designation of discovery materials as Confidential made hereunder, such person shall notify the designating party of such dispute in writing, specifying by exact Bates number(s) the discovery materials in dispute. The designating party shall respond in writing within 20 days of receiving this notification.

c. If the parties are unable to amicably resolve the dispute, the proponent of confidentiality may apply by motion to the Court for a ruling that discovery materials stamped as Confidential are entitled to such status and protection under Rule 26 of the Federal Rules of Civil Procedure and this Order, provided that such motion is made within forty five (45) days from the date the challenger of the confidential designation challenges the designation or such other time period as the parties may agree. The designating party shall have the burden of proof on such motion to establish the propriety of its Confidential designation.

d. If the time for filing a motion, as provided in paragraph 9.c, has expired without the filing of any such motion, or ten (10) business days (or such longer time as ordered by this Court) have elapsed after the appeal period for an order of this Court that the discovery material shall not be entitled to Confidential status, the Confidential Discovery Material shall lose its designation.

**10. Confidential Discovery Materials in Depositions**

a. Counsel for any party may show Confidential Discovery Materials to a deponent during deposition and examine the deponent about the materials so long as the deponent already knows the Confidential information contained therein or if the provisions of paragraph 6 are complied with. The party noticing a deposition shall obtain each witness' endorsement of the protective order in advance of the deposition and shall notify the designating party at least ten (10) days prior to the deposition if it has been unable to obtain that witness' endorsement. The designating party may then move the Court for an Order directing that the witness abide by the terms of the protective order, and no confidential document shall be shown to the deponent until the Court has ruled. Deponents shall not retain or copy portions of the

transcript of their depositions that contain Confidential information not provided by them or the entities they represent unless they sign the form described, and otherwise comply with the provisions in paragraph 6. A deponent who is not a party shall be furnished a copy of this Order before being examined about potentially Confidential Discovery Materials. While a deponent is being examined about any Confidential Discovery Materials or the Confidential information contained therein, persons to whom disclosure is not authorized under this Order shall be excluded from being present.

b. Parties (and deponents) may, within thirty (30) days after receiving a deposition, designate pages of the transcript (and exhibits thereto) as Confidential. Until expiration of such thirty (30) day period, the entire transcript, including exhibits, will be treated as subject to Confidential protection under this Order. If no party or deponent timely designates a transcript as Confidential, then none of the transcript or its exhibits will be treated as confidential.

**11. Confidential Discovery Materials Offered as Evidence at Trial**

Confidential Discovery Materials and the information therein may be offered in evidence at trial or any court hearing, provided that the proponent of the evidence gives notice to counsel for the party or other person that designated the discovery materials or information as Confidential in accordance with the Federal Rules of Evidence and any local rules, standing orders, or rulings in the Litigation governing identification and use of exhibits at trial. Any party may move the Court for an order that the evidence be received in camera or under other conditions to prevent unnecessary disclosure. The Court will then determine whether the proffered evidence should continue to be treated as Confidential and, if so, what protection, if any, may be afforded to such discovery materials or information at trial.

**12. Filing**

Confidential Discovery Materials shall not be filed with the Clerk except when required in connection with matters pending before the Court. If filed, they shall be filed in a sealed envelope, clearly marked:

**"THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT"**

and shall remain sealed while in the office of the Clerk so long as they retain their status as Confidential Discovery Materials. Said Confidential Discovery Materials shall be kept under seal until further order of the Court; however, said Confidential Discovery Materials and other papers filed under seal shall be available to the Court, to counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Order.

**13. Client Consultation**

Nothing in this Order shall prevent or otherwise restrict counsel from rendering advice to their clients in this Litigation and, in the course thereof, relying generally on examination of Confidential Discovery Materials; provided, however, that in rendering such advice and otherwise communicating with such client, counsel shall not make specific disclosure of any item so designated except pursuant to the procedures of paragraph 6.

**14. Subpoena by other Courts or Agencies**

If another court or an administrative agency subpoenas or otherwise orders production of Confidential Discovery Materials which a person has obtained under the terms of this Order, the person to whom the subpoena or other process is directed shall promptly notify the designating party in writing of all of the following: (1) the discovery materials that are requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the

litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. In no event shall confidential documents be produced prior to the receipt of written notice by the designating party and a reasonable opportunity to object. Furthermore, the person receiving the subpoena or other process shall cooperate with the producing party in any proceeding related thereto.

**15. Non-termination**

The provisions of this Order shall not terminate at the conclusion of this Litigation. Within ninety (90) days after final conclusion of all aspects of this Litigation, counsel shall, at their option, return or destroy Confidential Discovery Materials and all copies of same. If counsel elects to destroy Confidential Discovery Materials, they shall consult with counsel for the producing party on the manner of destruction and obtain such party's consent to the method and means of destruction. All counsel of record shall make certification of compliance herewith and shall deliver the same to counsel for the party who produced the discovery materials not more than one hundred twenty (120) days after final termination of this Litigation. Outside counsel, however, shall not be required to return or destroy any pretrial or trial records as are regularly maintained by that counsel in the ordinary course of business; which records will continue to be maintained as confidential in conformity with this Order.

**16. 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.

**17. Responsibility of Attorneys; Copies**

The attorneys of record are responsible for employing reasonable measures to control and record, consistent with this Order, duplication of, access to, and distribution of Confidential Discovery Materials, including abstracts and summaries thereof.

No duplications of Confidential Discovery Materials shall be made except for providing working copies and for filing in Court under seal; provided, however, that copies may

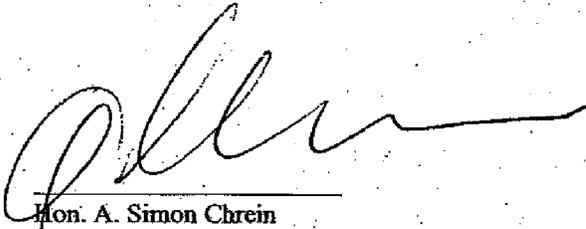
be made only by those persons specified in sections (a), (b) and (c) of paragraph 6 above. Any copy provided to a person listed in paragraph 6 shall be returned to counsel of record upon completion of the purpose for which such copy was provided. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order and new counsel shall sign this Order.

**18. No Waiver of Rights or Implication of Discoverability**

- a. No disclosure pursuant to any provision of this Order shall waive any rights or privileges of any party granted by this Order.
- b. This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation; nor shall this order imply that Confidential Discovery Materials are properly discoverable, relevant, or admissible in this or any other litigation. Each party reserves the right to object to any disclosure of information or production of any documents that the producing party designates as Confidential Discovery Materials on any other ground it may deem appropriate.
- c. The entry of this Order shall be without prejudice to the rights of the parties, or any one of them, or of any non-party to assert or apply for additional or different protection. Nothing in this Order shall prevent any party from seeking an appropriate protective order to further govern the use of Confidential Discovery Materials at trial.

**19. Improper Disclosure of Confidential Discovery Material**

Disclosure of discovery materials designated Confidential other than in accordance with the terms of this Protective Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate.



Hon. A. Simon Chreim  
United States Magistrate Judge

Dated: August 3, 2004.  
Brooklyn, New York

SO ORDERED as approving act of  
Magistrate Judge and Justice  
with respect to being habeas corpus.  
JBW

Hon. Jack B. Weinstein  
Senior District Judge

Dated: 8/3, 2004  
Brooklyn, New York